CancerCare Manitoba
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Practice Guideline: Symptom Management

Part 1. Methodology for Radiation-Induced Skin Toxicities in Breast Cancer Series

Part 1 of a 5 Part Series:

Evidence Based Recommendations for the Assessment and Management of Radiation-Induced Skin Toxicities in Breast Cancer

Effective Date: January 2018

CancerCare Manitoba Guideline
Symptom Management – Methodology for Radiation-Induced Skin Toxicities in Breast Cancer Series
Developed by: Clinical Practice Guideline Adaptation Working Group

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Preface

At CancerCare Manitoba (CCMB) the Clinical Practice Guidelines Initiative (CPGI) seeks to improve patient outcomes in terms of survival and quality of life through the development, dissemination, implementation, and evaluation of guidelines for the management of common clinical scenarios encountered by cancer patients throughout the province.

This practice guideline was created through the collective efforts of a dedicated group of front-line staff, guideline methodologists, and researchers from: CCMB, University of Manitoba's Faculty of Nursing, Queen's University School of Nursing in Kingston Ontario, and the Canadian Guideline Adaptation Study Group—an initiative of the Canadian Partnership Against Cancer (CPAC) Guidelines Advisory Group.

The content of this guideline was in large part adapted from guidelines produced by: the British Columbia Cancer Agency (BCCA, 2006), the Cancer Care Ontario Program in Evidence-Based Care (CCO, 2005), and the Winnipeg Regional Health Authority (WRHA, 2005).

The CCMB Department of Nursing and Radiation Oncology Program will review and update this document once every 3 years, unless emerging evidence from scientific research, or practice issues requiring urgent resolution dictate a need for a more immediate change in content.

Purpose

This document is intended as a guide to facilitate a shared, evidence-based approach to the clinical assessment and management of radiation-induced skin toxicities in adults with breast cancer.

For this purpose, it may be used by qualified and licensed healthcare practitioners involved with the care of oncology patients, which may include (but is not limited to): physicians, surgeons, nurses, radiation therapists, pharmacists, dieticians and psychosocial oncology professionals at CancerCare Manitoba's tertiary sites in Winnipeg, the Western Manitoba Cancer Centre in Brandon, and CCMB Community Oncology Program sites throughout the province.

Disclaimer

This guideline document should be viewed as an evidence-based practice tool, and as such, it does not represent an exhaustive text on the subject of radiation-induced skin toxicities. Clinicians are advised to use the guideline in their practice concomitantly with information from other evidence-based sources.

Use of this guideline in any setting should not preclude use of the practitioner's independent judgment, nor should it replace consultation with the appropriate oncology specialty when indicated (e.g. radiation or medical oncology, nursing, pharmacy, radiation therapy, psychosocial oncology, spiritual care, nutritional therapy). Clinicians are expected to apply the recommendations within the boundaries of professional standards and scope of practice, and according to their personal level of training and experience.

It is the responsibility of the practitioner to develop an individualized disease or symptom management plan for each patient under his/her care, and ideally this should take place within the context of an inter-professional team. The needs and preferences of the patient and the family should always be reflected in the plan of care.

CancerCare Manitoba

Symptom Management Recommendations

Methodology for Radiation-Induced Skin Toxicities in Breast Cancer Series

I. Introduction

Nature of the Problem

The Canadian Cancer Society states that 23,800 women have been diagnosed with breast cancer in 2013, and that 5,000 of these women will unfortunately die of the disease.[1,2] These same statistics estimated that 200 men would be diagnosed with breast cancer and sixty men would die of the disease.[1,2] Statistics from 2013 reveal that breast cancer made up 26.1% and 0.2% of the total distribution of new cancer cases in Canada during 2013, in females and males, respectively.[2] This means that 65 Canadian women are diagnosed with breast cancer every single day.[1,2] In 2007 it was estimated that the lifetime probability of developing breast cancer in females was 11.5%, or one in nine.[2]

Radiation therapy is used to treat between 45 - 62% of cancer patients in North America, making this treatment one of the core modalities used to treat the disease.[3-6] Within Canada, provincial use of radiation therapy ranges between 51 - 67%, with 56.2% of Manitobans receiving radiation therapy within two years of their diagnosis.[4] The use of radiation therapy has resulted in significantly improved survival rates which support it as a key treatment option.[1] Unfortunately, this means that tissue toxicity from radiation therapy is highly relevant to the patient's cancer experience and quality of life.[1]

The basal layer of the epidermis contains germinal or stem cells which divide and differentiate into mature skin cells.[7,8] McQuestion claims that approximately 10% of these cells undergo mitosis each day with complete replacement of the epidermis every four weeks.[4] Support structures (blood vessels, nerves, glands, and hair follicles) important to skin health are located in the dermis, underlying the epidermis.[4,5] Radiation damages the skin by inhibiting cell division and production of new cells, in essence destroying a fixed percentage of basal cells.[1,4,5] The remaining cells become cornified and quickly shed, triggering an unnatural cycle of basal cell destruction.[4] Changes that occur to the skin in response to radiation treatment are consistent with inflammatory responses to injury, releasing secretions of histamine and serotonin.[4] This causes a variety of symptoms including physical skin reactions, pain, burning, itching, irritation, sensitivity, numbness, warmth, tingling, and discomfort beginning around the third week of radiation treatment.[1,2,4] These experiences can have serious implications on a patient's quality of life leaving them with sleeping problems, emotional distress, body image disturbance, and severe fatigue.[2]

Skin reactions caused by radiation treatment occur along a continuum based on severity ranging from erythema to dry desquamation to moist desquamation, and in rare and severe cases, ulceration.[1,2,4,5] Collectively, these skin reactions are known as radiodermatitis and are experienced by between 74 - 100% of cancer patients.[2,4,5,9] Early

radiodermatitis can occur within a few weeks of treatment and can persist two to four weeks post-treatment.[4] Dermal capillary dilation and edema due to increased vascularity and obstruction are the first symptoms of radiodermatitis, specifically known as erythema.[4] No mathematical model connecting radiation treatment to radiodermatitis has been established.[1] However, it is known that erythema can be triggered by treatment factors related to treatment technique, type of treatment, total treatment dose, and daily treatment fraction.[3] In breast cancer patients the treatment field has an increased potential of skin breakdown due to the presence of skin folds and thin epidermis in axillary and inframammary areas.[1] Susceptibility to radiodermatitis can increase in areas where skin integrity has been disrupted due to burns, lesions or surgery.[4] Patient-related factors such as individual skin routine, nutritional status, chronic sun exposure, smoking, and environmental conditions may also put an individual at higher risk of radiodermatitis.[4] Other factors such as medication and existing skin conditions can also increase a patient's risk of developing radiodermatitis.

As these effects worsen, a patient may develop moist desquamation, and although rare, ulceration and necrosis of the skin can occur two to three months after therapy due to soft tissue injury or infection.[1,5] After completion of radiation treatment, a decrease in the size and number of blood vessels, as well as an increase in cutaneous fibrosis is observed.[1,2] This involves changes in skin texture, discomfort, telangiectasia, pain, and itching.[2] Although the skin has the ability to repair damage caused by radiation therapy, there are many factors which can interfere with healing.[1] These factors include a patient's general health, medical comorbidities, and other treatment therapies that may have been offered previously or at the same time as radiation.[1]

The opinion of many breast cancer patients holds that radiodermatitis should be managed proactively to alleviate the visibility and discomfort of their symptoms.[1] As radiodermatitis can affect activities of daily living and quality of life, patients are keen to learn how to self-manage their symptoms and soothe discomfort.[1,2,4,5] However, there is no current standard treatment for radiodermatitis as most practice is based on historical and anecdotal evidence.[6] In fact, skin care recommendations for patients who are receiving radiation treatment tend to vary depending on facility and practitioner.[5] As improvements in patient outcome and survival continue to be established, it is even more important to understand radiodermatitis as a symptom of radiation therapy.[1] Establishing current evidence-based recommendations is essential to improving the assessment, management, and patient experience of skin toxicities due to radiation therapy. [1,4]

Rationale for Guideline

In 2008, front-line allied healthcare professionals (nursing, radiation therapists) on the CancerCare Manitoba Radiotherapy Treatment Floor, along with patients and their families, identified several concerns indicating the need for development of a clinical practice guideline. The concerns identified were:

- Variation in practice between healthcare professionals (onsite and between sites) managing radiation-induced skin toxicities
- Use of out-dated or inappropriate interventions to manage skin toxicities in these patients
- Lack of current clinical practice guidelines available and/or lack of their use by healthcare professionals caring for these patients

- Variation in patient teaching related to self-management of radiation-induced skin toxicities provided by front-line staff
- Inadequate or non-existent resources for these patients and their families

Of particular concern to staff was the management of skin toxicities in breast cancer patients. It was felt that clearly defined parameters for wound assessment and management, as well as standardized patient education sheets (*See Appendices 2 to 5)*, clinical practice supports, and health record documentation templates could help resolve these issues. Further, it was decided that creating and implementing a clinical practice guideline would encourage practitioners to take a common approach in providing care to this patient population.

By February 2008, the Nurse Practitioner responsible for coordinating symptom management (CCMB Department of Radiotherapy) and the Coordinator of the CCMB Clinical Practice Guidelines Initiative had agreed to undertake development of an evidence-based symptom management guideline and associated patient information materials reflecting the guideline's recommendations *(See Appendices 2 to 5).* Feasibility of developing the guideline was discussed with nursing, radiotherapy, and oncologists. An interdisciplinary working group was established and the development process initiated.

In mid-March 2008, the opportunity arose for the CCMB group to participate in a national evaluative study taking place under the auspices of the Canadian Partnership Against Cancer Guidelines Action Group. CCMB participation in the CAN-ADAPTE Process Evaluation Study was discussed by the coordinators, and potential benefits were identified as follows:

- Professional development of front-line staff through participation in a national research study
- Definition of a process for guideline adaptation at CCMB
- Enhanced site capacity for guideline adaptation through training experience by using a standardized, validated tool
- Consensus process built into CAN-ADAPTE model may foster ownership of the guideline and enhance its use in clinical and community health settings
- Creation of a high-quality, evidence-based clinical practice guideline as a project outcome
- Design of tools and templates for use in guideline development and adaptation at CCMB

The support of senior CCMB leadership was elicited, and the coordinators proceeded with this guideline adaptation project. A panel group and Disease Site Group were then formed with sponsorship support from senior leadership. Work began in March 2008.

Anticipated Benefits

The guideline was developed for the purposes of addressing variation in local clinical approach to the problem, and patient self-management concerns related to practice inconsistency. It was anticipated that there would be many primary and secondary benefits realized at CCMB by undertaking this project. Such benefits include:

Patient Outcomes

- Improved care delivery and quality of life for adult breast cancer patients with radiation-induced skin reactions
- Enhanced treatment compliance
- Skin health promotion through hygiene, infection prevention, and protection from trauma
- Promotion of moist wound healing
- Improved symptom management (i.e. pruritus, pain)
- Minimized patient burden regarding dressings (i.e. cost, frequency/difficulty of dressing changes)
- Improved patient education regarding self-management of radiation skin toxicities

CCMB Outcomes

Healthcare Professionals

- Enhanced consistency in practice
- Provision of evidence-based care to adult breast cancer patients receiving radiotherapy
- Creation of a common language for, and standardized approaches to, assessment and management of radiation-induced skin reactions
- Improved knowledge base of clinical staff and trainees on assessment and management of radiation-induced skin reactions

Clinical Practice Guidelines Initiative

- Participation in the Canadian arm of an international study
- Education on the process involved in guideline adaptation
- Developing a transparent guideline adaptation process for local use
- Development of a high quality adapted clinical practice guideline
- Establishing a facilitation approach applicable to other guideline adaptations

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II. Scope of Guideline

Aim and Purpose

Development of this guideline was undertaken for the purposes of standardizing local clinical approach to assessment and management of radiation-induced skin toxicities in breast cancer, and to address related patient self-management concerns. The overall aim of the developers is to improve quality of life for this patient population through application of evidence-based interventions and promotion of best practices.

While the authors recognize that patients may experience varied degrees of psychosocial distress secondary to skin injury and wounds caused by radiotherapy, comprehensive recommendations for care within that domain are beyond the scope of this guideline.

CPG Development Panel

An on-site inter-professional group of fifteen individuals participated in creating the adapted CCMB guideline (external reviewers excluded). Off-site support to the panel was provided by the Cancer Guideline Adaptation and Implementation Project research study team based out of Queen's University in Kingston Ontario.

For full details regarding the panel please see CAN ADAPTE Set Up Phase, page 11.

Population

The recommendations in this guideline may be applied in the care of all adults (18 years of age or greater), male or female, who currently are receiving or have completed radiation therapy for breast cancer of any type or stage, and for any treatment intent (curative, palliative).

Healthcare Setting

The interventions recommended in this guideline are intended for use in ambulatory and community care settings, (including primary care clinics and in the home). Many of the interventions are applicable to the inpatient setting as well.

End-Users

This guideline is written for healthcare professionals caring for the patient population described above. Intended primarily for use by experienced and novice clinicians, and students from many disciplines (e.g. nursing, radiation therapy, pharmacy, and medicine), the guideline may also be of interest to healthcare administrators, policy-makers, and possibly to some members of the general public.

Certain interventions are intended for self-management and may be applied by patients and/or their personal caregivers following appropriate consultation with the radiation oncology care team, and provided that plans for patient monitoring and follow-up are in place.

III. Method for Guideline Development

CAN-ADAPTE Process

This practice guideline was created through CCMB's participation in the Cancer Guideline Adaptation and Implementation Project (CAN-IMPLEMENT, formerly CAN-ADAPTE. See http://www.cancerview.ca/), the Canadian arm of an international study evaluating ADAPTE Collaboration methodology for guideline adaptation (*see Guidelines International Network* website: http://www.g-i-n.net/). The Knowledge to Action Cycle (Figure 1 below) provided the conceptual framework for the development of this guideline.

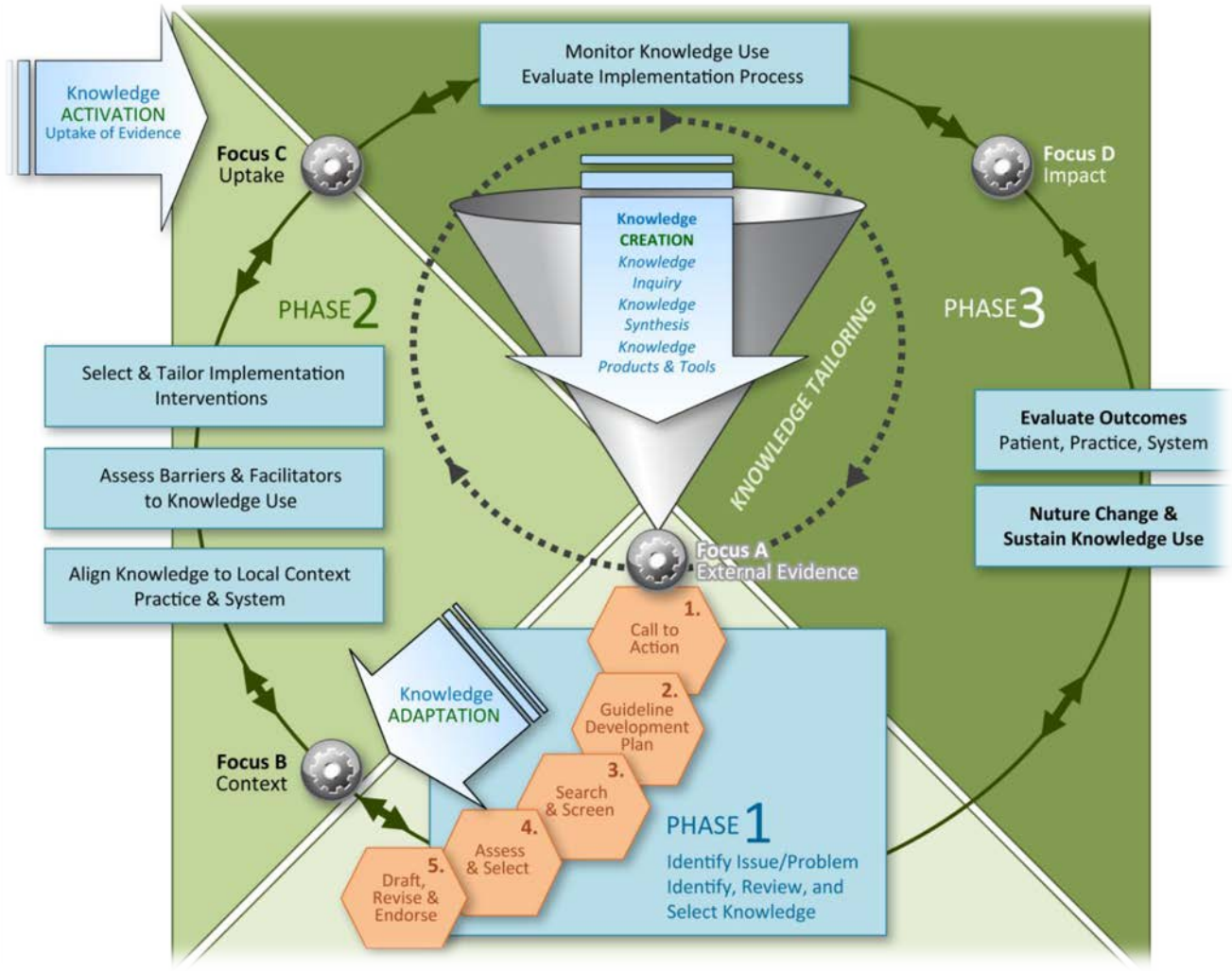

Figure 1. Knowledge to Action Process with integrated guideline adaptation and implementation.[1]

Set-Up Phase

1. Stakeholder Involvement

Panel

Three areas of expertise determined as essential for carrying out the CCMB guideline adaptation were:

- Clinical assessment and management of breast cancer patients receiving radiation therapy, particularly those with skin toxicities and wounds
- Research methodology and principles of evidence-based practice
- Clinical practice guideline development and implementation methodology

Inclusion of front-line staff on the guideline panel was a key consideration, as the impetus for the project arose from this group's desire to improve care. In keeping with the CPGI philosophy for guidelines development at CCMB, the panel composition was interdisciplinary. Clinicians from nursing, pharmacy, radiation therapy, and radiation oncology were invited to participate. The goal was to build a core group of staff members with experience in guideline development, and to encourage uptake and use of evidence-based interventions in the clinical setting. A large panel was formed in order to involve more front-line personnel in the guideline adaptation process.

Fourteen individuals participated in creating the CCMB guideline (external reviewers excluded); nine serving as panel members, and five as resource/support. The panel was chaired by a nurse practitioner, and was composed of six staff nurses, one radiation therapist, and one radiation therapy clinical resource educator. The resource team consisted of a PhD nurse researcher, one clinical pharmacist, one provincial guidelines coordinator, and an administrative assistant. The CCMB medical librarian provided assistance with the initial literature search and retrieval.

For educational purposes, two students were invited to sit in as observers on one panel meeting each, during the Decision-Selection Module of the Adaptation Phase (one nursing master's degree candidate on the first occasion and one pharmacy undergraduate student on the second).

Sponsors

The executive sponsor of this guideline adaptation project was CCMB's Chief of Professional Practice/Chief Nursing Officer. Support from the Department of Nursing and Radiation Therapy Program was elicited by the panel chair. The work was also supported in principle by the CPGI Lead /Advisory Panel Chair, Chair of the Breast Disease Site Group, and Section Heads of the CCMB Departments of Medical Oncology / Haematology and Radiation Oncology.

Patients

Since the CCMB guideline adaptation was undertaken partly as a professional development activity, patient involvement at a late stage in the process was deemed most appropriate. It was decided that panel members would advocate on behalf of patients when selecting interventions for inclusion in the CCMB guideline, based on their clinical experience in caring for this population. Further, during the Implementation Phase, feedback would be sought from patients and their caregivers concerning any educational / self-management tools developed according to the guideline's recommendations.

2. Structure

Roles and Governance

Several roles with discrete functions were defined for the guideline adaptation: chair, organizing committee, panel, resource team, and working group. Responsibilities, accountability or reporting structures, communication channels, and all other project governance matters were outlined in formal terms of reference drafted at the outset. Participants could serve in more than one role, for example as a resource team member and member of the working group. Final decisions regarding panel membership and roles were at the discretion of the chair.

Participation in the adaptation process was voluntary. Although members were asked to commit to a one-year term, individuals could withdraw at any time.

Conflict of Interest

A signed declaration of conflict of interest was collected from all individuals who would be attending panel meetings, participating in discussions, formulating recommendations, or writing content for the adapted guideline. The Medical Librarian and student observers were exempt.

One member had participated in development of a source guideline (WRHA, 2005) selected for review. This individual voluntarily sat as an observer during appraisal of that guideline and also did not participate in decision-making as to its suitability for inclusion in the Adaptation Phase. There were no other potential conflicting interests identified that might affect decision-making regarding content of the adapted guideline.

Funding

The adaptation and implementation phases of this project were funded by the CancerCare Manitoba Foundation and Queen's University through Canadian Partnership Against Cancer.

Editorial Independence

CCMB policy regarding sponsorship by industry was followed. No direct or indirect funding from pharmaceutical companies, manufacturers of biomedical products, or their representatives was received in support of any activity or material related to the guideline adaptation.

Sponsors and representatives of funding bodies did not participate in selection or appraisal of source guidelines nor in content development, authorship, or external review of the adapted CCMB guideline.

Decision-Making and Consensus Processes

For decisions regarding guideline content (e.g. selection of interventions for inclusion), and for other decisions where consensus was necessary and could not be reached through group discussion, a majority vote was taken by show of hands. In cases of a tie, the chair cast the deciding vote. *Note: In actual practice majority vote was rarely required, as group consensus was achieved primarily through discussion. Show of hands was used for accuracy in recording panel decisions following discussion.*

The group agreed that eighty percent of panel membership would constitute quorum for decision by vote. If attendance at a panel meeting was below quorum, items for decision were put to vote electronically (via email) prior to the next meeting date. *Note: This option was not exercised during the project; guideline content decisions were made at face-to-face meetings.*

Approval and Endorsement Process

It was determined that the panel would approve content of the CCMB guideline and its associated implementation tools, under advisement of the chair and working group. Following external review and revision, it was originally intended that the guideline would be presented to the CCMB Nursing Practice Council for formal endorsement. In actuality, approval and sign-off of the document became the prerogative of the head of the Department of Radiation Oncology and the CCMB Executive. The guideline was also presented to members of the Department of Nursing, Radiation Therapy Program, and Breast Disease Site Group (DSG) Radiation Oncologists to garner support.

Clinical Practice Guidelines Ownership and Maintenance

Authorship of the CCMB guideline was tasked to the chair and working group. Dissemination of the guideline was through existing and/or new institutional channels developed for purposes of staff education and distribution of evidence-based practice knowledge, both in-house and throughout the provincial oncology care system.

Implementation of the guideline was viewed as an institutional undertaking, to be led by the CCMB Department of Nursing in partnership with the Radiation Oncology Program and stakeholders. An initial draft for implementation was written into the Adaptation Plan as part of the study documentation. A full implementation plan was developed during the Finalization Phase.

The Department of Nursing will retain ownership, including responsibility for review and update of the guideline once every three years, unless emerging evidence from scientific research, or practice issues indicate a more immediate need for change.

3. Health Questions

The panel chair formulated several health questions relevant to the stated objectives for the guideline, and specific to the patient population of interest. The PIPOH framework (**P**atient population, **I**ntervention, **P**rofessionals, **O**utcome, **H**ealthcare setting) was used to structure the questions in order to assist with defining parameters of, and identifying key terms for the guidelines search.[1]

The questions were discussed at the initial panel meeting, and were revisited several times throughout the Adaptation Phase of the project to ensure they accurately reflected care issues that front-line clinicians wished to address. Prior to selecting recommendations for inclusion in the CCMB guideline, the group defined several categories of interventions and refined the health questions in order to present interventions in a logical format for ease of use by front-line clinicians, and to identify areas lacking evidence.

The following were approved by panel consensus:

1. *Assessment*: What elements should a thorough skin assessment include for adult breast cancer patients undergoing radiation therapy?
2. *Health Promotion*: What basic skin care practices should be used by adult breast cancer patients undergoing radiation therapy?
3. *Acute Symptom Management*: What are the optimal interventions for management of acute radiation-induced skin reactions in adult breast cancer patients?

4. *Follow-Up Care*: What are optimal interventions for the management of acute skin reactions in adult breast cancer patients following completion of radiation therapy, a) short-term, and b) long-term?
5. *Late Symptom Management*: What are optimal interventions for management of late radiation-induced skin reactions in adult breast cancer patients?

Within the context of these five categories, many other intervention-specific questions of interest arose during group discussions. Clinical topics or intervention-specific questions which were not addressed by the existing guidelines, or recommendations for which more supporting evidence was desired by the panel, were designated to the working group for further research. Their conclusions regarding outstanding questions were drafted and presented to the panel for consideration and approval during the Customization Module of the process.

4. Project Documentation

Documentation for the CCMB guideline adaptation was the responsibility of the resource team and was handled through the CPGI office. All documentation that was generated during the guideline adaptation (listed below) was forwarded to the Adaptation Study Group at Queen's University.

Verbal consent to include participants' names in meeting/teleconference notes and in CAN-ADAPTE resource kit tools or worksheets was given by the panel members and chair. All study documentation was stored securely at Queen's University as part of the researchers' casebook. Access to site materials was restricted to Queen's University, and to select researchers involved with the study or related research. Identifiers (site and individuals' names) were removed from site material once received by Queen's University, so as to ensure anonymity of participants.

Study Consent

Ethics approval for evaluation of the CAN-ADAPTE manual and resource kit was acquired through Queen's University by the research team overseeing the study, located at the site. Signed group consent was required for study participation, and was submitted by the CPGI office on behalf of CCMB after verbal approval to do so was granted by the panel members and chair.

Signed Declarations of Conflict of Interest

Signed declarations of conflict of interest were collected from all participants at the CCMB study site, as part of required study documentation.

Adaptation Planning

A work-plan was drawn up by the panel chair to anticipate potential workload increase that the adaptation might entail for front-line staff. This plan was approved by the CNO, and coverage for clinical duties was arranged by the panel chair with CCMB nursing and radiation therapy management to allow for staff attendance at panel meetings. A detailed project description was drafted by the CPGI coordinator outlining project parameters, timelines, deliverables, and expected resource demands for reporting purposes to CCMB senior leadership. An Adaptation Plan was completed in the Adaptation Phase as part of required study documentation.

Meeting and Teleconference Notes

Discussions were recorded through detailed note-taking at all meetings during the CCMB adaptation including: panel, organizing committee, resource team, and working group meetings. Similarly, teleconference discussions

between CCMB and Queen's University were manually recorded. Notes were distributed to CCMB team members according to their role function(s). The notes were circulated electronically and in hard copy to the panel.

The CPGI coordinator completed three online questionnaires during the course of the guideline adaptation study. The purpose of the surveys was to inform the international ADAPTE collaboration regarding developers' experiences in using the ADAPTE methodology.

CAN-ADAPTE Resources Kit Tools

As part of study participation sites were encouraged to use as many of the available CAN-ADAPTE tools as necessary to structure their guideline adaptation. Modification of the tools was encouraged to suit local context, as well as the sequence of their use. The organizing committee made a commitment to use all tools as suggested in the CAN-ADAPTE manual.

Table 1 describes the tools and resources used by the group to complete the CAN-ADAPTE process. Modifications are indicated by the delta (Δ) symbol. The working group met with the study coordinator during the Customization Phase to provide feedback concerning each tool. Discussion included the ease of use, clarity of purpose, contribution to furthering adaptation process versus duplication of work, and the order in which tools were presented in the manual. This information was used by Queen's University to refine the CAN-IMPLEMENT Manual and Toolkit.

Table 1. Tools and Resources Used During the CAN-ADAPTE Process

PROCESS	TASKS	MODULES	STEPS	TOOLS/ RESOURCES	USED (✓) OR MODIFIED (Δ)
I SET-UP PHASE	PREPARE FOR ADAPTE PROCESS	1.1 Preparation Module	1. Establish organizing committee 2. Select a topic 3. Check whether adaptation is feasible 4. Identify skills and resources needed 5. Complete set-up tasks 6. Write protocol	Tool 1: Guideline development and implementation resources	✓
				Tool 2: Search sources and strategies	Δ Design for initial search provided by Chair.
				Tool 3: Sample declaration of conflict of interest	✓
				Tool 4: Consensus Process	✓
				Tool 5: Work Plan Example	✓
II ADAPTATION PHASE	DEFINE HEALTH QUESTIONS SEARCH AND SCREEN GUIDELINES ASSESS GUIDELINES DECIDE AND SELECT DRAFT GUIDELINE REPORT	2.1 Scope and Purpose Module	7. Determine the health questions	Tool 6: PIPOH	Δ PIPOH questions formatted by Panel Chair.
		2.2 Search and Screen Module	8. Search for guidelines and other relevant documentation 9. Screen retrieved guidelines 10. Reduce total number of guidelines if there are more than can be dealt with by the panel	Tool 2: Search sources and strategies	✓
				Tool 7: Table for recording guideline characteristics	✓
				Tool 8: Table for recording clinical content of guidelines	✓
				Tool 9: AGREE Instrument	✓
				Tool 10: AGREE Inter-rater Agreement spreadsheet and AGREE score calculation spreadsheet	✓
		2.3 Assessment Module	11. Assess guideline quality 12. Assess guideline currency 13. Assess guideline content 14. Assess guideline consistency (search and selection of studies, links between evidence and recommendations) 15. Assess acceptability/ applicability of the recommendations	Tool 9: AGREE Instrument	✓
				Tool 10: AGREE Inter-rater Agreement spreadsheet and AGREE score calculation spreadsheet	✓
				Tool 11: Sample currency survey	Δ Currency of guidelines selected for adaptation was considered after initial search results were obtained. Decided currency would be re-addressed during customization module.
				Tool 12: Sample recommendations MATRIX	✓
				Tool 13: Table of criteria for assessing quality of study search and selection	✓
				Tool 14: Table for recording evaluation of consistency between evidence, its interpretations, and recommendations	✓
				Tool 15: Worksheet – Acceptability/Applicability Evaluation	Δ Discussion regarding acceptability and applicability took place during Decision and Selection Module.
		2.4 Decision and Selection Module	16. Review assessments to aid in decision making 17. Select between guidelines and recommendations to create an adapted guideline	Overall AGREE assessment	✓
				RAW AGREE scores	✓
				Summary AGREE dimension graphs	✓
				Tool 11: Sample currency survey	✓
				Tool 12: Sample recommendations MATRIX	✓
				Supporting material (e.g. systematic reviews, health technology assessments, articles)	Δ Supporting material for 3 selected guidelines was retrieved by CCMB Librarian for use by Chair and Resource Team. Panel discussion identified content that required further literature search to address gaps in existing literature.
				Tool 13: Table of criteria for assessing quality of study search and selection	✓
				Tool 14: Table for recording evaluations of consistency between evidence, its interpretations, and recommendations	✓
				Tool 15: Worksheet – Acceptability/ Applicability Evaluation	✓
		2.5 Customization Phase	18. Prepare draft that respects needs of end users and has detailed explanation of the process	Tool 16: Checklist of adapted guideline content	✓
				Tool 17: Report on results of updating process	✓
III FINALIZATION PHASE	EXTERNAL REVIEW PLAN FOR FUTURE REVIEW AND UPDATE PRODUCE FINAL GUIDELINE	3.1 External Review and Acknowledgement Module	19. External review by target users 20. Consult relevant endorsement bodies 21. Consult developers of source guidelines 22. Acknowledge source documents	Tool 18: Samples of external review surveys	Δ Guideline was distributed to users for format review and feedback survey.
		3.2 Aftercare Planning Module	23. Plan aftercare of adapted guideline		✓
		3.3 Final Production Module	24. Produce high quality final guideline		✓

Clinical Practice Guideline Development Process

The guideline was developed following the CAN-ADAPTE process, which began evaluation as a method for clinical practice guideline adaptation under the auspices of the Canadian Partnership Against Cancer Guidelines Action Group. The panel was guided through the process by Dr. Margaret Harrison's research team which was conducting the study out of Queen's University School of Nursing in Kingston, Ontario.

The CAN-ADAPTE process evaluation took place within the broader scope for the CancerCare Manitoba's Guideline Development and Aftercare Process, and assisted in the development of guideline adaptation processes at CCMB. The panel's work was supported and facilitated by the CPGI team.

5. Guidelines Search/Selection/Appraisal

As per step 8 of the CAN-ADAPTE process, several guideline databases were reviewed to locate guidelines related to radiodermatitis in breast cancer patients. Six electronic databases were searched systematically between 2008 and 2009 using key search terms: radiation; radiotherapy; skin care; breast cancer; skin; and skin reaction. These databases included PubMed, Cumulative Index to Nursing and Allied Health (CINHAL), Cochrane Reviews, National Guidelines Clearinghouse, Medline, and Google Scholar. Inclusion and exclusion filters were applied, including human studies, English language, and date published from 1998 - 2008. Additional guideline resources were obtained through citation chasing. Three guidelines were determined applicable to the proposed research questions. These guidelines were from established health agencies and included BC Cancer Agency (BCCA), Winnipeg Regional Health Authority (WRHA), and Cancer Care Ontario (CCO).[4,5,6]

After identifying key search terms, key documents and refining the topic area to ensure the clinical practice guidelines met desired specifications, a complete AGREE II appraisal was completed to assess guideline quality. The AGREE II instrument evaluates methodological quality.[2] Each guideline was scored independently by two panel members. Any scoring disparities were resolved through consensus discussion.

Table 2 shows AGREE rigour scores and overall quality assessment of each of the guidelines.

Table 2. AGREE II Rigour Scores and Overall Quality Appraisal for Adapted Clinical Practice Guidelines

	Guideline #1 BCCA 2006	Guideline #2 CCO 2005	Guideline #3 WRHA 2005
AGREE Rigour Score	66.66%	84.52%	17.85%
Overall Quality Assessment	50% with provisos or alterations 50% strongly recommended	75% with provisos or alterations 25% would not recommend	50% with provisos or alterations 50% would not recommend

6. Supporting Literature Search

Supporting literature was searched using PubMed and Google Scholar. It was necessary to conduct separate search strategies for each guideline topic. In addition, manual searches, citation chasing, and reference snowballing techniques were completed to find applicable articles within relevant journals, and reference lists of selected literature.

In 2013, an updated literature search was undertaken. Keywords used in the initial literature search (2009 – 2010), were refined as the search progressed and included various combinations of the following words: radiation; radiotherapy; skin care; skin; breast; neoplasm; skin reaction; steroid; Benadryl†; diphenhydramine;

antihistamine; Polysporin†; gramicidin; polymyxin; Neosporin; silver sulfadiazine; Flamazine†; wound; sofra-tulle; framycetin; No Sting Barrier† film; hydrogel; hydrocolloid; saline; cleansing; late reactions; adverse effects; fibrosis; atrophy; necrosis; hypopigmentation; hyperpigmentation; telangiectasia; pharmacogenomics; pentoxifylline; vitamin E; risk factors; recall; radiation recall; recall phenomenon; cornstarch; hydration; chlorine; acute skin reactions; impaired wound healing; wound assessment tools; hyaluronic acid; tumour*; carcinoma; malignanc*; chest; cancer. († refers to trade names)

Inclusion and exclusion criteria included limits to human studies, English language and year published from 2003 - 2013.

Each of the articles and abstracts were reviewed for guideline applicability. The reviews were completed by four different methodologists within a span of five years (2009 - 2013). The complete search strategy generated a total of 86 papers. Results are shown in a schematic drawing below (Figure 2).

In 2016, a final search was completed during the Finalization Phase to ensure no new relevant literature had become available. Twenty-three studies were reviewed in total in this final search.

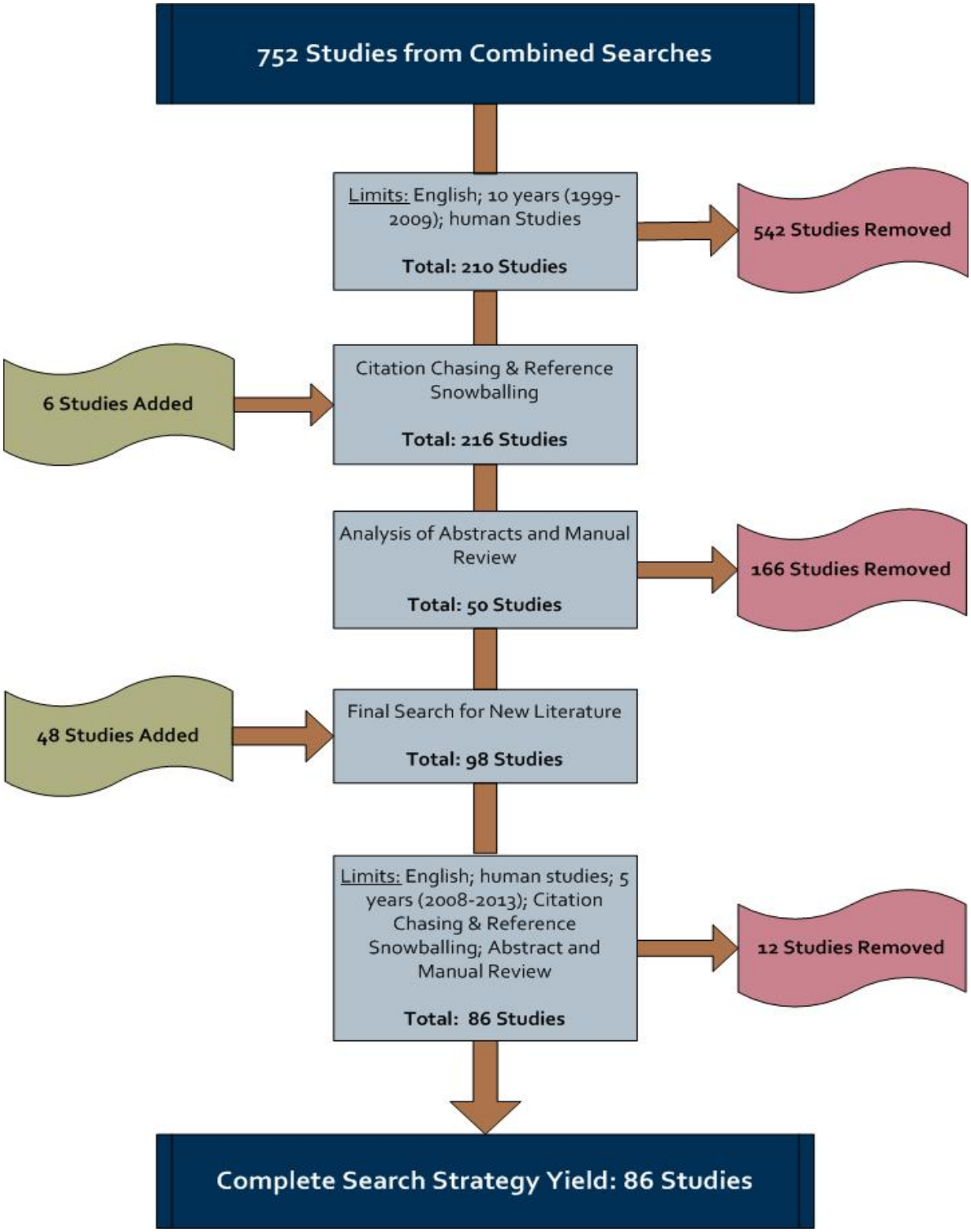

Figure 2. Schematic Search Strategy

7. Adaptation Phase

The organizing committee was in agreement regarding the need for a breast radiation wound care guideline. Three existing guidelines were adapted using the CAN-ADAPTE method. This method is proven to assist guideline developers along the entire adaptation process from topic identification to preparation of a guideline document. It involves three phases and nine modules in its 24 step process. The process also involved evaluation of the consistency of evidence, conclusions, and recommendations found in the three existing guidelines, and support through literature reviews of current evidence.

The organizing committee agreed to use all adaptation tools supplied by CAN-ADAPTE. As necessary, some tools were modified to local context. A democratic approach was used to form decisions, including a vote when consensus was not achieved. In the case of a tie vote, the decision was left to the panel chair. Quorum was set at 80% of the panel. Important adaptation tools that were used were #12, #13 and #14. Recommendation matrices (Tool #12) were used to easily compare recommendations from the three existing guidelines with respect to content, wording, and level of evidence. Tool #13 involved review of evaluation results regarding the search strategy and selection of supporting evidence. This tool was useful in assessing the comprehensiveness of the methods used to prepare each of the guidelines. Tool #14 provided important information regarding inconsistencies with guideline developers' interpretation of the evidence and its corresponding translation into recommendations within the guideline.

8. Selection of Recommendations

Recommendation matrices were used to record discussions and decisions regarding each of the guideline intervention recommendations, AGREE II scores, and level of evidence. Decision-making was based on the supporting level of evidence, clinician's familiarity with and acceptability of the recommendations, and assessment of patient benefits versus harms. Each recommendation selected for inclusion in the guideline was discussed in the context of best practice principles for skin and wound care.

The following tables show recorded decisions for each recommendation, including whether they were accepted, rejected, or accepted with modifications. Interventions and recommendations which required further research were identified and assigned to the working group. Clinical topics or intervention-specific questions which were not addressed by the existing guidelines, or recommendations for which more supporting evidence was desired by the panel, were designated to the working group for further research.

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Table 3. Health Promotion: Prevention

TOPIC	DECISION	PANEL COMMENTS
BCCA Guideline: Does not directly address prevention recommendations under other sections (ex. Erythema). May apply		
CCO Guideline[6]		
Recommendations: Prevention of Acute Skin Reaction. (Guideline, Section 1, P1): Skin washing should not be restricted in patients receiving radiation therapy. Recommended washing practices include gentle washing[1] with water along or gentle washing with mild soap[2] and water. [[1]"Gentle washing" involves using lukewarm water and taking care not to scrub the skin. Showers should also be lukewarm and low-pressure. [2]"Mild soap" is defined as a pH-balanced, non-scented product that does not contain lanolin. There is no evidence to suggest that one type of mild soap is preferable to another. However, in one study that rated the irritant quality of 18 soaps, "Dove®" was the only soap classified as mild and may therefore be considered (1).]	Modify → Leave in definition of mild soap → Leave out statement about Dove® soap	Discussion re: skin washing. We should include drying, also. Include "pat dry" or "air dry skin", "no rubbing with towel" (include rationale). Discussion re: lanolin. What are our practices here at CCMB? Decision: fine to use products with lanolin **outside** of RT treatment area. Do not put in "Dove®". As new products become available, the guideline outdates.
Patients receiving radiation therapy to the head should be advised to follow gentle washing practices with mild shampoo.	N/A	
Qualifying Statements, CCO Guideline, Section 1, P2: Given the evidence for skin washing, it would seem likely that the same recommendations would follow for hair washing with shampoo for patients receiving radiation therapy to the head, but there is limited evidence to support this.	N/A	
Limiting personal hygiene practices is not recommended as this may lead to psychosocial distress for the patient.	Modify	Discussion: expand on "limiting personal hygiene practices"; define what we mean by "hygiene practices".
Limited evidence suggests that calendula ointment may decrease the occurrence of ≥ Grade 2 radiation dermatitis in breast cancer patients. Its application in other types of cancer is unknown at this time.	Reject	Discussion re: calendula; what is its availability? What does "administration difficulties" mean? A comparative research trial would be helpful.
Qualifying Statements, CCO Guideline, Section 1, P2: One trial compared calendula ointment to Biafine® cream. The promising results of this large trial (n=254) in breast cancer patients suggest that calendula ointment may be beneficial to cancer patients undergoing radiation therapy. However, administration difficulties may lead to treatment discontinuation in some patients. No trial compared calendula to no treatment or placebo. It is currently unclear if calendula is superior to placebo or no treatment or whether these results can be generalized to cancer patients undergoing radiation therapy for other types of malignancies.		
CCO Guideline, Section 1, P2: There is insufficient evidence to support or refute other specific topical agents (i.e. corticosteroids, sucralfate cream, Biafine®, ascorbic acid, Aloe vera, chamomile cream, almond ointment, polymer adhesive skin sealant) for the prevention of acute skin reaction.	Accept with modifications	Discussion re: corticosteroids. There is evidence about possible harms (skin thinning). We should include a qualifying statement about the risks associated with steroid use. (See CCO guideline Qualifying Statements, Section 1, P2.)
Opinions, CCO Guideline, Section 1, P2: In the opinion of the Supportive Care Guidelines Group, clinical experience suggests that initial use of a plain, non-scented, lanolin-free hydrophilic cream is helpful in preventing radiation skin reactions. This type of cream attracts and traps moisture at the skin surface to increase the skin's moisture and maintain skin pliability. The cream should be discontinued when skin breakdown occurs.	Accept with modifications	The cream is actually hydrophilic

Table 3. Health Promotion: Prevention – cont'd		
TOPIC	**DECISION**	**PANEL COMMENTS**
CCO Guideline[6] – cont'd		
Qualifying Statements, CCO Guideline, Section 1, P2: Caution must be used to avoid the overuse of corticosteroid cream (3); however, there is limited evidence to suggest that skin thinning would pose a problem for normal corticosteroid use during an average course of treatment (up to 8 weeks). The practitioner must also be aware of potential patient allergies to topical corticosteroids and discontinue use if an allergic reaction occurs.		Use this statement in reference to "topical agents" recommendations, above.
CCO Guideline, Section 1, P2: There is insufficient evidence to support or refute specific oral agents (i.e. enzymes, sucralfate) or intravenous agents (i.e. amifostine) for the prevention of acute skin reaction. The side effects of these agents were more oppressive than those reported in the trials assessing topical agents, and therefore the benefits do not outweigh the risks.	Accept	Check references
WRHA Guideline		
PREVENTION STRATEGIES: WRHA P125		
Sucralfate cream (2x/day during treatment +2 weeks following completion of treatment).	Reject	Based on CCO guideline statement
3M™ Cavilon™ No Sting Barrier Film (2-3 x/week during treatment and for 2 weeks following completion of treatment)	Reject	Discussion re: clinical experience with Cavilon™ at CCMB. Became sticky with exposure to body heat, patients' skin surfaces adhered to each other. Product was difficult to remove, but later washed off with soap and water.
Calendula extract ointment: (at least 2x/day during treatment)	Reject	
Aqueous cream (3x/day throughout treatment and for 2 weeks following completion of treatment)	Accept with modifications	Discussion: use product when skin is intact; discontinue with skin breakdown. Schedule must change to reflect when/how often to apply product (pre- and post- treatment). Rationale must be included. Question was asked: "What is the evidence?"
Aloe vera gel (6-8x/day throughout treatment)	Accept with modifications *do not use "as is"	No evidence to support/refute specific topical agents other than calendula (CCO guideline). Discussion: Aloe vera has no moisturizing effect; commonly used by patients.
Silver-leaf nylon dressing (SLNC) remove dressing during treatment – throughout treatment and for 2 weeks following completion of treatment	Reject	Not applicable to breast RT patients (used for perianal RT). This dressing is available at CCMB. A study found the dressing is messy, uncomfortable to wear. However, study is dated and there may be a better/ improved product.
PATIENT EDUCATION/SELF-CARE TEACHING: WRHA P125-127. PROMOTE SKIN HYGIENE:		
Skin care regimen should begin on the first day of radiation treatment	Accept	Promote/maintain skin integrity (clinical opinion). Can be put in patient handout
Short showers or baths with warm water (avoid hot or cold)	Refer to CCO Guideline	Rationale: pathophysiology - increased exposure to H_2O leads to skin breakdown. Can be put in patient handout
Avoid using wash cloth	Accept with modifications Refer to CCO Guideline	Modify to say "avoid using wash cloth on skin in treatment area". Can be put in patient handout
Use mild skin cleansers with no perfume (e.g. Cetaphil®)	Refer to CCO Guideline	Can be put in patient handout
Avoid using alcohol-based hand sanitizers	Accept with modifications	"Avoid use of alcohol-based sanitizers in treatment area". Can be put in patient handout
Pat skin dry - Do not rub	Accept	Recommendation in CCO guideline
If the head is in the treatment field : use a mild shampoo, dry hair by air or use a hair dryer on cool setting, avoid hairspray, mousse, gel, and other styling products	Reject	Note: have to address hygiene practices for skin reactions. May want to include use of hair dryer on 'cool' setting for skin-drying after washing. This is currently being recommended to patients by some providers at CCMB.
Avoid hydrogen peroxide, povidone-iodine and other drying agents	Accept with modifications	Change to: "avoid hydrogen peroxide, povidone-iodine or other drying agents in the treatment area"
Avoid chlorinated swimming pools in presence of skin breakdown or rinse and moisturize immediately after swimming if skin intact	Accept	
RE-HYDRATE SKIN		
Ensure good nutrition and hydration (up to 3L/day unless contraindicated)	Accept with modifications	Discussion re: how much oral hydration is recommended to patients? What are clinics/treatment floors advising patients? 8-10 glasses? 2-3L? This is a lot of fluid. A consult to CCMB dietician is desirable.

Table 3. Health Promotion: Prevention – cont'd		
TOPIC	**DECISION**	**PANEL COMMENTS**
WRHA Guideline – cont'd		
RE-HYDRATE SKIN – cont'd		
Use hydrophilic preparations with no perfumes, alcohol or menthol (e.g. Lubriderm®)	Stated previously	
Try moisturizing cream (e.g. Cetaphil®-lipid base; Glaxal Base®; Lubriderm®)	Accept with modifications	Combine with WRHA
Consider normal saline (NS) compresses	Reject	Careful not to accept recommendations out of the context they were made
Can try non-adherent dressings (e.g. Adaptic® dressings) (avoid if wound is infected)	Reject	
Avoid using cornstarch especially in moist areas (e.g. axillae, groin) as it promotes fungal growth and secondary infections (may be suggested to assist in preserving marking)	Accept with modifications	Will look for evidence re: use of cornstarch contributing to fungal growth. Panel members aware of existing literature. Can be put in patient handout
Avoid talcum		The use of cornstarch and talcum powder could be addressed together.
Avoid trolamine, chamomile cream, almond ointment, topical vitamin C, gentian violet	Refer to CCO Guideline	Panel members are aware of existing literature
PREVENT INFECTION WRHA P126		
Good hand washing	Accept	Basic principle of infection control
Skin care	Reject	This is too vague
Avoid smoking (interferes with healing)	Accept with modifications	Principle of wound healing. We need evidence to support.
PROTECT FROM TRAUMA WRHA P126-127		
Avoid tape or band-aids in treatment field	Accept	Rationale: avoid trauma to skin
Avoid scratching	Accept	Rationale: avoid trauma to skin
Avoid wearing jewellery over the treatment field	Accept with modifications	Debated whether the guideline should include a definition of "treatment field". Debated whether jewellery would fall within the treatment field for breast cancer. Stated treatment field for breast may be as high as the clavicle. Panel member provided first-hand experience with a patient whose skin reaction was exacerbated where her necklace lay. Decided this should be defined in patient handout. Recommendation should be modified to state "in the treatment field", rather than "over the treatment field", with example ("E.g. necklace").
Protect from temperature extremes (avoid ice packs, heating pads, hot water bottles)	Accept	
Avoid hot tubs and saunas	Accept with modifications	This is standard for patients receiving RT. Should be modified to include rationale (e.g. hot tub exposes skin to risk of chemical & heat irritation, and infection).
Avoid friction (rubbing skin)	Dealt with previously	
Patients receiving radiation treatments in the perineal/perirectal area may wish to limit walking to decrease friction between legs	N/A	
Consider scrotal support to decrease friction	N/A	
Avoid shaving (or use an electric razor)	Accept	Hair loss is variable; sometimes there is only partial hair loss in the axilla (in RT field); re-growth after treatment variable.
Wear loose fitting, cotton clothing	Accept	
Use cotton bed sheets	Reject	Concern patients may not own cotton sheets and would have to incur needless expenses. Felt skin in treatment field would not be in direct contact with bed-sheets, therefore this was rejected.
Use low residue laundry soaps	Reject	No panel member had clinical experience with patient having had worsened RT skin reaction due to type of laundry soap used. Definition of "low residue" soap would be helpful.

Table 3. Health Promotion: Prevention – cont'd		
TOPIC	**DECISION**	**PANEL COMMENTS**
WRHA Guideline – cont'd		
PROTECT FROM THE ENVIRONMENT WRHA P127 – cont'd		
Protect from sun and wind	Accept	This is standard for RT patients (rationale: prevent thermal trauma to skin)
Use sunscreen or cover the area with clothing	Accept with modifications	Question was raised: Is there evidence to say "stop using sunscreen"? A literature search may be desirable. Recommendation should say: "Use sunscreen, or cover the area with clothing if out in the sun".
Avoid tanning parlours	Accept	This is standard for patients receiving RT. Standard skin cancer prevention recommendation for *all* persons.
Protect from frostbite	Reject. N/A	This was rejected. Panel members agreed it is unlikely skin in treatment area for breast cancer would be exposed to extreme cold.
PATIENTS RECEIVING RADIATION THERAPY TO THE HEAD AND NECK: WRHA P127		
Arrange dental assessment and provision of care prior to treatment	N/A	
Preventive oral hygiene: rinse mouth 5-6 times a day with saline or baking soda solution; use non-alcohol mouth was (e.g. Biotene™, may also consider Biotene™ toothpaste)	N/A	
Maintain nutrition: avoid spicy foods; avoid temperature extremes; consider early referral to dietician	N/A	
Maintain hydration: drink 2-3 litres per day unless contraindicated; avoid citrus fruits and juices; avoid alcohol	N/A	

Table 4. Basic Skin Care

WRHA Guideline: recommendations for basic skin care are categorized under "Prevention Strategies" in the WRHA guideline. (See: Point #7 – Patient Education/Self-Care Teaching P125-127.) Listed under "Prevention" heading.
BCCA Guideline: doesn't categorize recommendations under "basic skin care". Recommendations in sections "Erythema" (P7-10) and "Dry Desquamation" (P12-14) in BCCA guideline may apply to basic skin care. Listed under "Radiation Dermatitis/Erythema/Dry Desquamation" heading.
CCO Guideline: doesn't have "basic skin care" category for recommendations. Recommendations in "Prevention of Acute Skin Reaction" category, as well as "Opinions" and "Qualifying Statements" (Section 1, P1-2) are applicable. These are listed in the Prevention section.

Table 5. Assessment

TOPIC	DECISION	PANEL COMMENTS
CCO Guideline: does not directly address assessment		
WRHA Guideline: assessment recommendations addressed early in the CPG, prior to prevention and treatment. Includes RTOG/EORTC assessment scale.		
Assess nutritional status		
Assess patient's knowledge and learning needs		
Wound/skin reaction assessment (utilizing RTOG/EORTC or similar scale)		
Nursing History: smoking and alcohol use		
Nursing History: nutritional status		
Nursing History: pre-existing skin condition		
Nursing History: a personal and family history of radio-sensitive conditions		
Nursing History: comorbidities e.g. diabetes, hyper/hypothyroidism, MS, iron-deficiency anaemia		
Nursing History: use of mediations which cause photosensitivity e.g. antidepressants, antimicrobials, steroids, Imuran®, antipsychotics, St. John's wort		
Physical Examination: Thorough skin assessment at baseline and at regular intervals throughout treatment		
TOPIC	**DECISION**	**PANEL COMMENTS**
WRHA Guideline: assessment recommendations addressed early in the CPG, prior to prevention and treatment. Includes RTOG/EORTC assessment scale – cont'd		
Physical Examination: wound assessment (location, size of wound, colour/type/amount of discharge/drainage)		
Physical Examination: consider serial colour photos of chronic wounds (to be of benefit must be taken with the same camera, by the same person, in the same conditions – place, lighting, position) – to satisfy PHIA, a written consent is required prior to each photo		
Physical Examination: assessment of any signs and symptoms of infection		
Physical Examination: degree & specific type of patient discomfort		
BCCA Guideline:		
Recommendations for assessment are included under care management categories: **Erythema (BCCA Guideline P6)**: location, size of area, colour, discomfort (burning, itching, pulling, tenderness). **Dry Desquamation (BCCA Guideline P11)**: location, size of area, colour, discomfort (drying, itching, scaling, flaking, peeling), monitor closely for any drainage or open area (indicator of moist desquamation). **Moist Desquamation (BCCA Guideline P15)**: location (1. moist areas; 2. dry areas), size of area, wound base (granular tissue, eschar or necrotic tissue), exudates (1. type; 2. amount; 3. odour), discomfort (burning, itching, pulling, tenderness), Signs of clinical infection (1. fever; 2. foul odour; 3. purulent drainage; 4. pain & swelling extending outside of radiation area.). **Late Reactions (BCCA Guideline P19)**: location, size of area, colour, discomfort. **Recall Phenomenon (BCCA Guideline P21)**: location (1. moist areas; 2. dry areas), size of area, wound base (granular tissue, eschar or necrotic tissue), exudates (1. type; 2. amount; 3. odour), discomfort (burning, itching, pulling, tenderness), signs of clinical infection (1. fever; 2. foul odour; 3. purulent drainage; 4. pain & swelling extending outside of radiation area.)		

Table 6. Radiation Dermatitis/Erythema/Dry Desquamation

TOPIC	DECISION	PANEL COMMENTS
CCO Guideline: recommendations for treatment are made under the general heading: "Management of Acute Skin Reaction".		
MANAGEMENT OF ACUTE SKIN REACTION SECTION 1, P2		
There is insufficient evidence to support or refute topical agents such as corticosteroids, sucralfate cream, or specific dressings for the management of acute skin reaction.	Accept	
Opinions CCO Guideline, Section 1, P2: In the opinion of the Supportive Care Guidelines Group, clinical experience suggests that low dose (i.e. 1%) corticosteroid cream may be beneficial in the reduction of itching and irritation. There does appear to be an inflammatory process associated with radiation-induced erythema (2) that may be alleviated somewhat by corticosteroid creams. More evidence is needed to support firm recommendations.	Accept	
Qualifying Statements, CCO Guideline, Section 1, P2: Caution must be used to avoid the overuse of corticosteroid cream (3); however, there is limited evidence to suggest that skin thinning would pose a problem for normal corticosteroid use during an average course of treatment (up to 8 weeks). The practitioner must also be aware of potential patient allergies to topical corticosteroids and discontinue use if an allergic reaction occurs.	Accept	
BCCA Guideline: does not use the term "radiation dermatitis". Recommendations are separated into categories: "Erythema" and "Dry Desquamation". Recommendations are identical, except re: Aloe vera gel (see below).		
PROMOTE CLEANLINESS: BCCA GUIDELINE P7		
Use non-alkaline soap/mild unscented soap, e.g. Dove®, Ivory®, Neutrogena®, Basis®, baby soap.	Accept	
Bathe using lukewarm water and palm of hand to gently wash affected skin. Rinse well. Pat dry with a soft towel.	Accept	
Wash hair using lukewarm water and mild, non-medicated shampoo, e.g. baby shampoo	N/A	Discussed previously
Sitz baths, (perineal/rectal patients) from beginning of treatment course	N/A	Discussed previously
PROMOTE COMFORT: BCCA GUIDELINE P8-9		
Apply hydrophilic (water-based) body lotions or creams on affected area. Gently apply with clean hand twice a day. DO NOT rub skin. E.g. Lubriderm®, Keri® Lotion, Glaxal Base®, Dermal Therapy™, Eucerin®, and Aquaphor®.	Accept	
Aloe vera gel may be used on the skin (Erythema, BCCA Guideline, P8)	Accept with modifications	Should specify the %/strength; (patients can use plant itself – 100%)
Discontinue use of Aloe vera (Dry Desquamation, BCCA Guideline, P13)	Accept	
Avoid petroleum jelly based products (hydrophilic/water repelling) E.g. Vaseline®	Accept	
PROMOTE COMFORT: BCCA GUIDELINE P8-9 – cont'd		
Avoid irritant products containing alcohol, perfumes or additives and products containing alpha hydroxy acids (AHA)	Accept	
Cornstarch, talc and baby powder may be used on intact skin **but are not recommended**	Reject	Based on studies showing 'caking' and promotion of yeast infection; baby powder has metals (zinc) which promote irritation from RT
NS compresses	Accept with modifications	CCMB – it is recommended by nurses/physicians for symptom relief

Table 6. Radiation Dermatitis/Erythema/Dry Desquamation – cont'd

TOPIC	DECISION	PANEL COMMENTS
BCCA Guideline: does not use the term "radiation dermatitis". Recommendations are separated into categories: "Erythema" and "Dry Desquamation". Recommendations are identical, except re: Aloe vera gel (see below) – cont'd		
REDUCE INFLAMMATION: BCCA GUIDELINE P9		
Alleviate pruritis and inflammation; corticosteroid creams; use only on intact skin. Hydrocortisone cream used sparingly; may require prescription. Wash hands after applying.	Accept with modifications	No evidence to support this. Patients may find useful as comfort measure based on clinical experience. Modifications: Use 0.5% first; if not effective then 1%. Put in recommendations for patient handouts
PREVENT TRAUMA TO TREATMENT AREA: BCCA GUIDELINE P9-10		
For facial and underarm shaving use an electric razor		
Loose non-binding clothing e.g. soft breathable fabric like cotton		
Protect skin from direct sunlight & wind exposure, e.g. wear wide brimmed hat and protective clothing (long-sleeved cotton shirt)		
Avoid swimming in chlorinated pools, hot tubs & lakes		
Avoid extremes of heat and cold e.g. avoid heating pads and ice packs		
Avoid adhesive tape. Extend dressing out of treatment area. Adhere to intact skin with paper tape. E.g. secure dressing with cling gauze net tubing or under clothing.		
WRHA Guideline: recommendations categorized according to RTOG/EORTC scale grade of skin problem. **Erythema and Dry Desquamation** (RTOG/EORTC grades 1&2):		
MANAGE PAIN / PROMOTE COMFORT: WRHA GUIDELINE P128		
Non-steroidal anti-inflammatory medications	Accept with modifications	Do we agree with our patients using? Add in contraindications to NSAIDS. Patients may have coagulation problems.
Acetaminophen with codeine (Tylenol® with codeine No.3)	Accept with modifications	Want to add in contraindications to NSAIDS Tylenol®, codeine
Topical analgesics	Reject	Pharmacist: absorption can be poor, no better than oral
Topical steroids to reduce inflammation	Accept	
Maintain skin hydration (promote use of hydrophilic lotions or creams)	Accept	
Control the environment (cool, humid)	Accept	
MANAGE ITCHING: WRHA GUIDELINE P128		
Hydrocortisone 1% used sparingly and avoiding areas of breakdown or infection for relief of itchy, irritable, burning skin (short term use only)	Accept with modifications	Start with 0.5% then increase to 1%
Topical Benadryl®	Reject	Not seen clinically. Pharmacist: no benefit in additional topical agent
Oral antihistamines	Accept with modifications	Detail needed. DiphenhydrAMINE is used but there are side effects with its use (constipation, drowsiness). Is a less specific drug; offers best relief of symptoms. Isn't much difference between antihistamines, so limited options. May consider another antihistamine if excessive drowsiness is a problem for patient. [2017 TALLman lettering: diphenhydrAMINE]
Consider non-adherent dressings e.g. Adaptic® (avoid if wound is infected) (may become adherent if left in place for prolonged periods) LE IV	Reject	More painful to remove dressings than leave area without a dressing. At CCMB we are not doing dressings on dry desquamation. One panel member comments she has seen 1 or 2 patients in the past year or so with Telfa™ dressings.
Avoid smoking	Accept	
PREVENT INFECTION: WRHA GUIDELINE P128-129		
Monitor closely for clinical signs of infection – fever, odour, purulent discharge, swelling, increased pain	Accept	Standard of Care
Promote good skin hygiene	Accept	Standard of Care
Promote hand washing	Accept	Standard of Care
Sitz baths for patients receiving radiation therapy in the perineal/rectal area (10-15 minute tepid NS soaks up to 4 times per day or following each bowel movement)	N/A	
Stool softeners for patients receiving radiation therapy in the perineal/rectal area	N/A	

Table 6. Radiation Dermatitis/Erythema/Dry Desquamation – cont'd		
TOPIC	**DECISION**	**PANEL COMMENTS**
WRHA Guideline: recommendations categorized according to RTOG/EORTC scale grade of skin problem. **Erythema and Dry Desquamation** (RTOG/EORTC grades 1&2) – cont'd		
Cleanse with baby wipes following each bowel movement for patients receiving radiation therapy in the perineal/rectal area	N/A	
Patient teaching as above	N/A	
QUALITY OF LIFE: WRHA GUIDELINE P129		
Manage symptoms according to patient's priority	Accept	Holistic, Supportive Care
Enhance patient's personal sense of value and safety	Accept	Holistic, Supportive Care
Promote feelings of control with patient education/self-care teaching/ information sharing	Accept	Holistic, Supportive Care
Provide emotional support/ counselling to the patient and family	Accept	Holistic, Supportive Care
Referral to psychosocial oncology, counselling services, social work, child life program as appropriate	Accept	Holistic, Supportive Care
Facilitate access to pain and symptom clinic, art therapy, yoga, dietician, as indicated	Accept	Holistic, Supportive Care
TREAT THE WOUND: WRHA GUIDELINE P129		
Promote moist wound healing	Accept	
Principles for treatment are similar to those for first and second degree burns	Reject	This is not a recommendation, this is a rationale
NS irrigation with syringe for wound cleansing	Reject	
Semi-permeable film dressings can be used (and left in place throughout treatment) on areas of low or no exudates	Reject	
Consider 3M™ Cavilon™ No Sting Barrier Film, Adaptic®; Avoid if infection is present (Risk: may become adherent if left in place for prolonged periods)	Reject	
Hydrogel sheets (E.g. RadiaCare™ Gel Sheet) for dry or moist desquamation – can remain on up to 3 days	Reject	

Table 7. Moist Desquamation

TOPIC	DECISION	PANEL COMMENTS
CCO Guideline: does not address the management of dry desquamation and moist desquamation as separate categories		
BCCA Guideline		
PROMOTE CLEANLINESS: BCCA GUIDELINE P16		
Cleanse with room temperature NS. NS compress applied 3-4 times per day. (See BCCA Guideline suggested treatment P26).	Accept with modifications	No compress. Okay cleansing with NS at room temperature.
Sitz baths (See BCCA Guideline suggested treatment P27).	N/A	N/A
MAINTAIN PRINCIPLES OF MOIST HEALING: BCCA GUIDELINE P16-17		
Use moisture retentive protective barrier ointment after each saline soak. Remove prior to treatment. E.g. Proshield®	Reject	Proshield® product unknown at CCMB
Consider use of hydrogels. E.g. DuoDERM® Gel, Intrasite Gel™. (See BCCA Guideline suggested treatment P29).	Accept with modifications	Post-tx only. Re-look at evidence. Is it suitable for treatment setting?
Use non-adherent dressings over topical product. (E.g. Mepitel®)	Accept with modifications	Must clarify use of Mepitel®. Should we use it for everybody? Clinical experience: it's better than jelonet (other product). Patients find it comforting. Check Polysporin®
Use absorbent dressings over low-adherent dressings. Change as drainage warrants. E.g. Aquacel™ (moderate to heavy), Kaltostat® (bleeding wounds)	Accept	Rarely use Aquacel™/Keltostat® as bleeding wounds are seen infrequently. In malignant wound, there would probably be more bleeding. Will accept this
Control Drainage. Consider use of hydrocolloid dressings. E.g. DuoDERM® Dressing (moderate), Combiderm® (excessive). See BCCA Guideline suggested treatment P29-30	Accept with modifications	There's a wound care contract competition that may determine which products are available. HSC uses Adaptic®, CCMB using Mepitel® (special order). Nursing figured out pricing: no cost difference between Mepitel® & Adaptic® factoring in dressings etc. Should do some research on this. Adaptic® has to be changed daily. Mepitel® change outer dressing only up to 7 days. Could be option for people who don't want to touch the wound
Secure products with appropriate secondary dressing. E.g. Telfa™ (low adherent), Ete® (low adherent)	Accept	We use lots of Telfa™ here
Avoid adhesive tape. Extend dressing out of treatment area and adhere to intact skin with paper tape. (E.g. cling gauze, net tubing under clothing)	Accept with modifications	Remove paper tape. With most patients, we don't use tape; with Mepitel®, Telfa™ sticks to it
MANAGE PAIN: BCCA GUIDELINE P18		
Cover open areas to protect nerve endings. To significantly decrease burning and tenderness use appropriate dressings. E.g. Mepitel® (non-adherent), Telfa™ (low adherent), Ete® (low adherent)	Accept with modifications	No panel member has used . Ete® not available through contract at CCMB. Remove Ete® (low adherent)
Use analgesic as instructed by physician	Accept	
PREVENT INFECTION: BCCA GUIDELINE P18		
Regularly assess for signs of infection	Accept	Basic nursing practice
Culture wound following cleansing with NS	Accept	Basic nursing practice
Antibacterial/antifungal products as ordered by oncologist as symptoms warrant. (E.g. Flamazine™, Bactroban®. (See BCCA Guideline suggested treatment P28.)	Accept with modifications	When wound is moist, products are being ordered here. Some still using Flamazine™; burn ward HSC is not. Allergy concern with Flamazine™ (sulfa)
Avoid cornstarch, talc and baby powders	Accept	
Cleanse with NS. (See BCCA Guideline suggested treatment P26.)	Accept	
WRHA Guideline: recommendations categorized according to RTOG/EPRTC scale grade of skin problem. Moist Desquamation (RTOG/ EORTC grades 2&3)		
TREAT PATIENT-RELATED CONCERNS: MANAGE PAIN/PROMOTE COMFORT P129		
Tylenol® with Codeine No.3	Accept	
Morphine elixir	Accept	
Fentanyl patches	Accept	
Topical analgesics	Accept	Topical sprays – used in palliative care, (lidocaine) – used under dressings
Maintain skin hydration (promote use of hydrophilic lotions or creams)	Accept	
Control the environment (cool, humid)	Accept	

Table 7. Moist Desquamation – cont'd

TOPIC	DECISION	PANEL COMMENTS
WRHA Guideline: recommendations categorized according to RTOG/EPRTC scale grade of skin problem. Moist Desquamation (RTOG/ EORTC grades 2&3) – cont'd		
TREAT PATIENT-RELATED CONCERNS: MANAGE ITCHING – WRHA P129-130		
Oral antihistamines for itching	Accept with modifications	Add "e.g. Benadryl®". Oral antihistamines help with itching and Benadryl® is commonly used.
Avoid smoking	Accept	
TREAT PATIENT-RELATED CONCERNS: PREVENT INFECTION – WRHA P130		
Monitor closely for clinical signs of infection – fever, odour, purulent discharge, swelling, increased pain	Accept	Group liked how recommendation prompts by including 5 signs of infection.
Consider silver-sulfadiazine cream (Flamazine™) daily dressing (unless allergic to sulfa drugs)	Reject	Flamazine™ use has already been rejected. Concern about stating 'daily' dressings as some dressings are left on longer.
Consider non-adherent dressings e.g. Mepitel®; Adaptic®; avoid if infection is present; may become adherent if left in place for prolonged periods	Reject	
Patient teaching as above	Reject	This needs to be clarified
TREAT PATIENT-RELATED CONCERNS: MAINTAIN QUALITY OF LIFE – WRHA P130		
Manage symptoms according to patient's priority	Accept with modifications	Reword to patient preference. Discussion about meaning of this statement. Panel methodologist suggested there is emerging data about meaning of symptoms causing distress to patients. Overarching principles of care.
Enhance the patient's personal sense of value and safety	Accept	Overarching principles of care
Promote feelings of control with education/information sharing/self-care teaching	Accept	Overarching principles of care
Provide emotional support to the patient and family	Accept	Overarching principles of care
Offer counselling to the patient and family	Accept	Overarching principles of care
Offer spiritual support	Accept	Overarching principles of care
Referral to psychosocial oncology, counselling services, social work, child life program as appropriate	Accept with modifications	Overarching principles of care. Remove 'child life program' as CCMB guideline deals with adult patients. Include others, such as Kids can Cope, Family Services (community), this list could be updated.
Facilitate access to pain and symptom clinic, art therapy, yoga, dietician, as indicated	Accept	These are overarching principles of care.
TREAT THE WOUND – WRHA P130		
Promote moist wound healing	Accept	Principle of wound care
Principles for treatment are similar to those for first and second degree burns	Reject	Not a recommendation statement. It is a rationale
NS irrigation with a syringe for wound cleansing	Reject	We do not use WRHA wound guidelines, outline what to use
Consider non-adherent dressing e.g. Mepitel®, Adaptic®, for comfort for both dry and moist desquamation. Apply, cover with abdominal pad if necessary and secure with 'burn net'; avoid if infection present (risk: may become adherent if left in place for prolonged periods).	Accept	
Moisture retentive dressings	Reject	Not specific enough
Hydrogel sheets e.g. RadiaCare™ Gel Sheet - can remain on up to 3 days	Reject	Used on some rectal patients but never with breast. Expensive, not covered by Home Care.
Hydrocolloid e.g. DuoDERM®	Reject	
Consider vacuum assisted closure therapy for chronic slow-healing wounds	Reject	This is used more on surgical wounds
Swab any odorous lesions and treat infections promptly	Accept	Principle of wound care. Panel to provide procedural details for clinicians
Consider silver-sulfadiazine cream (Flamazine™) – unless allergic to sulfa	Reject	
Consider sofra-tulle dressings (contraindicated in patients allergic to lanolin) or Bacitracin™ for patients with sulfa allergies	Accept	

Table 8. Ulceration/Haemorrhage/Necrosis

TOPIC	DECISION	PANEL COMMENTS
CCO Guideline: does not address these clinical problems		
BCCA Guideline: does not address these clinical problems		
WRHA Guideline: recommendations categorized according to RTOG/EORTC scale grade of skin problem: Ulceration, haemorrhage, necrosis.(RTOG/EORTC grades 2&3):		
Skin necrosis and chronic ulceration may require skin grafting (rare)	Accept with modifications	Clarify wording to "with severe radiation reaction"
Refer to Malignant Wounds section	Accept	Can put in RT necrotic wound would be managed same as malignant necrotic wound

Table 9. Follow-Up

TOPIC	DECISION	PANEL COMMENTS
CCO Guideline: does not address this topic		
WRHA Guideline: gives recommendations for management of patients undergoing RT. Only reference to follow-up is on p125, under "Prevention Strategies", and refers to application of topical products for "2 weeks following completion of treatment"		
BCCA Guideline: provides recommendations for 2 categories under section "Potential Post Radiation Skin Reactions": Late Reactions and Recall Phenomenon		

Table 10. Potential Post-Radiation Skin Reaction: Late Reactions

TOPIC	DECISION	PANEL COMMENTS
BCCA Guideline		
MAINTAIN SKIN FLEXIBILITY – BCCA GUIDELINE P20		
Apply (hydrophilic) lotions to (water-based) body lotions or creams on the affected area. E.g. Lubriderm®, Keri® Lotion, Glaxal Base®, Dermal Therapy™, Eucerin®, Aquaphor®. (See BCCA Guideline suggested treatment P25.) LEIIB	Accept with modifications	Need to clarify using a standard definition: Late Reaction; Follow-Up (2 weeks post – ACUTE DELAYED LATE), Recall Phenomenon (see definition in BCCA Guidelines)
PREVENT INJURY: BCCA GUIDELINE P20		
Avoid excessive sun exposure e.g. wear protective clothing. Sun blocking creams or lotions with minimum SPF 30 are recommended at all times	Accept with modifications	Add in section Delayed Reaction. Add length of time

Table 11. Potential Post-Radiation Skin Reaction: Recall Phenomenon

TOPIC	DECISION	PANEL COMMENTS
BCCA Guideline		
PROMOTE CLEANLINESS: BCCA GUIDELINE P22		
Cleanse with room temperature NS. NS compress applied 3-4 times per day. (See suggested treatment BCCA Guideline P26)	Accept with modifications	Clarify how long and for dry desquamation only. NS compress: comfort only until skin breakdown. Some cases of skin sloughing on day 3 or 4 chemo
Sitz baths for perineal/rectal patients. (See suggested treatment BCCA Guideline P27)	N/A	
MAINTAIN PRINCIPLES OF MOIST HEALING: BCCA GUIDELINE P22-23		
Use moisture retentive protective barrier ointment after each saline soak. Remove prior to treatment e.g. Proshield®	Reject	Not available at CCMB
Consider use of hydrogels e.g. DuoDERM® Gel, Intrasite Gel™ (See suggested treatment BCCA Guideline P29-30).	Accept	Not receiving RT (off RT), so can leave on therefore usage is ok
Use non-adherent dressings over topical product e.g. Mepitel®	Accept	
Use absorbent dressings over low-adherent dressings. Change as drainage warrants e.g. Aquacel™ (moderate to heavy), Kaltostat® (bleeding wounds).	Accept with modifications	Add Mepilex® Border (a product being used that prevents skin maceration). Keep terminology the same
TOPIC	**DECISION**	**PANEL COMMENTS**
BCCA Guideline		
MAINTAIN PRINCIPLES OF MOIST HEALING: BCCA GUIDELINE P22-23 – cont'd		
Control drainage. Consider use of hydrocolloid dressings [DuoDERM® Dressing (moderate), Combiderm® (excessive)]. (See suggested treatment BCCA Guideline P29-30)	Accept	
Secure products with appropriate secondary dressing e.g. Telfa™, Ete®	Accept with modifications	Remove Ete®
Avoid adhesive tape. Extend dressing out of treatment area to adhere to intact skin with paper tape e.g. cling gauze, net tubing under clothing	Accept with modifications	Expansion needed. Remove 'with paper tape'. Mepitac®: re-usable silicone product; non-formulary; available for patients to buy from med/athletics supply. E.g. Diamond, Stevens Homecare, Shoppers will special order. Low cost. DuoDERM® strip can be used; attaches to tape
MANAGE PAIN: BCCA GUIDELINE P24		
Cover open areas to protect nerve endings. Use appropriate dressing to significantly decrease burning & tenderness e.g. Mepitel® (non-adherent), Telfa™ and Ete® (low adherent)	Accept with modifications	Remove Ete® (low adherent) as it is not available
Use analgesic medication as instructed by physician	Accept	Previously accepted
PREVENTION OF INFECTION: BCCA GUIDELINE P24		
Regularly assess for signs of infection. Culture wound if warranted following cleansing with NS	Accept	Previously accepted
Use antibacterial or antifungal products as ordered by oncologist, as symptoms warrant e.g. Flamazine™, Bactroban®. (See suggested treatment in BCCA Guideline P28)	Accept with modifications	Add Polysporin®. We use Polysporin®, not Flamazine™. If it's oncologists' preference, making recommendation could be hard. Glaxal Base® vs. antibacterial. Try to minimize use of antibacterial. If it hurts/burns, we tell patient "don't use it"
Cleanse with NS (See suggested treatment BCCA Guideline P26)	Accept	

9. Customization Phase

Guideline customization was completed by the working group in consultation with the larger panel. Discussion and decisions regarding tailoring the guideline's recommendations to local practice began early in the CAN-ADAPTE process and continued throughout the customization phase. Considerable effort was also put into deciding how to organize and present the guideline's recommendations for ease of use in the day-to-day clinical setting. Conclusions regarding outstanding questions that were tasked to the working group by the guideline development panel were researched, drafted into the guideline, and brought back to the panel for consideration and approval.

10. Finalization Phase

Restructuring of the working group led to considerable delay in the finalization of the clinical practice guideline. Two years after the original panel disbanded, the finalization phase was carried out by the panel chair and CPGI support team. The original panel had established a maintenance schedule of the adapted guideline to be completed every 3 years. Due to time elapsed, it was decided an update and review of the literature would satisfy the maintenance schedule and guideline finalization. Therefore an updated literature search was completed to reflect any new literature available since the original panel had formed. The finalized adaptation was presented to stakeholders and feedback was collected. Decisions regarding all feedback were made and the guideline was amended as required. Further review and update of the adapted guideline will take place every 3 years at CancerCare Manitoba, as presented in the maintenance schedule.

11. Implementation

A preliminary guideline implementation plan was developed based on the CAN-ADAPTE Adaptation Plan 2009, with a focus on multidisciplinary/multi-departmental effort. Implementation planning and discussion was considerable, and embedded throughout the entire guideline development process. Implementation decisions were recorded and set aside for later refinement of the preliminary implementation plan. It was during the development phase of the guideline that several implementation tools were initiated: pocket guide; algorithm; electronic environment for documenting wound assessment; various staff information and patient education sheets. *(See Appendices 2 to 5)*

Once the recommendations were drafted, two workshops were held to gather information from front-line nursing staff. The purpose of the first workshop was to introduce the guideline to end users (nurses and radiation therapists), identify barriers to, and garner support for, implementing the guideline. A key outcome of this workshop was identifying the need to provide extra resources in order to roll out the guideline and to provide staff education. A nursing facilitator was hired for this purpose. Nursing educators were also brought into the process to review the implementation plan and assist with review of the requested implementation tools.

The focus of the second workshop was to identify tools that would facilitate end user uptake and use of the guideline recommendations. At this workshop nurses identified practical issues affecting work flow and access to wound care supplies and equipment that would impede following the guideline recommendations. Importantly, infection prevention and control concerns were identified as a result of these discussions. In response, consultations were held with an Infection Prevention and Control Professional regarding equipment needs. Consultations with information technology specialists (Business Analysts) to develop electronic nursing

documentation were ongoing starting in the development phase of the guideline and continued throughout the implementation process. Other important consultations took place with graphic designers; language accessibility expert/adult education specialist; and other health care sub-specialities (e.g. Home Care, Dermatology, Burn Unit, Breast Cancer Patient and Family Educator, etc.).

The entire implementation process for the guideline was very iterative and did not occur sequentially as envisioned by the team. Rather, a number of parallel activities evolved in response to ideas and needs as they arose. In fact, the group found that early adopters enthusiastically began using the guideline recommendations in practice well before the guideline document was finalized, and before specialized implementation tools could be completed. It took several years, with ongoing revisions, to develop and roll out the following:

- Nursing documentation tools for the electronic health record (ARIA®)
- Pocket Cards for Wound Assessment and Wound Care Algorithms for staff
- Patient Information Sheets for Health Promotion and Self-Care which included -
    - Patient survey to ascertain baseline information on health care instruction before roll out of the guideline informed education sheets
    - Patient review and feedback of content, readability and appearance of education sheets
    - Consensus regarding content from Breast Disease Site Group Radiation Oncologists
    - Radiation Therapy and Nursing final editorial approval of the Information Sheets
- Specialized carts stocked with wound care supplies according to the guideline recommendations
- Laminated cards with tables containing all recommendations from the guideline for inclusion on the dressing carts
- Presentation of guideline recommendations and specialized implementation tools at Community Oncology Program (COP) annual conferences; Uniting Primary Care in Oncology Network (UPCON) Cancer Days; Patient Services rounds
- Guideline education sessions for front line staff (e.g. orientation of new staff nurses)
- Posting guideline on CCMB website

12. Internal and External Review Process

The guideline draft was reviewed by the working group and revised using consensus-based decisions. Internal and external peer review were then pursued, the results of which were appended to these guidelines. The internal review process was completed by Dr. Rashmi Koul, Radiation Oncologist. The external review process was completed by Dr. William Hunter, Radiation Oncologist, Western Manitoba Cancer Centre, Brandon Manitoba; Jordana Jones, RT Nurse, Western Manitoba Cancer Centre; Tamara Wells, Clinical Nurse Specialist Palliative Care, WRHA; and Kathleen Klassen, Acting Director of Centralized Operations, WRHA Home Care Program, WRHA. All reviewers completed a full review of the guideline document and a practitioner feedback survey (adapted from Brouwers and Colleagues).[3] Feedback was reviewed and discussed by the working group. Decisions to incorporate any changes into the guideline were consensus-based (acceptance, rejection, or acceptance with modifications).

13. Formal Endorsement Process

This clinical practice guideline was formally endorsed by Head of the Provincial Radiation Oncology Program. Following endorsement the guideline was released for posting on CCMB's website.

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IV. Appendices

Appendix 1 – Levels of Evidence

Levels of Evidence	
Ia	Evidence obtained from meta-analysis of randomised controlled trials
Ib	Evidence obtained from at least one randomised controlled trial
IIa	Evidence obtained from at least one well-designed controlled study without randomisation
IIb	Evidence obtained from at least one other type of well-designed, quasi- experimental study
III	Evidence obtained from well-designed, non-experimental descriptive studies, such as comparative studies, correlation studies and case studies
IV	Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

British Committee for Standards in Haematology 2007 http://www.bcshguidelines.com

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Appendix 2 – Basic Skin Care

Radiation Therapy Breast or Chestwall — Basic Skin Care

CancerCare Manitoba
ActionCancerManitoba

There are things you can do every day to take care of your skin during radiation.

You should start the following recommendations on the first day of your treatment and continue them until you are finished radiation and completely healed.

Promote Skin Hygiene — *keep radiated skin clean*

- Short, gentle, low pressure showers or baths with lukewarm Water.
- Mild soap may be used gently, if desired.
- Do not scrub the skin in the treatment area.
- Pat skin dry. Do not rub.
- Do not use a wash cloth in treatment areas.
- Deodorants and antiperspirants can be used on intact skin. Patients may continue to use deodorants and antiperspirants (includes aluminum based) if they wish. There is no evidence that skin reactions will be any worse. **Stop use if a skin reaction develops**.
- Do not freshly apply deodorant/antiperspirant on the day of your treatment until after treatment.

Promote Comfort

- Wear loose fitting non-binding clothing (e.g. soft breathable fabric like cotton; sports bra with wide band).

Prevent Infections

- Good hand washing.
- Do not use talcum, baby powder or cornstarch in treatment areas.

Protect from the Skin from Injury

- Do not use tape or bandages in treatment field.
- Do not scratch (e.g. keep your nails short).
- Do not wear jewelry over treatment area.
- Avoid using ice packs, heating pads and hot water bottles on the treatment area. You may not be able to feel extreme temperature changes in the radiated areas and you may cause an injury.
- Do not swim in lakes or pools if you have a radiation skin reaction. If the treatment area is intact, swimming in pools or lakes is permissible. After swimming immediately remove swimsuit and rinse the skin.
- Do not use hot tubs and saunas.
- Do not shave in treatment area (if necessary use an electric shaver instead).
- Do not use products containing alcohol, alpha hydroxyl acids, perfumes or other drying agents in treatment areas.
- Do not use petroleum based products.
- Do not freshly apply moisturizers within a two hour period before treatment.
- Do not use tanning lamps/salons.
- Avoid vigorous rubbing in the treatment area.

Reminder!

Do not freshly apply moisturizer within a ***two hour period*** before treatment.

Do not freshly apply deodorant/antiperspirant ***on the day of your treatment*** **until after treatment**.

Evidence Based Recommendations for the Assessment and Management of Radiation-Induced Skin Toxicities in Breast Cancer **Guideline** — Basic Breast or Chestwall Radiation Skin Care Version 1.0

Protect from Environment

- Treatment area should not be exposed to the sun.
- Cover treatment area with clothing and wear a wide brimmed hat to protect from the sun and wind.
- Use a sunscreen (SPF 30 or higher) if the treatment area cannot be kept out of the sun and as long as the skin is not open. Wash off the sun screen after being in the sun.
- Do not freshly apply sunscreen within a two hour period before treatment.

Keep Your Skin Healthy

- Drink enough fluids. Females should drink approximately 2.2 litres (9 cups) and males 3 litres (13 cups) total fluids per day.
- Limit how many drinks with caffeine you have each day. This includes coffee, tea and colas. It is recommended not to have more than 237-300 mL or 400 mg of caffeine per day. Having more caffeine can lead to dehydration.

Moisturizers should be non-scented, lanolin free, and alcohol free.
Use at least 2—3 times per day.

STOP using moisturizers if your skin becomes open **AND** call a member of your Radiation Oncology team!

- Follow Canada's Food Guide for good nutrition. Make sure you are eating enough protein. This can help your skin to heal.
- If you are having trouble eating and/or are experiencing weight loss, talk to your Radiation Oncology Team; they may refer you to see a dietician. You can take a multivitamin/mineral supplement to help you meet your nutritional needs.
- For diabetics, it is important to keep your blood sugar levels within your recommended range. If the blood sugar is too high, there may be delayed healing of the radiated skin or an increased risk for infection.
- Use a non-scented, lanolin free, alcohol free moisturizer (e.g. glaxal base cream) on your skin at least 2-3 times per day throughout treatment. **If your skin becomes open, stop using the moisturizer and call your Radiation Oncology Team.** Remember, do not freshly apply moisturizers within a two hour period before treatment.
- Aloe Vera gel can be used to cool the skin. It does not moisturize skin.

Advice is available at any time!

JUST ASK a member of your Radiation Oncology Team!

Additional Notes:

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Appendix 3 – Erythema and Dry Desquamation

Radiation Therapy Breast or Chestwall — Skin Changes/Reactions: Erythema and Dry Desquamation

CancerCare Manitoba
ActionCancerManitoba

Erythema — the radiated skin becomes pink to red in colour. There may also be mild swelling, burning, itching and pain. Usually occurs 2—3 weeks after starting treatment.

Dry Desquamation — dryness of the radiated skin, itching, scaling, flaking and peeling. These skin changes cause a break in the skin. Open skin can increase the risk of infection.

Important

If you notice that you have Erythema or Dry Desquamation talk to a member of your Radiation Oncology Team.

Continue to follow the guidelines laid out on the Radiation Therapy Breast or Chestwall — Basic Skin Care sheet that you were given. In addition:

Promote Skin Hygiene — *keep radiated skin clean*

- Continue to bath or shower if possible using recommended soaps, as tolerated.
- If you take baths, do not soak the open skin under the water. This water is dirty and can cause an infection.
- Deodorants and antiperspirants can be used on intact skin. Patients may continue to use deodorants and/or antiperspirants if they wish. There is no evidence that skin reactions will be any worse. **Stop use if a skin reaction develops.**
- Do not freshly apply deodorant/antiperspirant on the day of your treatment until after treatment.

Reminder!

Only use deodorants and antiperspirants on intact skin.

STOP use if you develop a skin reaction.

Do not freshly apply deodorant/ antiperspirant ***on the day of your treatment until after treatment***.

Itchy Skin

- Talk to your Radiation Oncology Team about hydrocortisone cream and/or an oral antihistamine to relieve itchiness.

Promote Comfort

- Medications are available to treat pain. Talk to your Radiation Oncology Team.

Prevent Infections

- Every day check for signs of infection (fever, odour, discharge, swelling or pain). Contact your Radiation Oncology Team if you have any signs of infection.

Protect the Skin from Injury

- Open skin is vulnerable to infection. Do not swim in pools or lakes. Chlorine can irritate and dry the skin. Lakes can contribute to skin infections.
- Do not freshly apply moisturizers within a two hour period before treatment.

Reminder!

Do not freshly apply moisturizer within a ***two hour period*** before treatment.

Protect from Environment

- Continue to follow basic skin care guidelines.

Keep Your Skin Healthy

- Continue to follow basic skin care guidelines.

Evidence Based Recommendations for the Assessment and Management of Radiation-Induced Skin Toxicities in Breast Cancer **Guideline** — Erythema, Itch and Dry Desquamation Version 1..0

Appendix 4 – Moist Desquamation

Radiation Therapy Breast or Chestwall — Skin Changes: Moist Desquamation

CancerCare Manitoba
ActionCancerManitoba

Moist Desquamation is when the skin peels, blisters and has clear yellow drainage. Open skin can be painful because the nerves in the skin are not protected. This can be worse in areas where the skin touches other skin. For example: in the armpit and side of chest being rubbed by the arm with movement.

Important

If you notice that you have moist desquamation talk to a member of your Radiation Oncology Team. The area usually needs to have a dressing put on to keep it clean and prevent infection.

Continue to follow the guidelines laid out on the Radiation Therapy Breast or Chestwall — Basic Skin Care and Radiation Therapy Breast of Chestwall — Skin Changes: Erythema, Itch and Dry Desquamation sheets that you were given. In addition:

Promote Skin Hygiene — *keep radiated skin clean*

- Do not use soap on open skin.
- Do not use deodorants and antiperspirants on open skin.

Promote Comfort

- Medications are available to treat pain. Talk to your oncology doctor or nurse.
- Talk to your radiation nurse who will help you with dressings if needed.

Prevent Infections

- Every day check for signs of infection (fever, odour, discharge, swelling or pain). Contact your Radiation Oncology Team if you have any signs of infection.

Protect the Skin from Injury

- Continue to follow basic skin care guidelines.
- Open skin is vulnerable to infection. Do not swim in pools or lakes. Chlorine can irritate and dry the skin. Lakes can contribute to skin infections.

Protect from Environment

- Continue to follow basic skin care guidelines.

Keep Your Skin Healthy

- Continue to follow basic skin care guidelines.
- Do not use moisturizer on open skin.

Reminder!

You should check daily for infections.

Signs of infection are:
Fever
Odor
Discharge
Swelling or pain

Evidence Based Recommendations for the Assessment and Management of Radiation-Induced Skin Toxicities in Breast Cancer **Guideline** — Moist Desquamation Version 1.0

Appendix 5 – Late Skin Effects

Caring For Yourself After Radiation

CancerCare Manitoba
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It is important to continue to follow the instructions given to you on the Radiation Therapy Breast or Chestwall — Basic Skin Care Information sheet; and any other additional sheets you may have been given (Radiation Therapy Breast or Chestwall — Skin Changes: Erythema, Itch, Dry Desquamation and/or Radiation Therapy Breast or Chestwall — Skin Changes: Moist Desquamation) until your side effects have gone away — usually within 6—8 weeks.

Skin Care

- Skin reactions (redness, itchiness, peeling and/or blistering) in the treated area may continue to increase for up to 7—10 days following the completion of your treatment. The reactions should then slowly start to improve. It may take up to 6—8 weeks before your skin is fully healed.
- Some patients have been given permanent tattoos, while others may have had marks drawn on their skin. Do not scrub off any skin marks—marks will disappear on their own.
- If your skin is peeling or blistering it is important that you follow the specific washing/cleaning instructions given to you by the nurse or therapist.
- Wait until the tenderness/redness and itchiness has gone away before resuming use of cosmetics or perfumes, and/or shaving in the treated area.
- Over time you may notice changes in the treated skin; it may appear slightly darker or tanned, or you might notice more freckles.
- The treated skin may always be more sensitive to the sun and cold. Keep treated areas well protected by covering up when outside. Use a sun block product with a SPF of at least 30; put it on 30 minutes before going out. Re-apply at least every two hours or after swimming or sweating. It is recommended to use sunscreen on sunny days in the winter. Remember to check sunscreen bottles for best before date—old sunscreen will not protect you.
- Do not use tanning beds.

Reminder!

You may experience fatigue for some time after the completion of treatment. Consider adjusting your life style for a few months (i.e. only return to work part-time).

Fatigue

- Tiredness and fatigue will continue while your body heals. Your energy levels will return with time, usually within 8—12 weeks after your last day of treatment. If fatigue persists see your physician. Follow *Canada's Food Guide* for recommendations of the amount and type of foods required to meet your nutritional and physical needs.

Follow Up Care

After your treatment is completed, a follow-up appointment will be scheduled. At this appointment you will be provided with a personalized follow-up care plan which will outline a follow-up schedule including necessary tests and appointments, what symptoms to watch for, and a summary of the treatments you received to treat your breast cancer. A copy of this follow-up plan will be provided to your family physician or nurse practitioner.

Additional information about available cancer and post treatment programs can be found by calling the **Breast & Gyne Cancer Centre of Hope** at 204-788-8014 or 1-888-660-4866 (toll free) or in a booklet entitled *Moving Forward after Cancer Treatment* is available online at movingforwardaftercancer.ca.

Important

If you do not receive a treatment summary/follow-up care plan from your Radiation Oncology Team please contact your clinic nurse ☺

Evidence Based Recommendations for the Assessment and Management of Radiation-Induced Skin Toxicities in Breast Cancer **Guideline** — Caring for Yourself and Late Skin Reactions Version 1.0

Late Effects

You may experience late effects from your radiation treatment. Late effects are side effects from radiation that may show up several months to years after the treatment has ended. Not everyone will have late effects, but it is important to know what to look for.

Within the treated area, the way your skin looks, feels and moves can change. It may be more severe for some people than others. These effects may be permanent or improve gradually over time. Late radiation skin changes may include:

- **Scaling** is when the skin peels and flakes. This dryness is caused by damage to the sweat/oil glands.
- **Atrophy** is when the radiated skin becomes thin **and** fragile. Skin may recover over time but it will never get back to the way it was before radiation.
- **Telangiectasia** is purplish-red spots on the skin surface that look like little spiders. This is caused by damage to tiny blood vessels in the skin. This can occur up to 8 years following radiation therapy.
- **Fibrosis** is when the skin feels hard, thick and uneven. This can cause tightness that limits movement of the area. Soft tissue under the skin can become hard and painful. Fibrosis can occur 4-6 months after treatment.
- An **ulcer** is an open sore that does not heal easily. An injury to the radiated area can cause the skin to become red, hot and painful. The skin may break open and cause an ulcer.
- **Hyperpigmentation** is a darkening of the skin. This often resolves in 3 months to a year after completion of radiation but may not go away. People with darker skin have more melanin and may experience more hyperpigmentation.
- **Hypopigmentation** is a lightening of the skin. This can be a permanent change that occurs following the resolution of hyperpigmentation.
- **Lymphedema** is a collection of fluids that causes swelling in the arms.

Please contact the **Breast and Gyne Cancer Centre of Hope** at 204-788-8014 or 1-888-660-4866 and ask to speak to the Breast Cancer Patient and Family Educator **as soon as possible** if you notice:

- Telangiectasia
- Severe fibrosis causing pain or which limits the ability to move the area and nearby limbs
- Tissue breakdown or ulceration
- Severe scaling
- Lymphedema

Additional Notes:

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CCMB Clinical Practice Guideline: Symptom Management
Management of Long-Term Effects of Radiation-Induced Skin Toxicities in Breast Cancer – A 5 Part Series
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