



Evidence-Based Series 5-3

The Management of Head and Neck Cancer in Ontario

*R Gilbert, M Devries-Aboud, E Winquist, J Waldron, M McQuestion,
and the Head and Neck Disease Site Group*

A Quality Initiative of the
Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)

Report Date: December 15, 2009

An assessment conducted in December 2012 deferred the review of Evidence-based Series (EBS) 5-3, which means that the document remains current until it is assessed again next year.

The full Evidence-based Series 5-3 is comprised of 3 sections and is available on the CCO website (<http://www.cancercare.on.ca>) PEBC Head & Neck DSG page at:

<http://www.cancercare.on.ca/toolbox/qualityguidelines/diseasesite/head-neck-eb/>

- Section 1: Organizational and Clinical Practice Guideline Recommendations
- Section 2: Evidentiary Base
- Section 3: EBS Development Methods and External Review Process

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Evidence-Based Series 5-3: Section 1

The Management of Head and Neck Cancer in Ontario: Organizational and Clinical Practice Guideline Recommendations

*R Gilbert, M Devries-Aboud, E Winqvist, J Waldron, M McQuestion,
and the Head and Neck Disease Site Group*

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PURPOSE OF THIS GUIDELINE

The Head and Neck Disease Site Group (DSG) has recognized a need for guidance regarding the organization and delivery of healthcare services for patients with head and neck cancer, including specific recommendations for the organization of care, the human and physical resources required, and appropriate treatment approaches that should be considered for this population of patients.

QUESTIONS

Organization of Care

- 1) What minimum requirements are necessary for the organization and delivery of multidisciplinary care to patients with head and neck mucosal malignancies? Areas of interest include healthcare teams and unique infrastructure.
- 2) What are the recommended staff requirements and expertise required by medical/surgical and allied healthcare professionals to provide optimal care for head and neck patients? Areas of interest include minimum volumes and training to optimize patient outcomes.

Clinical Management

- 3) What is the optimum clinical management recommended for patients with tumours of the head and neck?

TARGETTED PATIENT POPULATION

Adult patients who present with symptoms of, or have been diagnosed with, head and neck mucosal malignancies, including salivary and advanced skin, but not thyroid, cancer.

INTENDED USERS

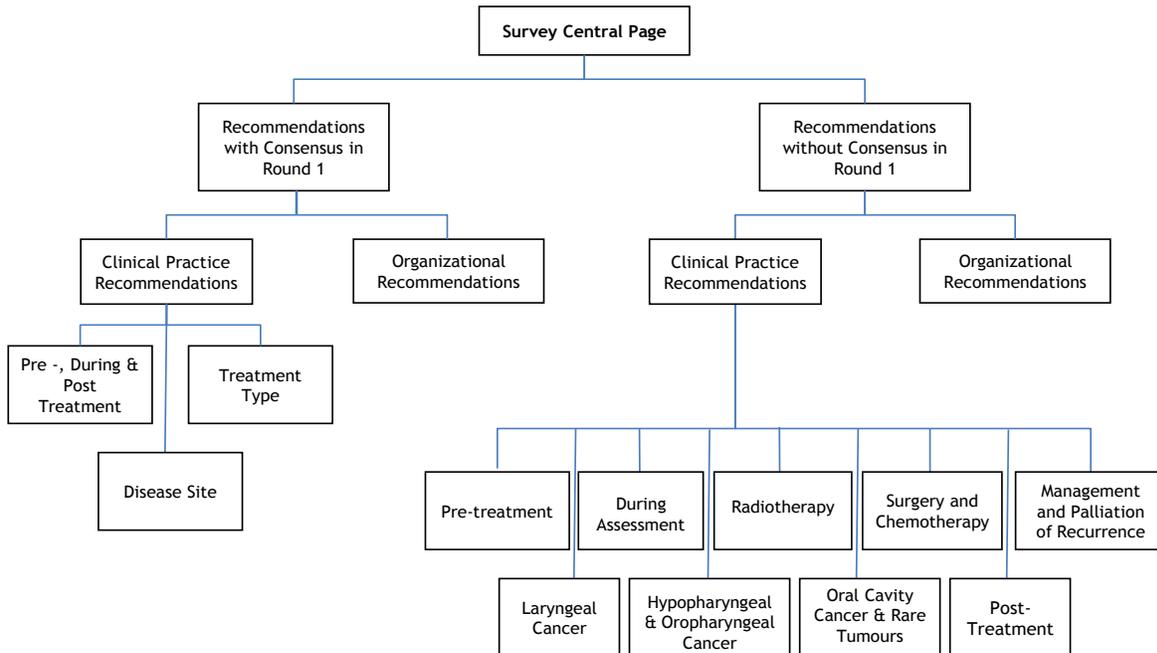
This document is intended for administrators responsible for developing and implementing new head and neck cancer programs, as well as oncology healthcare professionals who interact with head and neck cancer patients during the full continuum of care from diagnosis to post-treatment follow-up and rehabilitation.

OVERVIEW

The recommendations were developed by the Head and Neck Management Working Group (HNMWG) (see Section 2: Appendix 1 for list of members), using the methods of guideline adaptation (1), updating of evidence, and formal consensus in the following manner:

- Draft recommendations for the organization of care were adapted to the Ontario context from a service guidance document *Improving Outcomes in Head and Neck Cancers* published in 2004 by the National Institute for Health and Clinical Excellence (NICE) (2), and supplemented by the expert opinion of the working group. This yielded 27 draft organization of care recommendations.
- Draft recommendations for clinical management were adapted to the Ontario context from a clinical practice guideline *Diagnosis and Management of Head and Neck Cancer* published in 2006 by the Scottish Intercollegiate Guidelines Network (SIGN) (3). The guideline was supplemented by an additional literature search to update the evidence since 2004 (4-14), and to address areas not covered by the original source documents (e.g., IMRT) (15), and the expert opinion of the working group. The search yielded 150 draft clinical management recommendations.
- A modified Delphi process was used to review and come to consensus on the draft recommendations. A diverse group of individuals involved in the care of patients with head and neck cancer (medical oncologists, radiation oncologists, surgeons, nurses, registered dietitians, speech language pathologists, and social workers) participated in a two-round consensus process, conducted through an online survey (43 respondents in round 1 and 30 respondents in Round 2) (Figure 1) (see additional details in Section 2). Consensus was defined as 75% or more of respondent having registered strong agreement in favour of the recommendation. All 177 recommendations developed through the consensus process are presented, according to the outline below. For 144 recommendations (81%), consensus in favour of the recommendation was met. For 33 recommendations (19%), the threshold level for consensus was not met. Of these, the level of agreement reached 65%. Each of the recommendations that did not achieve consensus is marked by a cross symbol (†). There are a few recommendations that were thought to have reached consensus in round one, but it was later discovered this was not the case. However, since there was no disagreement with any of these draft recommendations, they were left unchanged. They are marked as having reached consensus in round 1 with a pie symbol (consensus round 1^π).

Figure 1: Schematic drawing showing the steps of the second round of the survey.



RECOMMENDATIONS

Overall

The specific recommendations made in this document are set out with a light blue background; explanatory text and qualifying statements have no background. Each recommendation is listed with a source, (i.e., NICE, SIGN, and HNMWG), the level (%) of agreement, and in which round consensus was achieved. Recommendations whose source is marked with an asterisk (*) are based on the expert opinion of the source. Each of the recommendations that did not achieve consensus is marked by a cross symbol (†).

The HNMWG recommends that all 177 recommendations should be implemented.

Key Evidence and Adaption

Two guidelines identified through the environmental scan were considered the most appropriate to answer the guideline questions. The NICE document *Guidance on Cancer Services - Improving Outcomes in Head and Neck Cancer (2)* addressed the organization of care questions. The SIGN document *Diagnosis and Management of Head and Neck Cancer (3)* addressed the clinical management questions. These two documents served as the basis for this guideline and were supplemented by evidence obtained through an updated search of the literature. Both guidelines clearly defined their scope and purpose, as well as providing clear and concise recommendations. Systematic review methodologies were used comprehensively by both, and each assessed and addressed the scientific quality of the included studies. The quality of included research in these two guidelines ranged from satisfactory to high quality.

The working group utilized the ADAPTE process (<http://www.adapte.org/>) to adapt recommendations from these two guidelines (1). The objective of the ADAPTE process is to take advantage of existing guidelines in order to enhance the efficient production and use of the resulting high-quality adapted guidelines. The adaptation process has been designed to ensure that the resulting and final recommendations address specific health questions relevant for the context of use and that they are suited to the needs, priorities, legislation, policies, and resources in the targeted setting, without undermining their validity.

Following the ADAPTE protocol, the relevant guidelines identified were screened and assessed for quality, currency, content, consistency, and acceptability/applicability, using the Appraisal of Guidelines Research and Evaluation (AGREE) instrument (16). Quality was assessed by three independent reviewers. With the instrument, agreement with a series of statements, intended to capture dimensions of guideline quality, is rated on a scale of 1 to 4 for each of the 23 instrument statements.

The guideline development process, utilizing ADAPT, proceeds under the assumption that the original recommendations are reasonable and supported by the evidence. Confidence in this assumption is fostered from satisfactory AGREE scores. It is beyond the scope of the guideline development process and this document to make the connection between the recommendations and the original key evidence. For those who wish to do so, please refer the NICE (2) and SIGN (3) documents.

The complete evidentiary base for this process included:

- Six organizational guideline:
 - 1) Guidance on Cancer Services - Improving Outcomes in Head and Neck Cancer, NICE, 2005
 - 2) Upper Aerodigestive Tract (Including Salivary Glands), College of American Pathologists, 2005
 - 3) Organizational Standards for the Delivery of Intensity Modulated Radiation Therapy (IMRT) in Ontario, Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO), 2008
 - 4) Provider-Patient Communication: A Report of Evidence-Based Recommendations to Guide Practice in Cancer, PEBC, CCO, 2008
 - 5) Cancer-related Pain Management: A Report of Evidence-Based Recommendations to Guide Practice, PEBC, CCO, 2008
 - 6) Organizational Standards for Diagnostic Assessment Programs, PEBC, CCO, 2007
- Four clinical practice guidelines:
 - 1) Diagnosis and Management of Head and Neck Cancer, SIGN, 2006
 - 2) Clinical Practice Guidelines for the Prevention and Treatment of Cancer Therapy-Induced Oral and Gastrointestinal Mucositis, Multinational Association of Supportive Care in Cancer (MASCC), 2004
 - 3) American Society of Clinical Oncology Guideline for Antiemetics in Oncology: Update 2006, American Society of Clinical Oncology, 2006
 - 4) 2006 Update of Recommendations for the Use of White Blood Cell Growth Factors: An Evidence-Based Clinical Practice Guideline, J Clin Oncol, 2006
-
- One meta-analysis:
 - 1) Hyperfractionated or Accelerated Radiotherapy in Head and Neck Cancer: A Meta-analysis, Lancet, 2006
- Two randomized controlled trials:

- 1) Cisplatin, Fluorouracil, and Docetaxel in Unresectable Head and Neck Cancer, N Engl J Med, 2007
- 2) Cisplatin and Fluorouracil alone or with Docetaxel in Head and Neck Cancer, N Engl J Med, 2007

The HNMWG acknowledges that in some cases the available evidence listed above did not directly establish optimal strategies in the management of head and neck cancer. In such instances, the HNMWG drafted recommendations based on the collective expert opinion of the working group members.

Structure and Organization of the Head and Neck Management Recommendations

A. ORGANIZATION OF CARE RECOMMENDATIONS	8
I. Preamble	8
II. Teams	8
1. Core Team List	8
2. Primary Care Physician.....	9
3. Extended Team List	9
III. Minimum skill set and experience	9
1. Core Team	9
2. Primary Care Physician	12
IV. Volumes	12
1. Cancer Centre	12
2. Practitioner specific.....	12
V. Unique Infrastructure requirements	14
B. CLINICAL PRACTICE RECOMMENDATIONS	15
I. Pre-Treatment: Diagnosis and Assessment	15
1. Referral and Diagnosis	15
2. Histopathology Reporting.....	16
II. During Assessment and Treatment	17
1. Patient Support	17
III. Treatment	18
i. Modality Specific	18
1. Overview of treatment for primary tumour and neck.....	18
2. Radiotherapy as the major first-line treatment modality	19
3. Prevention and treatment of radiation side effects.....	21
4. Surgery as the major first-line treatment modality	22
5. Chemotherapy in combination with surgery or radiotherapy as first-line treatment .	23
6. Management of potentially curable locoregional recurrence.....	25
7. Palliation of incurable disease	26
ii. Site Specific	27
1. Laryngeal Cancer.....	27
a. Early laryngeal cancer (stage I & II)	27
b. Locally advanced laryngeal cancer (III & IV)	27
2. Hypopharyngeal Cancer	28
a. Early hypopharyngeal cancer (stage I & II).....	28
b. Locally advanced hypopharyngeal cancer (III & IV)	29
3. Oropharyngeal Cancer.....	30
a. Early oropharyngeal cancer (stage I & II)	30
b. Locally advanced oropharyngeal cancer (III & IV)	31

4. Oral Cavity Cancer	32
a. Early oral cavity cancer (stage I & II)	32
b. Advanced oral cavity cancer (III & IV)	32
5. Rare Tumours	33
IV. Post-Treatment	34
1. Follow up, Rehabilitation, and Patient Support.....	34

A. ORGANIZATION OF CARE RECOMMENDATIONS

I. Preamble

In order to ensure the provision of the highest quality of care for patients with head and neck mucosal malignancy, the working and consensus groups have developed a set of organizational standards and treatment recommendations. The organizational recommendations were developed to establish the minimum requirements to maintain a head and neck disease site program. The recommendations are intended to ensure that the proper equipment is in place, and that medical and support staff are experienced and properly trained. The recommendations establish standards for minimum new patient volumes for regional cancer centre disease site groups in an attempt to ensure that all patients have access to the highest standard of care available in Ontario.

II. Teams

The teams will include a core team, primary care provider, and extended team. The care of patients with head and neck cancer should be coordinated among members of an experienced Core Team, comprised of a group of physicians and allied healthcare providers who will be responsible for the assessment, treatment, planning, management, survivorship, and rehabilitation of the patient. The Primary Care Provider will be responsible for the ongoing overall health of the patient and will offer supportive care after treatment. The Extended Team will be called upon by the core team to facilitate treatment, planning, management, survivorship, and rehabilitation of the patient. Members of the Teams must have training or experience managing patients with head and neck cancers.

1. The Core Team

Recommendation

- The Core Team is comprised of a group of physicians and allied healthcare providers who will be responsible for the assessment, treatment, planning, management, survivorship, and rehabilitation of the patient.
- The care of patients with head and neck cancer should be coordinated among members of the core team, who include the following:
 - Head and neck surgeon/Reconstructive surgeon
 - Medical oncologist
 - Radiation oncologist
 - Dentist with expertise/interest in dental oncology
 - Pathologist with expertise in both histopathology and cytopathology
 - Clinical Nurse Specialist or Nurse Practitioner
 - Primary Registered Nurse - Inpatient and Ambulatory nurses
 - Medical imaging physician
 - Speech-Language Pathologist
 - Registered Dietitian
 - Social Worker

(Source: NICE, Consensus 80%, Round 2)

2. Primary Care Physician

Recommendation

- The primary care physician is not involved in the day to day treatment of the head and neck cancer patient but plays an important role in post-treatment supportive care and is responsible for the ongoing overall health of the patient.

(Source: HNMWG*, Consensus 77%, Round 2)

3. The Extended Team

Recommendation

- The Extended Team will be called upon by the core team to facilitate treatment, planning, management, survivorship, and rehabilitation of the patient.
- Members of the extended team must have training or experience managing patients with head and neck cancers. The team is comprised of:
 - Oral Surgeon: Doctor of Dental Surgery (DDS) with fellowship training in maxillofacial surgery, as well as a proficiency with implantation techniques
 - Prosthodontist/Prosthetic anaplastologist
 - Anesthesiologist with a special interest in airway management
 - Healthcare providers with expertise in gastrostomy creation, feeding tube placement, and support for patients who require tube feeding
 - Interventional radiologist
 - Ophthalmologist
 - Pain management specialist
 - Palliative care specialist
 - Dental technicians and hygienists
 - Mental health providers, including psychiatrist or psychologist
 - Physiotherapist
 - Occupational therapist
 - Radiation physicist
 - Radiation therapist
 - Respiratory therapist
 - Hyperbaric medicine
 - Home care team

(Source: NICE, Consensus 90%, Round 2)

III. Minimum Skill Set and Experience for Treating Head and Neck Carcinomas

1. The Core Team

Head and Neck Surgeon/Reconstructive Surgeon

Recommendation

- Has completed a degree in medicine or equivalent, including a Royal College of Physicians and Surgeons of Canada (RCPSC) Specialist Certificate in a surgical discipline. *Head and neck surgeon* is defined as a surgeon trained in otolaryngology/head and neck surgery, general surgery, or plastic surgery, with advanced training in head and neck oncology. *Advanced training* is defined as having an Advanced Training in Head & Neck Oncologic Surgery Fellowship through the American Head and Neck Society or equivalent.

- Reconstruction expertise is required for the surgical management of patients with head and neck tumours and necessitates a fellowship-trained microvascular surgeon with specific training in head and neck reconstruction.

(Source: HNMWG, Consensus 88%, Round 1)*

Medical Oncologist

Recommendation

- Has completed a degree in medicine or equivalent, including the RCPSC Specialist Certificate in Internal Medicine or equivalent, as well as the RCPSC Certificate of Special Competence in Medical Oncology or equivalent.
- Has enhanced knowledge and skill in the treatment of head and neck cancer patients, acquired from either a formal clinical fellowship or significant clinical training in head and neck cancer treatment at an expert centre during medical oncology residency or fellowship.

(Source: HNMWG, Consensus 88%, Round 1)*

Radiation Oncologist

Recommendation

- Has completed a degree in medicine or equivalent, including the RCPSC Specialist Certificate in Radiation Oncology or equivalent.
- Has enhanced knowledge and skill in the treatment of head and neck cancer patients, acquired from either a formal clinical fellowship or significant clinical training in head and neck cancer treatment at an expert centre during radiation oncology residency or fellowship.

(Source: HNMWG, Consensus 88%, Round 1)*

Dentist

Recommendation

- Has completed a university-based degree in dentistry and fulfilled the requirements of the Royal College of Dental Surgeons of Ontario (RCDSO).

(Source: HNMWG, Consensus 88%, Round 1)*

Pathologist

Recommendation

- Has completed a degree in medicine or equivalent, including the RCPSC Certificate of Special Competence in Anatomical Pathology.
- Has enhanced knowledge and skill in the pathology of head and neck cancer malignancies, acquired from either a formal fellowship or significant training in head and neck cancer at an expert centre.

(Source: HNMWG, Consensus 85%, Round 1)*

Registered Nurses and Advanced Practice Nurses

Recommendation[†]

- All entry-to-practice nurses shall have a bachelors degree in nursing and be registered with the College of Nurses of Ontario (CNO). Ideally, all nurses will be Certified Oncology Nurses in Canada (CON(C)), as well as members of the Canadian Association of Nurses in Oncology (CANO).

(Source: HNMWG, Consensus 71%, Round 2)*

Generalized and Specialized Oncology Nurse

Recommendation

- Has enhanced specialty knowledge and skill and practices in an environment where the majority of individuals have a diagnosis of cancer or are at risk of developing cancer. The registered nurse (RN) is able to conduct a comprehensive Health Assessment, engage in supportive and therapeutic relationships with patients and families, manage cancer symptoms and treatment side effects; provide teaching, coaching, psychosocial-spiritual support, and counselling across the continuum; facilitate continuity of care and system navigation, self-determination, and informed decision making for the individual/family; and integrate best practice/evidence-based knowledge in the care of patients and families (CANO Standards & Competencies, 2006). Ideally, an RN working with this patient population will have general oncology experience and/or be mentored to develop the skills to work with the patient population.
- Specialized oncology nurses should be aligned to both inpatient and outpatient/ambulatory care settings
- In ambulatory care, a Primary RN or Case Management model should be established in order for patients and families to receive consistent care across the trajectory (diagnosis, treatment, and survivorship/palliation) and care settings (new patient clinics, reviews, and follow-up) for assessment, treatment planning, symptom management, psychosocial support, and long term follow-up.

(Source: HNMWG, Consensus 92%, Round 1)*

Advanced Practice Oncology Nurse (*Clinical Nurse Specialist and/or Nurse Practitioner*)

Recommendation

- Has a masters degree in nursing, with knowledge and expertise in an area of cancer nursing. There is a greater breadth and depth of knowledge compared to the specialized oncology nurse. The advanced practice nurse (APN) functions in the domains of direct clinical care, education, research, organizational leadership, and professional development. The APN should have prior oncology experience and expertise but may require role mentoring to develop specific oncology expertise.

(Source: HNMWG, Consensus 83%, Round 1)*

Medical Imaging Physician

Recommendation

- Has completed a degree in medicine or equivalent and is a member of the RCPS of Ontario, as well as having completed the RCPSC five-year residency program and received a Certificate of Special Competence in Diagnostic Radiology.
- The residency should be followed by one or more years of fellowship training in a subspecialty discipline.

(Source: HNMWG, Consensus 88%, Round 1)*

Speech-Language Pathologist

Recommendation

- Has a masters degree or equivalent in speech pathology and is a registered member of the College of Audiologists and Speech-Language Pathologists of Ontario, as well as, being an Independent Authorizer with the Assistive Devices Program. Knowledge and expertise in clinical swallowing assessment and therapy, video fluoroscopic swallowing assessment, and the management of patients with tracheotomies is required. If required to do voice restoration work for larygectomized patients, the speech pathologist should be approved

for delegated controlled acts and have specialized training in tracheoesophageal puncture (TEP).

(Source: HNMWG*, Consensus 92%, Round 1)

Registered Dietitian

Recommendation

- Has a bachelor's degree accredited by the Dietitians of Canada (DC) and successful completion of a dietetic internship program accredited by the DC. Registration with the College of Dietitians of Ontario and a DC member. Hospital or patient care experience and/or oncology expertise is recommended.
- Experience and training in enteral and parenteral nutrition support is valuable.

(Source: HNMWG*, Consensus 89%, Round 1)

Social Worker

Recommendation

- Has a Masters Degree in Social Work (MSW) and registration (RSW) with the Ontario College of Social Workers and Social Service Workers (OCSWSSW). Has hospital or patient care experience as well as, oncology expertise. Ideally, social workers should have experience providing teaching, coaching, and psychosocial-spiritual support and counselling across the continuum with patients and families.
- Affiliation and membership with professional oncology social work organizations such as the Canadian Association of Social Workers (CASW) are recommended.

(Source: HNMWG*, Consensus 83%, Round 2)

2. Primary Care Physician

Recommendation[†]

- Has completed a degree in medicine or equivalent, ideally including a College of Family Physicians of Canada Certificate in Family Medicine.

(Source: HNMWG*, Consensus 72%, Round 2)

IV. VOLUMES

1. Cancer Centre Volumes

Recommendation

- Innovative collaborations between high-volume and low-volume centres and/or regions should be expanded and defined in order to maintain the high quality of care being provided to this group of patients. This might include virtual Multidisciplinary Case Conferencing options, joint care planning with regional care delivery models.

(Source: HNMWG*, Consensus 89%, Round 2)

Recommendation[†]

- The development of small-volume, non-multidisciplinary treatment programs for patients with head and neck cancer should be strongly discouraged.

(Source: HNMWG*, Consensus 68%, Round 2)

2. Practitioner Specific Volumes

Recommendation[†]

- Although there are no data in Ontario or elsewhere to directly inform minimum volume thresholds for surgeons, medical oncologists, and radiation oncologists, to ensure high-quality care, the HNMWG endorses the volumes recommended by NICE (2). Additionally,

there are no data in Ontario or elsewhere or existing clinical practice guidelines to directly inform the minimum volumes for specialized oncology nurses, advanced practice nurses, speech language pathologists, registered dietitians, and social workers. While more research and outcome evaluations are required, the opinion of the HNMWG is that the following volumes are reasonable goals in Ontario:

Core team members and recommendations.

Core Team Member	<i>Recommendations for minimum volumes required</i>
Surgery/ Oncology	Assess 50 new patients and major surgery* on 40 patients per year (Source: HNMWG* and NICE)
Surgery/Reconstructive	20 microsurgery cases annually (Source: HNMWG*)
Medical Oncologist	1.0 FTE per 200 head and neck cancer patients seen in consultation and a minimum of 25 patients treated annually (Source: NICE)
Radiation Oncologist	1.0 FTE per 150 head and neck cancer patients seen in consultation and a minimum of 50 patients treated annually (Source: NICE)
<i>The volume recommendations for the above practitioners were put forward as a single recommendation. The level of consensus was 59%, achieved in Round 2.</i>	
Specialized Oncology Nurse	1.0 FTE per 100 patients seen in consultation per year (Source: HNMWG*)
Advanced Practice Nurse	1.0 FTE per H&N site group (especially with larger site groups seeing > 200 patients in consultation per year OR shared across another site group) (Source: HNMWG*)
<i>The volume recommendations for the above practitioners were put forward as a single recommendation. The level of consensus was 60%, achieved in Round 2.</i>	
Speech Language Pathologist	1.0 FTE per 150 patients seen in consultation per year (Source: HNMWG*)
Registered Dietitian	1.0 FTE per 150 patients seen in consultation per year (Source: HNMWG*)
Social Worker	1.0 FTE per 150 patients seen in consultation per year (Source: HNMWG*)
<i>The volume recommendations for the above practitioners were put forward as a single recommendation. The level of consensus was 56%, achieved in Round 2.</i>	
NOTES: FTE: full-time equivalent; HNMWG: Head and Neck Management Working Group; NICE: National Institute for Health and clinical Excellence. Major is defined as: 1) Neck dissection or equivalent complexity; 2) Composite dissection or equivalent complexity; or 3) Laryngectomy or equivalent complexity.	

V. Unique Infrastructure Requirements*

Team Member	<i>Recommendations for infrastructure requirements</i>
Surgical Oncologist	Infrastructure for microvascular, laser and minimally invasive surgery Perioperative monitoring (Level III or greater) Specialized surgical nursing (head and neck) Clinic equipment - nasopharyngoscopy and image capture <i>(Source: NICE, Consensus 82%, Round 1)</i>
Medical Oncologist	Ambulatory chemotherapy unit and oncology pharmacy support Access to inpatient services including ability to administer chemotherapy <i>(Source: NICE, Consensus 83%, Round 1)</i>
Radiation Oncologist	Radiation Treatment Facility including the following: <ul style="list-style-type: none"> - linear accelerator based external beam radiation treatment with multileaf collimation and IMRT capability - portal or CT based on board treatment verification - CT simulation (with IV contrast available) and custom immobilization capabilities - IMRT-capable treatment planning system - medical dosimetry and physics support for plan development and quality assurance - resources for staff and infrastructure: for requirements, refer to the PEBC/CCO IMRT organizational standards document (15) <i>(Source: NICE and IMRT, Consensus 75%, Round 2)</i>
Registered Nurses and Advanced Practice Nurses	Access to interventional radiology for insertion of PEG tubes Feeding pumps for inpatient and ambulatory settings <i>(Source: NICE, Consensus 83%, Round 2)</i>
Speech Language Pathologist	Specialized equipment for speech rehabilitation (post-laryngectomy) Availability and access to radiology for completion of modified barium swallows and equipment to support the analysis of swallowing function <i>(Source: NICE, Consensus 92%, Round 2)</i>
Registered Dietitian	Access to interventional radiology for insertion of PEG tubes Feeding pumps for inpatient and ambulatory settings Access to endoscopy suite or interventional radiology for G-tube placement <i>(Source: NICE, Consensus 82%, Round 1)</i>
NOTES: CCO: Cancer Care Ontario; CT: computerized tomography; IMRT: intensity-modulated radiation therapy; IV: intravenous; NICE: National Institute for Health and Clinical Excellence; PEBC: Program in Evidence-based Care; PEG: percutaneous endoscopic gastroscopy. * Please note that these requirements are unique to the treatment of Head and Neck Cancer and are beyond those requirements that would typically be found in these settings.	

B. CLINICAL PRACTICE RECOMMENDATIONS

SIGN (3) developed the following recommendations through a systematic review and evaluation of the evidence. The quality of evidence was graded, as was the strength of the evidence (but not its clinical importance), for the recommendations.

The following recommendations were all either adapted from *SIGN 90; Diagnosis and Management of Head and Neck Cancer. A National Clinical Guideline* (3), other practice guidelines identified in an updated search (4-14) (see Section 2 for a list of these documents), or the clinical expertise of the HNMWG. Modifications were made to ensure the document would be pertinent to the Ontario healthcare setting.

I. Pre-Treatment: Diagnosis and Assessment

1. Referral and Diagnosis

	RECOMMENDATIONS
Referral	
	Rapid access or “one-stop” clinics should be available for patients who fulfill appropriate referral criteria. For further detail, refer to PEBC Diagnostic Assessment standard of care document (4). (Source: SIGN and DAP, Consensus 93%, Round 2)
	Patients should be seen by an experienced clinician with access to the necessary diagnostic tools, within two weeks of urgent referral. (Source: SIGN*, Consensus 88%, Round 1)
	Primary care physicians and dental practitioners should be aware of symptoms and physical findings suggestive of head and neck cancer. (Source: SIGN*, Consensus 100%, Round 1)
Diagnosis and Staging	
Investigating neck masses	† Fine needle aspiration cytology should be used in the investigation of head and neck masses. (Source: SIGN, Consensus 68%, Round 2)
Endoscopy	All patients with head and neck cancer should have direct pharyngolaryngoscopy and chest imaging with symptom-directed endoscopy where indicated. (Source: SIGN, Consensus 82%, Round 1)
Imaging the primary tumour	CT or MRI of the primary tumour site should be performed to help define the T category of the tumour. (Source: SIGN, Consensus 93%, Round 1)
	† MRI should be used to stage oropharyngeal and oral tumours. (Source: SIGN, Consensus 67%, Round 2)
	† MRI should be used in assessing tumour involvement of the skull base, orbit, cervical spine, or neurovascular structures (most suprahyoid tumours). (Source: SIGN, Consensus 71%, Round 2)
Imaging neck	CT or MRI from skull-base to sternoclavicular joints should be performed in all patients at the time of imaging the primary tumour to stage the neck

Nodes	for nodal metastatic disease. (Source: SIGN, Consensus 79%, Round 2)
	Where the nodal staging on CT and MRI is equivocal, ultrasound guided fine needle aspiration and/or FDG-PET may increase the accuracy of nodal staging. (Source: SIGN, Consensus 75%, Round 2)
Imaging of thorax for distant metastases and synchronous tumours	All patients with stage II or greater disease should undergo CT of the thorax. (Source: SIGN, Consensus 83%, Round 2)
Metastatic cervical lymph nodes with unknown primary	† In patients presenting with cervical lymph node metastases, where physical exam, examination under anaesthetic and CT or MRI does not demonstrate an obvious primary tumour, FDG-PET should be performed as the next investigation of choice. (Source: SIGN, Consensus 71%, Round 2)

NOTES: CT: computerized tomography; DAP: Diagnostic Assessment Program; FDG-PET: [18F]-2-fluoro-deoxy-D-glucose-positron emission tomography; MRI: magnetic resonance imaging; PEBC: Program in Evidence-based Care; SIGN: Scottish Intercollegiate Guidelines Network.

2. Histopathological Reporting

	RECOMMENDATIONS
	Pathologists are advised to use the CAP-CCO standards for reporting head and neck malignancies (5). (Source: CAP-CCO*, Consensus 86%, Round 2)
Nodal Metastatic Disease	The reporting of nodal dissections should include a description of the levels and structures included in the specimen, including number of involved and uninvolved nodes, level of these nodes, and the presence and location of extracapsular spread of tumour. (Source: SIGN and HNMWG*, Consensus 83%, Round 1)
Primary Site	Histopathology reporting of specimens from the primary site of head and neck cancer should include: <ul style="list-style-type: none"> - tumour site, tumour grade, maximum tumour dimension, maximum depth of invasion, margin involvement by invasive and/or severe dysplasia and margin dimensions, pattern of infiltration, and perineural involvement, - tumour type, and (Source: SIGN, Consensus 88%, Round 1) - lymphatic/vascular permeation. (Source: SIGN*, Consensus 75%, Round 1)

NOTES: CAP-CCO: College of American Pathologists-Cancer Care Ontario; HNMWG: Head and Neck Management Working Group; SIGN: Scottish Intercollegiate Guidelines Network.

II. During Assessment and Treatment

1. Patient Support

Patients should have the following support in place during the full continuum of care: oncology nursing personnel, a speech-language pathologist (SLP), a registered dietitian, and a social worker.

	RECOMMENDATIONS
Dysphagia	Head and neck cancer patients with dysphagia should receive appropriate speech and language therapy to optimize residual swallow function and reduce aspiration risk. <i>(Source: SIGN, Consensus 95%, Round 1)</i>
	All patients with oral, oropharyngeal, hypopharyngeal, and laryngeal cancer should have access to instrumental investigation for dysphagia. <i>(Source: SIGN and HNMWG*)</i>
	Modified barium swallow and fiberoptic endoscopic evaluation of swallow are both valid methods for assessing dysphagia. <i>(Source: HNMWG*)</i> The SLP should consider which is the most appropriate for different patients in different settings. <i>(Source: HNMWG*, Consensus 91%, Round 1)</i>
Communication	All patients undergoing chemoradiation should have access to an SLP therapist before, during, and after treatment. <i>(Source: SIGN, Consensus 80%, Round 1)</i>
	Where communication problems are likely to occur, patients should be seen by an SLP soon after diagnosis and before treatment commences. <i>(Source: SIGN, Consensus 85%, Round 1)</i>
	Patients undergoing laryngectomy should have a speech language pathologist to restore voice either by a tracheoesophageal voice prosthesis, esophageal speech, or electrolarynx. <i>(Source: SIGN, Consensus 87%, Round 1)</i>
Nutritional Support	All head and neck cancer patients should be screened at diagnosis for nutritional status using a validated screening tool appropriate to the patient population (BMI, nutrient intake, weight history). <i>(Source: SIGN*, Consensus 82%, Round 1)</i>
	After screening, at-risk patients should receive early intervention for nutritional support by an experienced dietitian, including considerations of nutritional supplements and pharmacological interventions. <i>(Source: SIGN, Consensus 90%, Round 1)</i>
	The multidisciplinary team should include healthcare professionals skilled in feeding tube placement (percutaneous gastrostomy, gastrojejunostomy, nasogastric). <i>(Source: SIGN, Consensus 82%, Round 1)</i>
	Feeding tube insertion should be considered for individuals initially presenting with one or more of the following: significant weight loss

	(greater than 5% in one month or greater than 10% in 6 months), BMI < 18.5, dysphagia, anorexia, dehydration, pain, or any other symptoms that interfere with the ability to eat. (Source: HNMWG*, Consensus 96%, Round 2)
Smoking Cessation	<p>Patients should be provided with information about, and assistance with access to, drug therapy and counselling to stop smoking prior to and during treatment.</p> <p>If no centre-based smoking cessation program exists, patients should be referred to their primary care physician. (Source: HNMWG*, Consensus 93%, Round 1)</p>
Support Requirements	Patients should be assessed for psychosocial needs. (see PEBC Provider-Patient Communications document (6)). (Source: PPC*, Consensus 90%, Round 1)
	Patients should be offered information about support groups. (Source: SIGN*, Consensus 88%, Round 1)
Information Needs	Leaflets about risk factors, prevention, and early detection of head and neck cancer should be available in primary care facilities. (Source: SIGN, Consensus 95%, Round 1)
	Patients should be given information about their diagnosis and treatment on more than one occasion prior to the onset of treatment. Information should be individualized. (see PEBC Provider-Patient Communications document (6)). (Source: SIGN and PPC*, Consensus 83%, Round 1)

NOTES: BMI: body mass index; HNMWG: Head and Neck Management Working Group; PPC: Provider-Patient Communications document; SIGN: Scottish Intercollegiate Guidelines Network.

III. Treatment

i. Modality Specific

1. Overview of Treatment of the Primary Tumour and Neck

	RECOMMENDATIONS
First Line Treatment	Patients with head and neck cancer, especially those planned for resection of oral cancers or whose mandible and/or major salivary glands are to be included in a radiotherapy field, should have the opportunity for a pre-treatment assessment by a dental oncologist (see Core Team for definition). (Source: SIGN, Consensus 91%, Round 1)
	The treatment approach should be formulated by a multidisciplinary team in consultation with the patient. (Source: SIGN*, Consensus 98%, Round 1)
	Individual patient and tumour characteristics, as well as, patient preference should guide management of head and neck cancer. (Source: SIGN*, Consensus 95%, Round 1)

Treatment of the Primary Tumour	<p>All options for definitive locoregional treatment including radiation therapy, chemotherapy, and surgery should be discussed with the patient.</p> <p>If an organ preservation (radiotherapy with or without chemotherapy) approach is to be utilized, follow-up and salvage surgery must be available.</p> <p>Following surgical resection, postoperative adjuvant radiotherapy with or without chemotherapy should be considered where indicated.</p> <p><i>(Source: HNMWG*, Consensus 91%, Round 1)</i></p>
Treatment of the N0 Neck	<p>Patients with a clinically N0 neck, with more than 20% risk of occult nodal metastases, should be offered prophylactic treatment of the neck, by appropriate selective or modified radical neck dissection or external beam radiotherapy. <i>(Source: SIGN, Consensus 80%, Round 2)</i></p>

NOTES: HNMWG: Head and Neck Management Working Group; SIGN: Scottish Intercollegiate Guidelines Network.

2. Radiotherapy as the Major First-line Treatment Modality

	RECOMMENDATIONS
Conventional Fractionation	<p>† Overall treatment time from surgery to completion of post-operative radiotherapy should be 10 to 11 weeks or less in the absence of postoperative medical or surgical complications. <i>(Source: SIGN, Consensus 67%, Round 2)</i></p>
Altered Fractionation	<p>† Where radiotherapy is the primary treatment modality for advanced disease, moderately accelerated schedules (six fractions/week) or hyperfractionated schedules with increased total dose can be considered as an alternative approach for patients with head and neck cancer who are unable to receive or decline concurrent chemotherapy or other systemic therapies.</p> <p>Altered fractionation regimens should be individualized for patients over the age of 70 (7). <i>(Source: SIGN and Bourhis, Consensus 73%, Round 2)</i></p> <p>If altered fractionation is being considered there must be:</p> <ul style="list-style-type: none"> - adequate monitoring and support for acute toxicity during and after treatment. - access to outpatient and inpatient services for treatment of acute toxicity and nutritional support. <p><i>(Source: SIGN*, Consensus 81%, Round 1)</i></p>
Radiotherapy Planning	<p>Planning CT data should be downloaded into a treatment planning system and relevant targets and normal tissues should be contoured on the planning CT scan.</p> <p>Volumetric radiation planning should be performed so as to achieve uniformity in prescribed dose to the specified targets (PTVs) with minimal dose to organs at risk (PRVs and OARs).</p>

	<p>Specific predefined standards should be adhered to in terms of mean, median, maximum, and minimum dose acceptable to both targets and organs at risk.</p> <p>All radiation plans generated should undergo quality assurance review by the Radiation Oncologist and Medical Physicist prior to implementation.</p> <p>The following should be contoured on the planning CT data set:</p> <ul style="list-style-type: none"> - Gross Tumour Volume (GTV) for both the primary site and nodes determined to be involved or at high risk of involvement with grossly visible disease - the precise location of these gross objects is to be contoured with reference to the appropriate history, physical exam, diagnostic imaging, and examination under anaesthetic and pathology reports. - Clinical Target Volumes (CTV) which will represent expansions of the GTV (primary site and nodes) to account for microscopic disease extension from these regions as well as neck nodal regions thought to be at risk of harbouring microscopic nodal metastasis. - Organs at risk (OARs) that are anticipated to receive any radiation either in or close to the treated volumes should be contoured. These could include: spinal cord, brainstem, eyes, optic nerves, optic chiasm, inner ear, major salivary glands, mandible, mucosa not contained within CTVs. - Planning target volumes (PTV) will represent expansions of all CTVs for the purposes of dose calculation and assessment to take into account the uncertainty in patient positioning for treatment each day. - Planning Risk Volumes (PRV) will represent expansions of the following OR's: spinal cord, brainstem, optic nerves and optic chiasm for the purposes of dose calculation and assessment to take into account the uncertainty in patient positioning for treatment each day. <p><i>(Source: HNMWG*, Consensus 80%, Round 2)</i></p>
<p>Commencement and interruptions of planned radiotherapy treatment schedules</p>	<p>The time between decision to treat with radiation as the primary modality and the commencement of treatment should be no longer than two weeks.</p> <p>Overall treatment time from surgery to completion of post-operative radiotherapy should be 10-11 weeks or less in the absence of postoperative medical or surgical complications.</p> <p>Interrupting and prolonging a course of radical radiotherapy should be avoided.</p> <p>When radiation is the primary treatment modality interruptions should be compensated for by using either a bid treatment or a weekend fraction delivered on the week before or after the interruption.</p> <p><i>(Source: SIGN and HNMWG*, Consensus 80%, Round 2)</i></p>
<p>Brachytherapy</p>	<p>Patients with small accessible (T1/2) tumours of the oral cavity may be</p>

	<p>treated by interstitial brachytherapy to a dose of 65-70Gy preferably by low dose rate or pulsed dose rate brachytherapy. Selected small volume oropharyngeal tumours may receive a brachytherapy boost following external beam radiation therapy.</p> <p>Interstitial brachytherapy for patients with head and neck cancer should be performed by an experienced team in centres with an appropriate infrastructure. (Source: SIGN and HNMWG*, Consensus 89%, Round 2)</p>
Intensity Modulated Radiotherapy (IMRT)	<p>For most cases of head and neck cancer, which require significant volumes of tissue to be irradiated to high dose in close proximity to multiple organs at risk, radiation delivery with IMRT is the treatment of choice given superior dose conformality and avoidance. (Source: HNMWG*, Consensus 75%, Round 2)</p>
	<p>In order to treat head and neck cancer with IMRT, centres should implement and deliver IMRT according to the organizational standards developed by CCO (15).</p> <p>Centres unable to implement these standards should consider referring patients requiring curative treatment to those that do. (Source: IMRT and HNMWG*, Consensus 87%, Round 2)</p>

NOTES: CT: computerized tomography; HNMWG: Head and Neck Management Working Group; IMRT: intensity-modulated radiation therapy; SIGN: Scottish Intercollegiate Guidelines Network.

3. Prevention and Management of Radiation Side Effects

	RECOMMENDATIONS
Examination and Assessment	<p>Patients undergoing a course of radiation therapy for head and neck cancer should be examined weekly (as a minimum) by the treating radiation oncologist for the purposes of assessing toxicity and response to treatment. (Source: HNMWG*, Consensus 85%, Round 1)</p>
Prevention and treatment of radiation-induced mucositis	<p>† Health care practitioners should treat patients in accordance with the MASCC guidelines (8). (Source: MASCC and HNMWG*, Consensus 72%, Round 1ⁿ)</p>
	<p>Patients with oral cavity, laryngeal, oropharyngeal or hypopharyngeal tumours who are being treated with radiotherapy should be offered oral rinses including local topical anaesthetics before, during, and up to three weeks after completion of radiotherapy. (Source: SIGN)</p> <p>Patients should be advised on how to maintain good oral hygiene during and after radiotherapy.</p> <p>Patient mucosa should be inspected regularly during treatment, and analgesia (9) and antimicrobial/antifungal agents to treat infection should be made available. (Source: SIGN, HNMWG* and CCO-PEBC, Consensus 92%, Round 1)</p>

Prevention and treatment of radiation-induced xerostomia	† When possible, radiation doses to the major salivary glands should be kept as low as reasonably achievable without compromising dose to the PTVs. Limiting parotid doses <26 Gy (mean) and <30 Gy (median) have been shown to result in improvement in subsequent parotid function. Pharmacological therapy should be considered to improve or reduce radiation-induced xerostomia. (Source: HNMWG*, Consensus 73%, Round 2)
	Patients with chronic xerostomia following radiotherapy should be encouraged to maintain good oral hygiene. They should have regular dental assessment with access to a dental oncologist where necessary. (Source: SIGN*, Consensus 89%, Round 1)

NOTES: CCO: Cancer Care Ontario; PEBC: Program in Evidence-based Care; HNMWG: Head and Neck Management Working Group; MASSC: Multinational Association for Supportive Care in Cancer; SIGN: Scottish Intercollegiate Guidelines Network.

4. Surgery as the major first-line treatment modality

	RECOMMENDATIONS
Resection	† If an inadequate initial excision biopsy has been performed or if the tumour has been excised with positive excision margins, re-resection should be considered where technically feasible. (Source: SIGN, Consensus 71%, Round 2)
	If re-resection is not possible, postoperative radiotherapy should be considered. (Source: SIGN*, Consensus 79%, Round 1)
Reconstruction	<p>Surgical reconstruction should be available for patients undergoing extensive surgical resection for head and neck cancer.</p> <p>Reconstruction should be performed by appropriately trained and experienced surgical teams (who should be familiar with a variety of reconstruction techniques).</p> <p>Choice of reconstruction technique should be made on an individual basis for each patient according to the anatomical location of the tumour, the general condition of the patient, and patient and surgeon preference. (Source: SIGN*, Consensus 100%, Round 1)</p>
Adjuvant radiotherapy following surgery	<p>Postoperative radiotherapy should be considered following surgical resection of oral cavity, oropharyngeal, laryngeal, and hypopharyngeal cancers for patients with any of the following adverse risk features:</p> <ul style="list-style-type: none"> - advanced T-stage - close or positive surgical margins - perineural invasion - lymphovascular invasion: 2 or greater nodes positive - positive nodes at level IV or V - N2 or greater nodal involvement

	<p>- extracapsular lymph node spread (Source: SIGN, Consensus 83%, Round 1)</p>
	<p>Postoperative radiotherapy should be conventionally fractionated:</p> <ul style="list-style-type: none"> • 54-60 Gy in 27-30 fractions over 5.5-6 weeks to the primary site and nodes at risk • 66 Gy in 33 fractions over 6.5 weeks to areas of very high risk <p>(Source: SIGN, Consensus 83%, Round 2)</p>
	<p>In patients with extracapsular spread and/or positive surgical margins, who are medically fit, postoperative concurrent chemoradiotherapy with single-agent cisplatin and conventionally fractionated radiotherapy should be considered. (Source: SIGN, Consensus 82%, Round 1)</p>
	<p>In patients who are not fit for chemotherapy, conventionally fractionated radiotherapy alone may be used. (Source: SIGN*, Consensus 85%, Round 2)</p>
	<p>The decision to undertake a course of postoperative radiotherapy or chemoradiotherapy should be made in consultation with the patient and multidisciplinary team. (Source: SIGN*, Consensus 95%, Round 1)</p>
Chemotherapy in Combination with Surgery	<p>† There is little evidence to support the routine use of neoadjuvant or adjuvant chemotherapy in combination with surgery in laryngeal, oral cavity, oropharyngeal, or hypopharyngeal cancer. (Source: SIGN and HNMWG*, Consensus 69%, Round 2)</p>

NOTES: HNMWG: Head and Neck Management Working Group; SIGN: Scottish Intercollegiate Guidelines Network.

5. Chemotherapy in Combination with Surgery or Radiotherapy as First-line Treatment

	RECOMMENDATIONS
Chemotherapy Alone	<p>No evidence was identified to support the use of chemotherapy alone as a curative treatment for squamous cell carcinoma of the head and neck. (Source: HNMWG*, Consensus 75%, Round 2)</p>
Chemotherapy with locoregional therapy	<p>In patients with locally advanced non-metastatic squamous carcinoma of the oral cavity, oropharynx, larynx, and hypopharynx, who are medically fit for chemotherapy, (especially those aged 70 or under), concurrent chemotherapy should be considered rather than radiotherapy alone if:</p> <ul style="list-style-type: none"> - organ preservation is the goal. - the primary tumour is unresectable or considered surgically incurable. <p>(Source: SIGN, Consensus 75%, Round 2)</p>
	<p>† Single-agent cisplatin is recommended as the chemotherapeutic agent of choice in concurrent chemoradiotherapy. (Source: SIGN, Consensus 73%, Round 1ⁿ)</p>
	<p>Concurrent chemoradiotherapy should only be administered where</p>

	<p>there are appropriate facilities for monitoring toxicity, with rapid access to appropriate outpatient and inpatient support for the treatment of acute radiotherapy and chemotherapy toxicity (10, 11). (Source: Vermorken NEJM, Posner NEJM Consensus 97%, Round 1)</p> <p>† If neoadjuvant chemotherapy is used, docetaxel/cisplatin/5-fluorouracil (5FU) (TPF) appears to provide higher response and survival rates with similar safety to cisplatin plus 5FU and should be considered (10, 11). (Source: Vermorken NEJM, Posner NEJM, Consensus 46%, Round 2)</p>
Adjuvant Chemotherapy	<p>The routine use of adjuvant chemotherapy following either surgery or radiotherapy is not recommended. (Source: SIGN, Consensus 85%, Round 2)</p>
Support for treatment related toxicities	<p>Nausea and vomiting: Patients receiving chemotherapy should be treated in accordance with standard antiemetic guidelines developed by ASCO (12). (Source: ASCO, Consensus 81%, Round 1)</p> <p>† Patients receiving high-dose cisplatin should be considered for Apreitant therapy. (Source: HNMWG*, Consensus 45%, Round 2)</p> <p>Febrile neutropenia should be managed in accordance with ASCO guidelines (13). (Source: ASCO, Consensus 78%, Round 2)</p> <p>Hearing Loss: Patients reporting hearing loss or persistent tinnitus after treatment should have audiology testing. (Source: HNMWG*, Consensus 83%, Round 1)</p>

NOTES: ASCO: American Society of Clinical Oncology; HNMWG: Head and Neck Management Working Group; NEJM: New England Journal of Medicine; SIGN: Scottish Intercollegiate Guidelines Network.

6. Management of Potentially Curable Locoregional Recurrence

	RECOMMENDATIONS
Management of locoregional recurrence	<p>Decisions regarding the appropriate management of a locoregional recurrence of head and neck cancer should be made on an individual basis taking into account:</p> <ul style="list-style-type: none"> - the stage of recurrent tumour and its potential resectability. - previous treatment. - likely treatment efficacy. - likely treatment-related morbidity and functional outcome and consequent effects on quality of life. - patient's general health. - patient's preference. <p>(Source: SIGN*, Consensus 94%, Round 1)</p>
	<p>Decisions regarding the management of locoregional recurrence of head and neck cancer should be made by the multidisciplinary team in consultation with the patient, following histological confirmation of recurrence and full restaging (clinical and radiological). (Source: SIGN*, Consensus 97%, Round 1)</p>
	<p>Patients and their relatives/carers should be carefully counselled about the likely outcome of surgical and radiotherapeutic salvage, with respect to survival, risk of treatment-related morbidity and mortality, and quality of life. (Source: SIGN*, Consensus 98%, Round 1)</p>
	<p>Early referral to palliative care services for symptom control should be considered. (Source: SIGN* Consensus 95%, Round 1)</p>
Salvage surgery after previous radiotherapy or surgery	<p>Salvage surgery should be considered in any patient with a resectable locoregional recurrence of oral cavity, oropharyngeal, laryngeal, or hypopharyngeal cancer following previous radiotherapy or surgery. (Source: SIGN, Consensus 83%, Round 2)</p>
	<p>Salvage surgery should only be performed by an experienced surgical team with adequate experience in reconstructive techniques, in centres with appropriate facilities for medical support and rehabilitation. (Source: SIGN*, Consensus 97%, Round 1)</p>
Radiotherapy and re-irradiation	<p>† External beam radiotherapy should be considered as potentially curative salvage treatment for patients with locoregional recurrent disease after previous surgery, particularly if the recurrence is unresectable, or resection would result in unacceptable loss of function or cosmesis. (Source: SIGN*, Consensus 72%, Round 1[†])</p>
	<p>Selected patients who have unresectable locally recurrent disease following previous radiotherapy may be considered for potentially curative re-irradiation.</p> <p>Re-irradiation should be considered cautiously and performed in centres</p>

	with adequate expertise. (<i>Source: SIGN*, Consensus 88%, Round 2</i>)
	† Patients with small accessible recurrences in a previously irradiated region may be considered for interstitial brachytherapy in centres with appropriate facilities and expertise. (<i>Source: SIGN, Consensus 70%, Round 2</i>)
	† As a general principle re-irradiation should be delivered to as limited a volume as possible with bid treatment schedules to limit fraction size. (<i>Source: HNMWG*, Consensus 55%, Round 2</i>)

NOTES: HNMWG: Head and Neck Management Working Group; SIGN: Scottish Intercollegiate Guidelines Network.

7. Palliation of Incurable Disease

	RECOMMENDATIONS
Palliative Care	The care of patients with incurable head and neck cancer should be managed by the palliative care services in conjunction with the multidisciplinary team. (<i>Source: SIGN*, Consensus 93%, Round 1</i>)
	All modalities of therapy should be considered as options for the palliation of head and neck cancer. (<i>Source: SIGN*, Consensus 89%, Round 1</i>)
	Short term toxicity and length of hospital stay should be balanced against likely symptomatic relief. (<i>Source: SIGN*, Consensus 86%, Round 1</i>)
	A documented pathway of care should be discussed and agreed upon by the patient, relatives, caregivers, and primary care physician. (<i>Source: SIGN*, Consensus 76%, Round 1</i>)
Palliative Chemotherapy	Patients with adequate performance status may be considered for palliative chemotherapy which may improve symptoms by reducing tumour volume. (<i>Source: SIGN, Consensus 88%, Round 1</i>)
	† Methotrexate, cisplatin, or combinations such as cisplatin/5FU and cisplatin/paclitaxel may be considered as palliative treatment in patients with head and neck cancer. (<i>Source: SIGN, Consensus 69%, Round 2</i>)
	Excessive toxicity from chemotherapeutic combination regimens should be avoided. (<i>Source: SIGN, Consensus 94%, Round 1</i>)
Palliative Radiotherapy	Radiotherapy may be considered for palliative treatment in patients with locally advanced incurable head and neck cancer. (<i>Source: SIGN, Consensus 87%, Round 1</i>)
Palliative Surgery	Appropriate surgical procedures should be considered for palliation of particular symptoms, taking local expertise into consideration. (<i>Source: SIGN*, Consensus 88%, Round 1</i>)

NOTES: SIGN: Scottish Intercollegiate Guidelines Network; HNMWG: Head and Neck Management Working Group.

ii. Site Specific

1. Laryngeal Cancer

	RECOMMENDATIONS
a. Early Laryngeal Cancer (Stage I and II)	
Early Glottic Cancer	At least one member of the surgical team should be trained and familiar with the technique of endoscopic resection. <i>(Source: SIGN*, Consensus 84%, Round 1)</i>
	Patients with early glottic cancer may be treated either by external beam radiotherapy or conservation surgery. <i>(Source: SIGN, Consensus 76%, Round 1)</i>
	Patients with T1 glottic cancer should never receive concurrent chemotherapy with radical radiotherapy treatment. <i>(Source: SIGN*, Consensus 100%, Round 2)</i>
	<i>When surgery is selected for patients with early glottic cancer, either endoscopic laser excision or partial laryngectomy may be used. (Source: SIGN, Consensus 87%, Round 2)</i>
	† Prophylactic treatment of the neck nodes is not usually required for patients with T1/T2 early glottic cancer. <i>(Source: SIGN, Consensus 73%, Round 2)</i>
Early Supraglottic Cancer	Patients with early supraglottic cancer may be treated by either external beam radiotherapy or conservation surgery. <i>(Source: SIGN, Consensus 77%, Round 2)</i>
	Radiotherapy for patients with early supraglottic cancer usually includes prophylactic bilateral treatment of levels II-III lymph nodes in the neck. <i>(Source: SIGN, Consensus 89%, Round 2)</i>
	† Endoscopic laser excisions or supraglottic laryngectomy with selective neck dissection to include levels II-III nodes may be considered for patients with early supraglottic cancer. <i>(Source: SIGN, Consensus 58%, Round 2)</i>
	<i>Bilateral neck dissection should be considered if the tumour is close to the midline (Source: SIGN, Consensus 80%, Round 2)</i>
b. Locally Advanced Laryngeal Cancer (Stage III and IV)	
Treatment Options	Patients with locally advanced resectable laryngeal cancer can be treated by either: <ul style="list-style-type: none"> - total laryngectomy with or without postoperative radiotherapy OR <ul style="list-style-type: none"> - initial organ preservation strategy with radiation and concurrent chemotherapy, reserving surgery for salvage. <i>(Source: SIGN, Consensus 76%, Round 1)</i>

	The choice of approach will be dependent on the patient's desire for organ preservation and general performance status. (Source: SIGN*, Consensus 79%, Round 1)
Organ Preservation	Treatment for organ preservation or non-resectable disease should be concurrent chemoradiation with single-agent cisplatin. (Source: SIGN, Consensus 78%, Round 1)
	Standard radiotherapy (once daily) should only be used as a single modality when comorbidity precludes the use of concurrent chemotherapy or surgery. (Source: SIGN, Consensus 91%, Round 2)
	Where radiotherapy is being used as a single agent without concurrent chemotherapy, an altered fractionation schedule should be considered. (Source: SIGN, Consensus 80%, Round 2)
Total Laryngectomy	Patients with bulky T4 tumours extending through cartilage into soft tissue whose voices are unlikely to be spared with an organ preservation approach might best be treated by total laryngectomy with postoperative radiotherapy. (Source: SIGN*, Consensus 80%, Round 1)
N0 disease	† In patients with clinically N0 disease, nodal level II-IV should be treated prophylactically by either surgery or radiation depending on the primary treatment approach selected. (Source: SIGN, Consensus 73%, Round 2)
Nodal disease	Patients with clinically node positive neck are managed based on the planned primary treatment, if an organ preservation approach is selected as the primary treatment, neck dissection is considered in patients with clinical or radiologic evidence of residual disease and control of the primary site.
	The role of planned neck dissection for N2 and N3 disease remains controversial. If surgery is the primary modality of therapy, comprehensive neck dissection with postoperative chemoradiotherapy or radiotherapy should be considered. (Source: SIGN and HNMWG*, Consensus 82%, Round 2)

NOTES: SIGN: Scottish Intercollegiate Guidelines Network; HNMWG: Head and Neck Management Working Group.

2. Hypopharyngeal Cancer

RECOMMENDATIONS	
a. Early Hypopharyngeal Cancer (Stage I and II)	
Treatment Options	† Patients with early hypopharyngeal cancer may be treated by: <ul style="list-style-type: none"> - radical external beam radiotherapy with concomitant cisplatin chemotherapy and prophylactic irradiation of neck nodes (levels II-IV bilaterally). - conservative surgery and bilateral selective neck dissection (levels II-IV, where local expertise is available).

	<ul style="list-style-type: none"> - radiotherapy alone, including altered fractionation regimes, in those patients who are not suitable for either concurrent chemoradiation or surgery due to comorbidity. <p>(Source: SIGN, Consensus 58%, Round 2)</p>
b. Locally Advanced Hypopharyngeal Cancer (Stage III and IV)	
Treatment Options	<p>Patients with locally advanced resectable hypopharyngeal cancer can be treated by either:</p> <ul style="list-style-type: none"> - surgical resection with postoperative radiotherapy <p>OR</p> <ul style="list-style-type: none"> - an organ preservation strategy with radiation and concurrent chemotherapy or altered fractionation radiation reserving surgery for salvage. <p>(Source: SIGN, Consensus 92%, Round 2)</p>
Surgical Resection	<p>Surgical resection is usually laryngopharyngectomy with appropriate reconstruction and should be performed in centres with adequate expertise in the surgical technique and postoperative rehabilitation. (Source: SIGN*, Consensus 84%, Round 1)</p>
	<p>Patients with resectable locally advanced disease should not be treated by standard radiotherapy (once daily) alone unless comorbidity precludes both surgery and concurrent chemotherapy. (Source: SIGN, Consensus 78%, Round 1)</p>
Organ Preservation	<p>† Patients with unresectable disease should be considered for external beam radiotherapy with concurrent cisplatin chemoradiotherapy. (Source: SIGN, Consensus 73%, Round 2)</p>
	<p>Where radiotherapy is being used as a single modality without concurrent chemotherapy, an altered fractionation schedule should be considered. (Source: SIGN, Consensus 82%, Round 2)</p>
N0 disease	<p>Patients with a clinically N0 neck should undergo prophylactic treatment of the neck, whether by selective neck dissection or radiotherapy, including nodal levels II-IV bilaterally (Source: SIGN, Consensus 78%, Round 2)</p>
Nodal Disease	<p>Patients with clinically node positive neck are managed based on the planned primary treatment, if an organ preservation approach is selected as the primary treatment, neck dissection is considered in patients with clinical or radiologic evidence of residual disease and control of the primary site.</p>
	<p>The role of planned neck dissection for N2 and N3 disease remains controversial.</p> <p>If surgery is the primary modality of therapy comprehensive neck dissection with postoperative chemoradiotherapy or radiotherapy should be considered. (Source: SIGN and HNMWG*, Consensus 80%, Round 2)</p>
Post-operative	<p>Postoperative adjuvant therapy should be based on criteria described in the</p>

Adjuvant Therapy	SIGN Surgical section (see section #6 - adjuvant radiotherapy following surgery). (Source: SIGN, Consensus 75%, Round 1)
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NOTES: HNMWG: Head and Neck Management Working Group; SIGN: Scottish Intercollegiate Guidelines Network.

3. Oropharyngeal Cancer

	RECOMMENDATIONS
a. Early Oropharyngeal Cancer (Stage I and II)	
Primary Treatment	<p>Management of early oropharyngeal cancer should be individual for each patient.</p> <p>Decisions regarding the choice of primary treatment modality should be made in consultation with the patient and should take into account the anatomical location of the tumour and the functional results associated with the available treatments.</p> <p>(Source: SIGN*, Consensus 100%, Round 1)</p>
	<p>† Patients with early oropharyngeal cancer may be treated by:</p> <ul style="list-style-type: none"> - Primary resection, with reconstruction as appropriate, and neck dissection (selective neck dissection encompassing nodal levels II-IV) <p>OR</p> <ul style="list-style-type: none"> - External beam radiotherapy encompassing the primary tumour and neck nodes (levels II-IV). <p>(Source: SIGN, Consensus 64%, Round 2)</p>
Primary Radiotherapy	<p>† Patients may be treated by a combination of external beam radiotherapy and brachytherapy in centres with appropriate expertise.</p> <p>(Source: SIGN, Consensus 64%, Round 2)</p>
	<p>† In patients with early stage, well-lateralized tumours, prophylactic treatment of the ipsilateral neck only may be considered.</p> <p>(Source: SIGN, Consensus 70%, Round 2)</p>
	<p>Bilateral treatment of the neck is recommended when the incidence of occult disease in the contralateral neck is high (tumour is encroaching on base of tongue or soft palette). (Source: SIGN, Consensus 82%, Round 1)</p>
Postoperative Treatment	<p>Postoperative radiotherapy or concurrent chemoradiotherapy should be used based on the SIGN recommendations in “Treatment: surgery as the major treatment modality” (section #6). (Source: SIGN, Consensus 84%, Round 1)</p>
	<p>Administration of cisplatin chemotherapy concurrently with postoperative radiotherapy should be considered, particularly in patients with extracapsular spread and/or positive surgical margins.</p> <p>(Source: SIGN, Consensus 85%, Round 1)</p>

b. Locally Advanced Oropharyngeal Cancer (Stage III and IV)	
Primary Treatment	The decision regarding the choice of primary treatment in advanced oropharyngeal cancer should be made in consultation with the patient and based on an understanding of the functional outcome and quality of life associated with each treatment option. (<i>Source: SIGN*, Consensus 97%, Round 1</i>)
	† Patients with advanced oropharyngeal cancer may be treated by primary surgery or an organ preservation approach. (<i>Source: SIGN, Consensus 64%, Round 2</i>)
Primary Surgery	Resection of the primary tumour should be followed by reconstruction as necessary. (<i>Source: SIGN*, Consensus 81%, Round 1</i>)
	Patients treated by primary surgery who have a clinically node positive neck should have a comprehensive neck dissection. (<i>Source: SIGN, Consensus 83%, Round 1</i>)
	Ipsilateral neck dissection may be performed if the tumour is well lateralized. Prophylactic treatment of the contralateral neck should be considered, especially when tumours encroach on the midline. (<i>Source: SIGN*, Consensus 90%, Round 2</i>)
Organ Preservation Therapy	Radiotherapy should be administered with concurrent cisplatin chemotherapy. (<i>Source: SIGN, Consensus 78%, Round 1</i>)
	† The primary tumour and neck node levels (II-IV) should be treated bilaterally. (<i>Source: SIGN, Consensus 73%, Round 2</i>)
	Where radiotherapy is being used as a single modality without concurrent chemotherapy, a modified fractionation schedule should be considered. (<i>Source: SIGN, Consensus 82%, Round 2</i>)
	Patients with clinically node positive neck are managed based on the planned primary treatment. If an organ preservation approach is selected as the primary treatment, neck dissection is considered in patients with clinical or radiologic evidence of residual disease and control of the primary site. The role of planned neck dissection for N2 and N3 disease remains controversial. (<i>Source: SIGN and HNMWG*, Consensus 92%, Round 2</i>)

NOTES: HNMWG: Head and Neck Management Working Group; SIGN: Scottish Intercollegiate Guidelines Network.

4. Oral Cavity Cancer

	RECOMMENDATIONS
a. Early Oral Cavity Cancer (Stage I and II)	
Primary Treatment	<p>Management of early oral cavity tumours should be individualized for each patient.</p> <p>Decisions regarding the choice of primary treatment modality should be made in consultation with the patient and should take into account the anatomical location of the tumour and the functional results associated with the available treatments.</p> <p><i>(Source: SIGN*, Consensus 100%, Round 1)</i></p>
	<p>Patients with early oral cavity cancer may be treated by surgical resection. In situations where bone removal is required for clear margins, rim rather than segmental resection should be performed, where possible. <i>(Source: SIGN, Consensus 83%, Round 2)</i></p>
Brachytherapy	<p>† Where expertise is available, brachytherapy can be used alone (60 to 70 Gy) for T1 lesions or as a boost (20 to 40 Gy) for T2 tumours of the oral cavity (mobile tongue, floor of mouth, buccal mucosa).</p> <p><i>(Source: HNMWG*, Consensus 50%, Round 2)</i></p>
Re-resection	<p>Re-resection should be considered to achieve clear histological margins if the initial resection has positive surgical margins. <i>(Source: SIGN, Consensus 75%, Round 2)</i></p>
Reconstruction	<p>Reconstruction should be performed where necessary following surgical resection to achieve a good functional and cosmetic result. <i>(Source: SIGN*, Consensus 92%, Round 1)</i></p>
N0 disease	<p>The clinically N0 neck (levels I-III) should be treated prophylactically either by external beam radiotherapy or selective neck dissection for tumours involving the oral tongue or floor of mouth with depth of invasion > 4mm. <i>(Source: SIGN, Consensus 78%, Round 2)</i></p>
Postoperative Radiotherapy	<p>Postoperative radiotherapy should be considered for patients with clinical and pathological features that indicate a high risk of recurrence as per the SIGN Surgery Section (section #4). <i>(Source: SIGN, Consensus 79%, Round 1)</i></p>
b. Advanced Oral Cavity Cancer (Stage III and IV)	
Treatment Options	<p>Patients with resectable disease who are fit for surgery should have surgical resection with reconstruction. <i>(Source: SIGN, Consensus 89%, Round 1)</i></p>
	<p>The likelihood of obtaining adequate surgical margins with acceptable morbidity, functional outcome, and quality of life must be considered before undertaking surgical resection. <i>(Source: SIGN*, Consensus 97%, Round 1)</i></p>

<p>Organ Preservation</p>	<p>† An organ preservation approach should be considered when the:</p> <ul style="list-style-type: none"> - tumour cannot be adequately resected. - patient's general condition precludes surgery. - patient does not wish to undergo surgical resection <p>(Source: SIGN, Consensus 69%, Round 1ⁿ)</p>
<p>Nodal Disease</p>	<p>Patients with node positive disease may be treated by selective or comprehensive neck dissection. Patients with high volume multi-level disease should be considered for more comprehensive dissection.</p> <p>Elective dissection of the contralateral neck should be considered if the primary tumour is locally advanced, arises from the midline, or if there are multiple ipsilateral nodes involved.</p> <p>(Source: SIGN and HNMWG*, Consensus 89%, Round 2)</p> <hr/> <p>Patients with clinically node positive neck are managed based on the planned primary treatment. If an organ preservation approach is selected as the primary treatment, neck dissection is considered in patients with clinical or radiologic evidence of residual disease and control of the primary site.</p> <p>The role of planned neck dissection for N2 and N3 disease remains controversial.</p> <p>(Source: SIGN and HNMWG*, Consensus 91%, Round 2)</p>
<p>Radiotherapy</p>	<p>When radiotherapy is being used as a single modality without concurrent chemotherapy, a modified fractionation schedule should be considered.</p> <p>(Source: SIGN, Consensus 82%, Round 2)</p>

NOTES: HNMWG: Head and Neck Management Working Group; SIGN: Scottish Intercollegiate Guidelines Network.

5. Rare Tumours in Head and Neck Cancer

Recommendations

- It is recommended that patients with rare tumours or other uncommon histologies not addressed in this management document be referred to the Head and Neck Cancer Multidisciplinary team at a centre seeing at least 100 head and neck cases annually, to develop a treatment plan that may be executed in whole or in part closer to home in collaboration with the referring centre. These cancers would include nasopharyngeal carcinoma; rare cancers of the skin (e.g., Merkel cell carcinoma); sarcomas; skull based tumours, including esthesioneuroblastoma; malignant paranasal sinus tumours; and malignant tumours of the salivary glands.
- A CCO PEBC clinical practice guideline for the use of chemoradiotherapy in nasopharyngeal carcinoma recommends that cisplatin-based concurrent radiochemotherapy be routinely offered to patients with newly diagnosed locally advanced squamous cell or undifferentiated nasopharyngeal cancer (stage III or IV) (14).
(Source: HNMWG* and CCO-PEBC, Consensus 86%, Round 2)

IV. Post-Treatment

1. Follow-up, Rehabilitation and Patient Support

	RECOMMENDATIONS
Frequency of Follow-up	Patients should be seen and examined by one or more core team members (every 3 months for year 1, every 4 months for year 2 and every 6 months in year 3). <i>(Source: SIGN, Consensus 79%, Round 1)</i>
	Assessment of the late complications of treatment is an important component of the follow-up of patients treated for head and neck cancer. <i>(Source: HNMWG*, Consensus 95%, Round 1)</i>
	† There is no evidence that follow up imaging improves locoregional control or survival. Follow-up imaging should be symptom directed and not part of routine screening. <i>(Source: HNMWG*, Consensus 59%, Round 2)</i>
	Every patient should have access to psychosocial support integrated into their care. Assessment of distress, anxiety, and coping should be included in routine assessments. <i>(Source: HNMWG*, Consensus 93%, Round 1)</i>
Oral and Dental Rehabilitation	Patients receiving oral surgery or radiotherapy to the mouth (with or without adjuvant chemotherapy) should have post-treatment dental rehabilitation. <i>(Source: SIGN, Consensus 97%, Round 1)</i>
	Patients should access lifelong dental follow up and dental rehabilitation. <i>(Source: SIGN, Consensus 92%, Round 1)</i>
	Dental extractions in irradiated jaws should be carried out in hospital by a dental oncologist or oral surgeon. <i>(Source: SIGN, Consensus 82%, Round 1)</i>
	Hyperbaric oxygen facilities should be available for selected patients. <i>(Source: SIGN, Consensus 77%, Round 1)</i>

NOTES: SIGN: Scottish Intercollegiate Guidelines Network; HNMWG: Head and Neck Management Working Group.

RELATED GUIDELINES

PEBC Evidence-based Series reports:

- EBS 5-7: Chemotherapy with Radiotherapy for Nasopharyngeal Cancer: A Clinical Practice Guideline.
- EBS 19-1: Provider-Patient Communications.
- EBS 21-1: Organizational Standards for the Delivery of Intensity Modulated Radiation Therapy (IMRT) in Ontario.
- EBS Report: Organizational Standards for Diagnostic Assessment Programs.

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Evidence-Based Series #5-3: Section 2

The Management of Head and Neck Cancer in Ontario: Evidentiary Base

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A Quality Initiative of the
Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)

Report Date: December 15, 2009

QUESTIONS

Organization of Care

- 1) What minimum requirements are necessary for the organization and delivery of multidisciplinary care to patients with head and neck mucosal malignancies? Areas of interest include healthcare teams and unique infrastructure.
- 2) What are the recommended staff requirements and expertise required by medical/surgical and allied healthcare professionals to provide optimal care for head and neck patients? Areas of interest include minimum volumes and training to optimize patient outcomes.

Clinical Management

- 3) What is the optimum clinical management recommended for patients with tumours of the head and neck?

INTRODUCTION

The patient presenting with a head and neck cancer poses a significant challenge to the healthcare provider and the system responsible for cancer treatment in Ontario. Head and neck malignancies represent a variety of different tumour types arising from numerous anatomic regions in the head and neck. These tumours affect physiologic functions that are essential for communication and nutrition and specifically impact on swallowing, speech and facial form, movement, and aesthetics. To further complicate care, patients presenting with head and neck tumours often have significant medical co-morbidities, specifically tobacco use and alcohol consumption, that put them at risk for developing a head and neck malignancy.

In 2006-2007, approximately 1500 new mucosal head and neck cancers were evaluated and treated in the province's regional cancer centres (1). The treatment for most head and neck tumours requires the use of multimodality therapy, usually a combination of radiation therapy, with or without chemotherapy, and some form of surgical therapy. Radiation treatment for most advanced tumours is highly complicated because of the technical nuances

around treatment planning and the requirement for conformal therapy to avoid damaging structures that are involved with the functions of speech and swallowing. The surgical treatment of this population is often complex, requiring specialized expertise in ablative and reconstructive surgery, usually with multiple surgical teams from a variety of surgical disciplines. This population of patients has many special needs because of disabilities associated with the treatment approaches and the requirements for ongoing supportive care in the domains of nutrition, pain management, and psychosocial support.

In most jurisdictions throughout the world, and in Ontario, the care of patients with head and neck cancers is highly regionalized and focused in centres with highly trained and experienced multidisciplinary teams and comprehensive supportive programs. Ontario has embarked on a program of development of new regional cancer centres, with the goals of increasing the capacity for patient treatment and providing care closer to home. In this environment, the Head and Neck Disease Site Group (DSG) has recognized a need for guidance on the organization and delivery of healthcare services for patients with head and neck cancer, including specific recommendations regarding the organization of care, the human and physical resources required, and appropriate treatment approaches that should be considered for this population of patients.

METHODS

The evidence-based series (EBS) guidelines developed by Cancer Care Ontario's Program in Evidence-Based Care (PEBC) use the methods of the Practice Guidelines Development Cycle (2). For this project, the core methodologies used to develop the evidentiary base were adaptation, supplemented by a literature search to update the evidence from the adapted guidelines and formal consensus. Evidence was selected and reviewed by four members of the PEBC Head and Neck Management Working Group (HNMWG) (see Section 2: Appendix 1 for list of members) and one methodologist.

This review is a convenient and up-to-date source of the best available evidence on the management of head and neck cancer. The body of evidence in this review is primarily comprised of guidelines from credible organizations or government bodies, as well as mature randomized controlled trial (RCT) data. That evidence, combined with consensus opinion of individuals working with head and neck cancer patients, forms the basis of the organizational and clinical recommendations for the optimal delivery of the management of head and neck cancer in Ontario.

The evidence base and companion recommendations are intended to promote evidence-based practice in Ontario, Canada. The PEBC is supported by the Ontario Ministry of Health and Long-Term Care through Cancer Care Ontario. All work produced by the PEBC is editorially independent from its funding source.

Environmental Scan

The environmental scan involved an Internet search for guidelines relevant to our research question, using the PEBC preferred list (Table 1) of guideline developers and guideline directories of Canadian and international health organizations and the National Guidelines Clearinghouse.

Table 1. Websites reviewed.

Scottish Intercollegiate Guidelines Network (SIGN) National Institute for Clinical Excellence (NICE) Cancer Society of New Zealand Cancer Care Ontario (CCO) clinical practice guidelines - Head and Neck Cancer DSG British Columbia Cancer Agency

Nova Scotia Cancer Agency
 Cochrane Reviews
 American Society of Clinical Oncology (ASCO)
 American Society for Therapeutic Radiology and Oncology (ASTRO)
 American Cancer Society
 National Guidelines Clearinghouse
 National Comprehensive Cancer Network (NCCN)

Adaptation

Two guidelines identified through the environmental scan were considered the most appropriate to answer this guideline's questions. The National Institute for Clinical Excellence (NICE) 2005 document *Guidance on Cancer Services - Improving Outcomes in Head and Neck Cancer* (3) addressed the organization of care questions. The Scottish Intercollegiate Guidelines Network (SIGN) 2006 document *Diagnosis and Management of Head and Neck Cancer* (4) addressed the clinical management questions.

The HNMWG utilized the ADAPTE process (<http://www.adapte.org/>) to adapt recommendations from these two guidelines (5). The objective of the ADAPTE process is to take advantage of existing guidelines in order to enhance the efficient production and use of the resulting high-quality adapted guidelines. The adaptation process has been designed to ensure that the resulting and final recommendations address specific health questions relevant for the context of use and that they are suited to the needs, priorities, legislation, policies, and resources in the targeted setting, without undermining their validity.

Following the ADAPTE protocol, the relevant guidelines identified through the environmental scan were screened and assessed for quality, currency, content, consistency, and acceptability/applicability. Quality was assessed by three independent reviewers, using the Appraisal of Guidelines Research and Evaluation (AGREE) instrument (6). With the instrument, agreement with a series of statements that are intended to capture dimensions of guideline quality is rated on a scale of 1 to 4 for each of the 23 instrument statements. The 23 statements are divided among six domains intended to capture guideline quality. For each statement, a rating of 1 indicates strong disagreement, of 2 indicates disagreement, of 3 indicates agreement, and of 4 indicates strong agreement with that statement. Scores for each domain are calculated by summing the results for each of the individual statements in a domain and presenting the total amount of reviewer agreement as a percentage of the maximum possible score for that domain.

Systematic Review

The literature search strategy from the SIGN document was used to update the evidence pertaining to the clinical management of patients with head and neck cancer. The SIGN search covered material published from 1998 to 2004. The updated search covered material published from January 2005 through November 2007. Only phase III RCTs, systematic reviews, meta-analyses, and practice guidelines were included in the update of the literature search. Though the original search was performed in MEDLINE, EMBASE, CINAHL, and the Cochrane Library, the updated search used only the MEDLINE database (OVID, from 2005 to November, week 4 2007), because that was the only search strategy available. Reference lists from relevant articles and reviews were searched for additional reports. The full SIGN systematic review search strategy can be found at: <http://www.sign.ac.uk/guidelines/published/support/guideline90/index.html>.

The SIGN guideline did not include recommendations for intensity modulated radiation therapy (IMRT). A separate literature search was conducted to obtain evidence on this topic,

covering the time period of 2005 through January 2008. The complete search strategy is included in Appendix 2.

Study Selection Criteria

Inclusion Criteria

Articles were included if they provided new data on the management of head and neck cancer. To ensure the highest quality of evidence was used to frame new clinical recommendations, only fully published phase III RCTs, systematic reviews, meta-analyses, and practice guidelines were included in this document.

IMRT is a relatively new field of treatment for head and neck cancer, and there have been no phase III randomized trials published to date. Therefore, for this area of treatment alone, all recommendations are based on the expert opinion of the HNMWG.

Exclusion Criteria

Fully published phase III RCTs reporting only initial results, non-phase III RCTs, review articles that did not provide a search strategy, and abstracts and publications dealing specifically with thyroid cancer were not included in this document. Relevant systematic reviews and meta-analyses published between July 2005 and December 2007 were excluded if the search date ended prior to July 2005. Articles in a language other than English were also excluded, because resources were not available for their translation.

RESULTS

Environmental Scan Results

The environmental scan identified two relevant guidelines, a standard of care guidance document by NICE) (3) and a clinical practice guideline by SIGN (4).

Adaptation

Quality Assessment

Practice and Organization Guidelines

To ensure that the SIGN (4) and NICE (3) documents met the clinical and organizational requirements of a PEBC document, the AGREE assessment tool (6) was used to determine their relevance (Table 2). Both documents clearly defined their scope and purpose, as well as providing clear and concise clinical recommendations for the treatment of head and neck cancer. Even though both documents conducted systematic reviews and briefly described the search strategies in their methods sections, only the SIGN document provided a separate, thoroughly comprehensive search strategy that could be duplicated. The NICE document, however, was more applicable and provided a comprehensive layout to the organizational section of this document. Both documents assessed and addressed the scientific quality of the included studies.

Table 2. AGREE scores for selected guidelines. (# of reviewers: SIGN - 3, NICE - 2).

Guideline	Domain					
	Scope & Purpose	Stakeholder Involvement	Rigor of Development	Clarity and Presentation	Applicability	Editorial Independence
SIGN	70.4%	55.6%	71.4%	88.9%	37%	33.3%
NICE	88.9%	70.8%	35.7%	62.5%	72.2%	8.3%

Systematic Review Update

The SIGN systematic review search strategy was used to update the search and retrieve recent relevant articles. A new search on the topic of IMRT was also conducted. From these searches, an additional five organizational and four clinical practice guidelines, one meta-analysis, and two RCTs met the inclusion criteria. Table 3 lists all the relevant documents identified and included in this adaptation.

Table 3. Reports included in this adaptation.

Report Type	Number of reports	References
Organizational Guidelines	6	NICE (3), PEBC - IMRT (7), DAP (8), Provider-Patient Communication (9), Pain Management (10), Histopathological reporting (11),
Practice Guidelines	4	SIGN (4), Smith 2006 (12), Kris 2006 (13), Rubenstein 2004 (14)
Meta-analysis	1	Bourhis 2006 (15)
Randomized Controlled Trials	2	Vermorken 2007 (16), Posner 2007 (17)

Organizational and Practice Guidelines

As the guidelines identified by the updated literature search were only used to inform one or two recommendations, running the AGREE tool on these organizational and practice guidelines was deemed unnecessary. However, a detailed description of their contents is included below. Various forms of grading were used by the developers of the organizational and practice guidelines.

Meta-analysis and Randomized Controlled Trials

The purpose and methods of the meta-analysis were clearly defined. The criteria for study inclusion, data collection, and quality control were extensive and are well detailed in the protocol document (18). The literature search strategy and the power calculations to detect a 5% improvement in survival if 2500 and 4000 patients were included in the meta-analysis were provided and were also in the protocol document (18).

Quality characteristics of the RCTs identified in the update of the SIGN literature search are found in Table 4.

Table 4. Randomized controlled trial qualities.

Author, Year, Reference	Posner 2007 (17)	Vermorken 2007 (16)
Location	USA	Belgium
Type of Trial	Multicentre, phase III	Multicentre, phase III
Randomization method described	Biased-coin minimization	Variance-minimization method
Statistical power calculation reported	91% power to detect death HR 0.65 (median OS TPF 43 vs. PF 28 m)	85% power to detect 50% increase in median PFS (TPF 15 vs. PF 10 m; HR 0.67)
Blinded	No	No
Drop-outs described	494/501 started induction CT; 68 in TPF & 79 in PF stopped trtmt	352/358 started induction CT; 9 in TPF & 10 in PF lost to follow-up; 46 in TPF and 66 in PF stopped trtmt
Intent to treat analysis	Yes	Efficacy - 100% Safety CT & CRT - 4 excl Safety RT - 109 excl
Balanced Arms	T4 lesions: TPF > PF; otherwise balanced	Yes
Commercial sponsorship	Sanofi-Aventis	Sanofi-Aventis

Abbreviations: CRT: chemoradiotherapy; CT: chemotherapy; excl: excluded; HR: hazard ratio; m: months; OS: overall survival; PF: cisplatin, fluorouracil; PFS: progression-free survival; RT: radiotherapy; TPF: docetaxel, cisplatin, fluorouracil; trtmt: treatment; vs.: versus.

Description of Included Documents

Organization of Care Guidance: Organization of Care Guidelines

Guidance on Cancer Services - Improving Outcomes in Head and Neck Cancer: NICE, 2005 (3)

The NICE developed head and neck cancer organizational guidelines to provide guidance to the National Health Service (NHS) cancer care system to ensure that health services in England and Wales had organizational arrangements in place for securing improvements in cancer services. The intended users of this guideline are individuals responsible for the implementation of services for head and neck cancer patients within Health Services. The report consists of three parts: 1) Scoping outline for the main documents, 2) Research evidence, and 3) the Manual. An extensive systematic review was conducted to retrieve all relevant studies, spanning database inception through 2002/2003 (depending on the question). The recommendations encompass referral, structure of services, initial investigation and diagnosis, pre-treatment assessment and management, primary treatment, aftercare and rehabilitation, follow-up and recurrent disease, and palliative interventions and care.

Upper Aerodigestive Tract (Including Salivary Glands) - Head and Neck: CAP, 2005 (11)

CAP presents a checklist for histopathological reporting for the upper aerodigestive tract and salivary glands. The procedures covered include cytology, biopsy, and resection. The guideline includes checklists for documenting histologic type, specimen type, tumour site, tumour size, histologic grade, pathologic staging, margins, venous lymphatic invasions, perineural invasion, additional pathologic findings, and laterality depending on whether

the tumour is macroscopic or microscopic. Additionally, the guideline provides background documentation requirements and explanatory notes.

Organizational Standards for Diagnostic Assessment Programs: PEBC Special Report of the Diagnostic Assessment Standards Panel, CCO, 2007 (8)

The purpose of the Diagnostic Assessment Program (DAP) is to coordinate patient care from referral through definitive diagnosis. This guideline sought to outline the optimal organizational and practice setting features for a cancer diagnostic assessment program in Ontario. The Diagnostic Assessment Standards Panel that developed this guideline is comprised of clinical oncology experts, regional vice presidents, clinical administrative leaders, health services researchers, and methodologists. A systematic review by Gagliardi (19) and an update of its literature search provided the basis for the recommendations. The update of the literature search used MEDLINE, EMBASE, the Cochrane Library, the Canadian Medical Association Infobase, and the National Guideline Clearinghouse and spanned 2002 to October 2006. The recommendations for the DAP include standards related to: 1) Purpose and principles, 2) Diagnostic assessment programs, 3) Regional centralized access to DAPs, 4) Scope of cancer diagnostic activity within a DAP, 5) Cancer diagnostic assessment team criteria, 6) Cancer DAPs linkages and collaborations, 7) Provincial indicators of quality for cancer DAPs, and 8) Guidelines, standards, and service frameworks.

Organizational Standards for the Delivery of Intensity Modulated Radiation Therapy (IMRT) in Ontario: PEBC Report 21-1, CCO, 2008 (7)

The PEBC sought to determine what the optimal organization standards for the delivery of IMRT are in Ontario. The report contains three sections: 1) the Recommendations, 2) the Systematic Review/Evidentiary Base, and 3) the Methodology of the Standards Development and External Review Process. MEDLINE, EMBASE, and the Cochrane, National Guidelines Clearinghouse, and Health Technology Assessment databases were systematically searched for documents published between 1996 and June 2006 that provided guidance on organizational standards for the delivery of IMRT. Additionally, an environmental scan using the Google search engine (©2009 Google) was performed in June 2006 to identify standards and practice guidelines pertaining to IMRT. The recommendations encompass 1) Implementation of an IMRT program, 2) Practice setting, 3) Tools, devices and equipment requirements, 4) Professional training requirements, and 5) Quality assurance and safety.

Provider-Patient Communication: PEBC EBS 19-2, CCO, 2008 (9)

The PEBC sought to determine what aspects of provider-patient communication have an impact on clinical outcomes in cancer patients. The intended users of this document are oncology healthcare professionals interacting with cancer patients during critical points of care. The guideline is made up of three parts: 1) the Recommendations, 2) the Evidentiary Base, and 3) the EBS Development Methods and External Review Process. The literature was searched using MEDLINE, HealthSTAR, PsycINFO, EMBASE, CINAHL, and the Cochrane Database of Systematic Reviews and Clinical Trials Register through March 2007 to identify relevant evidence-based practice guidelines, systematic reviews, or meta-analyses, as well as RCTs. Additionally, an environmental scan was performed in July 2006 to find current guidelines and standards related to provider-patient communication and psychosocial distress. The PEBC used the Australian National Breast Cancer Centre and National Cancer Control Initiative (NBCC-NCCI) *Clinical Practice Guidelines for the Psychosocial Care of Adults with Cancer* as the framework for their document. The

recommendations made in the PEBC report are the result of the integration of the NBCC-NCCI recommendations, an update of the systematic literature search used by the NBCC-NCCI, and consensus by the PEBC Provider-Patient Communications Working Group. The recommendations cover the following topics: 1) General interaction skills, 2) How to discuss prognosis, 3) How to discuss treatment options, and 4) How to prepare patients for medical procedures.

Cancer-related Pain Management: PEBC EBS 16-2, CCO, 2008 (10)

The PEBC presents evidence-based recommendations to guide practice regarding the management of cancer-related pain. The guideline is made up of three parts: 1) the Recommendations, 2) the Evidentiary Base and 3) the EBS Development Methods and External Review Process. The literature was searched for published guidelines related to pain management published between 2000 and May 2006, using MEDLINE. Additionally, an environmental scan was conducted to find Canadian and international unpublished guidelines providing information on cancer-related pain management. A total of eight high-quality, relevant pain-management guidelines were identified and selected or adapted, upon working group consensus of agreement, to form the base of the recommendations for this guideline. The recommendations cover the following topics: 1) Assessment of pain, 2) Assessors of pain, 3) Timing and frequency of assessment, 4) Components of pain assessment, 5) Assessment of pain in special populations, 6) Plan of care, 7) Pharmacological intervention, 8) Safety and efficacy, 9) Documentation, 10) Education, and 11) Outcome measures.

Clinical Practice Guidance: Clinical Practice Guidelines

Diagnosis and Management of Head and Neck Cancer: SIGN, 2006 (4)

The SIGN was formed to develop guidelines to improve healthcare quality in Scotland by systematically reviewing evidence. The identified clinical practice guideline dealt with the diagnosis and management of head and neck cancer in Scotland. The intended users for this guideline included healthcare professionals working with patients with head and neck cancers, including clinical oncologists; ear, nose and throat specialists; oral and maxillofacial surgeons; plastic surgeons; general surgeons; nurses; and allied health professionals. The literature search strategy ranged from 1998 through 2004; however, for several questions, the search went back to 1990. The recommendations were rated on the levels of evidence and encompassed: presentation, screening, and risk factors; referral and diagnosis; histopathology reporting; treatment—by modality; management of locoregional recurrence; palliation of incurable disease; and treatment—by disease site.

Clinical Practice Guidelines for the Prevention and Treatment of Cancer Therapy - Induced Oral and Gastrointestinal Mucositis: MASCC, 2004 (14)

MASCC assembled an expert panel to create evidence-based guidelines for preventing, evaluating, and treating oral and gastrointestinal mucositis. The intended users of this guideline are oral healthcare specialists, oncology and oral medicine patients, oncologists, clinical investigators, and policy makers. The guideline is divided into four topics: 1) Biologic basis and pathogenesis, 2) Epidemiology, 3) Clinical practice guidelines for care of patients with oral mucositis, and 4) Clinical practice guidelines for the prevention and treatment of GI mucositis. There were a total of 14 working groups, each made up of two to five members, among whom were oral oncologists, radiation oncologists, hematologists, medical oncologists, surgeons, pathologists, nurses, dental hygienists, basic scientists, microbiologists, epidemiologists, outcomes researchers, and a medical librarian. The literature was searched using MEDLINE and CancerLit for articles published between

January 1966 and May 31, 2002. The identified literature was circulated to each member of the working group to score. Over the course of two meetings, recommendations were drafted and subsequently circulated to allow panelists an opportunity to comment on the levels of evidence and grading of the recommendations. All panelists approved the final version of the guideline.

American Society of Clinical Oncology (ASCO) Guideline for Antiemetics in Oncology: Update 2006 (13)

The ASCO update committee reviewed and analyzed data published between 1998 and February 2006 to update the 1999 guideline for antiemetics in oncology. The update expert panel consisted of 10 representatives, including oncologists, patient representatives, a nurse, and a clinical researcher. The guideline is broken up into two topics: 1) Emesis caused by intravenously (IV) administered antineoplastic agents and 2) Radiation-induced emesis. Additionally, the IV drug induced emesis topic was broken down into three subsections: a) Vomiting occurring 0 to 24 hours after therapy (acute emesis), b) Vomiting occurring 24 or more hours after chemotherapy (delayed emesis), and c) Special emetic problems. The MEDLINE and Cochrane Library databases were searched for articles published between 1998 and February 2006. RCTs, systematic reviews, and meta-analyses of published phase II and III RCTs were reviewed. The committee also reviewed the guidelines and consensus statements released from the International Antiemetic Consensus Conference, hosted by MASCC, in 2004. The final draft was reviewed and approved by each member of the update expert panel. Additionally, the update was approved by the ASCO Health Services Committee and the ASCO Board of Directors.

2006 Update of Recommendations for the Use of White Blood Cell Growth Factors: An Evidence-Based Clinical Practice Guideline: ASCO, 2006 (12)

The ASCO update committee reviewed and rated evidence published between 1999 and September 2005 to update the 2000 ASCO guideline on the use of hematopoietic colony-stimulating factors (CSF). The update expert panel was comprised of 23 individuals who met on four separate occasions to discuss the evidence for each of the recommendations. The guideline is divided into 13 sections: 1) Recommendations for primary prophylactic CSF administration (first and subsequent-cycle use), 2) Recommendations for secondary prophylactic CSF administration, 3) Recommendations for therapeutic use of CSF, 4) Recommendations for use of CSFs to increase chemotherapy dose intensity and dose density, 5) Recommendation for the use of CSFs as adjuncts to progenitor-cell transplantation, 6) Recommendations for use of CSFs in patients with acute leukemia and myelodysplastic syndromes, 7) Recommendations for use of CSFs in patients receiving radiotherapy with or without concurrent chemotherapy, 8) Recommendations for use of CSFs in older patients, 9) Recommendations for use of CSFs in the pediatric population, 10) Recommendations for CSF initiation, duration, dosing and administration, 11) Special comments on comparative clinical activity of G-CSF and GM-CSF, 12) Special comments on growth factors as a treatment for radiation injury, and 13) Impact of CSFs on quality of life and healthcare costs. MEDLINE and the Cochrane Library databases were searched for articles published between 1999 and September 2005. The levels and grades of evidence were rated as described above in the ASCO guideline on antiemetics in oncology. The expert panel drafted recommendations, and the guideline was circulated for review and approval. The final document was also approved by the ASCO Health Services Committee and the ASCO Board of Directors.

Clinical Practice Guidance: Meta-analysis**Hyperfractionated or Accelerated Radiotherapy in Head and Neck Cancer: A Meta-analysis, 2006 (15)**

The purpose of the meta-analysis was to assess whether hyperfractionated or accelerated radiotherapy could increase survival in patients with head and neck cancer by comparing it to conventional radiotherapy. The main endpoint was survival, and the secondary endpoint was time-to-first event (local or distance failure, second primary tumour). MEDLINE, EMBASE, CancerLit, and the Physicians Data Query clinical trial registry were searched between 1980 and 1997 for clinical trials comparing altered fractionation to conventional radiotherapy (search strategies are detailed in the protocol document (18).

Clinical Practice Guidance: Randomized Controlled Trials**Cisplatin and Fluorouracil Alone or in Combination with Docetaxel, 2007 (16,17).**

The purpose of these two RCTs was to determine the effect of induction chemotherapy with docetaxel plus cisplatin and fluorouracil to cisplatin and fluorouracil alone on overall survival (17) and progression-free survival (16). Study details are found in Table 5. Patients in both studies were randomized by treatment regimen to docetaxel/cisplatin/fluorouracil (TPF) or cisplatin/fluorouracil (PF). Once chemotherapy was completed, patients in both studies were further treated with radiation therapy (16) or chemoradiotherapy (and surgery if patients had a partial response to induction chemotherapy or residual disease following chemotherapy and radiation therapy) (17).

Table 5. Study details of RCTs comparing docetaxel plus cisplatin and fluorouracil to cisplatin and fluorouracil alone.

Study	Characteristics	Trial Arm Regimens	Primary Site (%)	Pts (Total)
Posner, 2007 (17)	Pts w nonmetastatic, unresectable/low surgical curability/desire organ preservation, histo-confirmed stage III/IV HNSCC (oral cavity, larynx, oropharynx, hypopharynx), \geq 18y.	PF - P: 100mg/m ² 0.5-3h IV \rightarrow F: 1000mg/m ² /d cont IV d1-5, every 3 wks, 3 cycles, followed by CRT and surgery	Hypopharynx - 34 (14) Larynx - 42 (17) Oral cavity - 38 (15) Oropharynx - 131 (53) Other - 1 (<1)	246
		TPF - T: 75mg/m ² 1h IV \rightarrow P: 100 mg/m ² 0.5-3h IV \rightarrow F: 1000 mg/m ² /d cont IV d1-4, every 3 wks, 3 cycles, followed by CRT and surgery	Hypopharynx - 43 (17) Larynx - 47 (18) Oral cavity - 33 (13) Oropharynx - 132 (52) Other - 0 (0)	
Vermorke n, 2007 (16)	Pts w prev untreated, nonmet, unresectable, histo/cyto confirmed stage III/IV HNSCC (excl nasopharynx, nasal and paranasal cavity), b/w 18-70 y.	PF - P: 100mg/m ² 1h IV d1 \rightarrow F:1000mg/m ² /d d1-5, every 3 weeks, up to 4 cycles vs.	Hypopharynx - 52 (28.7) Larynx - 13 (7.2) Oral cavity - 32 (17.7) Oropharynx - 84 (46.4)	181
		TPF - T: 75mg/m ² 1 h IV d1 \rightarrow P: 75 mg/m ² 1 h IV d1 \rightarrow F: 50mg/m ² /d d1-5, every 3 weeks, up to 4 cycles	Hypopharynx - 53 (29.9) Larynx - 12 (6.8) Oral cavity - 31 (17.5) Oropharynx - 81 (45.8)	

Abbreviations: CRT: chemoradiotherapy; d: day; histo/cyto: histological/cytological; HNSCC: head and neck squamous cell carcinoma; IV: intravenously; nonmet: non metastatic; PF: cisplatin and fluorouracil; prev: previously; Pts: patients; TPF: docetaxel, cisplatin, and fluorouracil; vs.: versus.

Outcomes

Organization of Care Guidance

Improving Outcomes in Head and Neck Cancer: NICE, 2005 (3)

NICE provides organizations with guidance on head and neck cancer services. Their recommendations focus on services that will impact health outcomes. The evidentiary base used to inform the recommendations in this guidance consisted of 127 published reports. With the exception of the recommendations on primary treatment, which were based primarily on evidence derived from RCTs or systematic reviews of randomized trials, the remaining recommendations were based primarily on evidence from non-RCTs and observational studies.

Based on these recommendations the HNMWG put forward 27 recommendations pertaining to the organization of head and neck cancer care (see Section 1: Organization Recommendations).

Upper Aerodigestive Tract Histopathological Reporting: CAP, 2005 (11)

CAP provides protocols for use by physicians and other healthcare providers reporting on surgical specimens. These protocols are an educational tool meant to assist pathologists in reporting useful and relevant information on surgical specimens. CAP indicates that the checklists included in this document are essential elements of pathological reporting. As of January 2004, the use of the document checklists was mandated by the Commission on Cancer of the American College of Surgeons as part of their Cancer Program Standards for Approved Cancer Programs. The protocols for histopathological reporting proposed by CAP are based on expert opinion.

Based on these standards the HNMWG put forward the following recommendation:

- 1) Pathologists are advised to use the CCO-CAP standards for reporting head and neck malignancies, available from:
http://www.cap.org/apps/docs/committees/cancer/cancer_protocols/2005/upperae_ro05_pw.pdf

Organizational Standards for Diagnostic Assessment Programs: PEBC, 2007 (8)

The PEBC reports on the coordination of patient care from referral to definitive diagnosis. The standards were based on an update of a previously published systematic review (19) and study formats included RCTs, prospective or retrospective cohort studies, and case series that provided sufficient methodological detail. The evidentiary base used to develop these standards was made up of 35 published studies and 15 guidance documents. A total of eight studies dealing specifically with head and neck diagnostic assessment programs were identified. Additionally, the SIGN document (4), which forms the basis for the clinical practice recommendations in this present document, was identified during an environmental scan as a guidance document dealing with organizational matters related to diagnostic assessment programs.

Based on these standards, the HNMWG included the following recommendation:

- 1) Rapid access or “one-stop” clinics should be available for patients who fulfill appropriate referral criteria. For further details, refer to the PEBC Diagnostic assessment standard of care document available from:
<http://www.cancercare.on.ca/pdf/pebcDAPf.pdf>.

Organizational Standards for Delivery of Intensity Modulated Radiation Therapy (IMRT) in Ontario: PEBC, 2008 (7)

The PEBC reports on the optimal organizational standards for the delivery of IMRT in Ontario. Standards were based on published and unpublished documents presenting guidance on organizational standards for the delivery of IMRT in a cancer program. The evidentiary base used to develop these standards was comprised of 12 published documents and 10 unpublished reports providing guidance on planning a new IMRT program; the practice setting; tools, devices, and equipment requirements; professional training requirements; the role of personnel; and/or quality assurance and safety. The standards are based upon the consensus opinion of the IMRT expert panel, because there was limited evidence available to inform the organizational standards.

Based on these standards the HNMWG put forward the following recommendations.

- 1) Unique infrastructure requirements for a Radiation Oncologist Radiation treatment facility including the following:
 - a) Linear accelerator based external beam radiation treatment with multi-leaf collimation and IMRT capability
 - b) Portal or CT based on board treatment verification
 - c) CT simulation (with IV contrast available) and custom immobilization capabilities
 - d) IMRT capable treatment planning system
 - e) Medical Dosimetry and Physics Support for plan development and quality assurance
 - f) Staff and infrastructure resource requirements: refer to the CCO PEBC IMRT organizational standards EBS (<http://www.cancercare.on.ca/pdf/pebc21-1s.pdf>)
- 2) In order to treat head and neck cancer with IMRT, centres should implement and deliver IMRT according to the organizational standards developed by the CCO PEBC (<http://www.cancercare.on.ca/pdf/pebc21-1s.pdf>). Centres unable to implement these standards should consider referring patients requiring curative treatment to centres that do have the capability.

Provider-Patient Communication: PEBC, 2008 (9)

(<http://www.cancercare.on.ca/pdf/pebc19-2f.pdf>)

The PEBC reports on the aspects of provider-patient communication that impact on clinical outcomes in patients with cancer. The recommendations are based on the NBCC-NCCI guidelines *Clinical practice guidelines for the psychosocial care of adults with cancer* (http://www.nhmrc.gov.au/publications/synopses/_files/cp90.pdf), an update of the systematic review since the release of the aforementioned document, and consensus of the PEBC Patient-Provider Communications Working Group. The outcomes of interest include psychosocial or emotional distress in patients, patient satisfaction, patient quality of life, and patient recall or understanding of information communicated by providers. The main focus of this report is the communication styles and approaches between the healthcare provider and the patient.

Based on these recommendations the HNMWG proposed the following recommendations:

- 1) Patients should be assessed for psychosocial needs.
- 2) Patients should be given information about their diagnosis and treatment on more than one occasion prior to the onset of treatment. Information should be individualized.

Cancer-related Pain Management: PEBC, 2008 (10)

The recommendations in the PEBC report on the management of cancer-related pain are based on eight high-quality pain guidelines (20-27). The quality of each guideline was assessed using the AGREE instrument, as well as by evaluating the domains included in each guideline. Expert opinion was used to reach consensus on each recommendation.

Based on these recommendations, the HNMWG proposed the following recommendation:

- 1) Patients with oral cavity, laryngeal, oropharyngeal or hypopharyngeal tumours who are being treated with radiotherapy should be offered oral rinses including local topical anaesthetics before, during, and up to three weeks after completion of radiotherapy. Patients should be advised on how to maintain good oral hygiene during and after radiotherapy. Patient mucosa should be inspected regularly during treatment, and analgesia (<http://www.cancercare.on.ca/pdf/pebc16-2s.pdf>) and antimicrobial/antifungal agents to treat infection should be made available.

Clinical Practice Guidance**Diagnosis and Management of Head and Neck Cancer: SIGN, 2006 (4)**

SIGN presents clinical practice guidelines for the management of head and neck cancer. The evidentiary base for this document is comprised of 511 published reports spanning prevention and awareness to follow-up and rehabilitation. With the exception of recommendations related to treatment, which were based on at least one meta-analysis, a systematic review of RCTs, and RCTs, the recommendations were primarily based on well conducted control or cohort studies, non-analytical studies, and expert opinion.

Based on these recommendations, the HNMWG put forward 144 recommendations pertaining to the management of head and neck cancer patients. These recommendations form the majority of the head and neck management recommendations presented in Section 1.

Prevention and Treatment of Oral Mucositis: MASCC, 2004, (14)

MASCC reports on the prevention and treatment of cancer treatment-induced oral and gastrointestinal mucositis. Recommendations were based on higher level evidence. Suggestions were put forward in the case of a lack of evidence or consensus among panellists regarding a given topic. Recommendations spanned foundations of care, prevention of radiotherapy-induced oral mucositis, prevention of standard dose chemotherapy-induced oral mucositis, treatment of standard dose chemotherapy-induced oral mucositis, and prevention of high-dose chemotherapy with or without total body irradiation plus hematopoietic stem cell transplantation-induced oral mucositis.

Based on this guideline, the HNMWG proposed the following recommendation:

- 1) Healthcare practitioners should treat patients in accordance with MASCC guidelines.

Antiemetics in Oncology: ASCO, 2006 (13)

ASCO reports on the use of antiemetics in oncology, providing recommendations based on published RCTs and systematic reviews and meta-analyses of published phase II and phase III RCTs. Recommendations spanned emesis caused by IV-administered antineoplastic agents and radiation-induced emesis.

Based on those recommendations, the HNMWG put forward the following recommendation:

- 1) Nausea and vomiting: Patients receiving chemotherapy should be treated in accordance with the standard antiemetic guidelines developed by ASCO (<http://jco.ascopubs.org/cgi/content/abstract/24/18/2932>).

Use of Hematopoietic Colony-Stimulating Factors in Oncology: ASCO, 2006 (12)

ASCO reports on the use of colony-stimulating factors to reduce febrile neutropenia in patients with cancer. The recommendations dealt with improvements in survival, quality of life, toxicity reduction, and cost-effectiveness.

Based on the recommendations presented in this document, the HNMWG put forward the following recommendation:

- 1) Febrile neutropenia should be managed in accordance with ASCO guidelines (<http://jco.ascopubs.org/cgi/reprint/24/19/3187>).

Altered Fractionation Radiotherapy in Patients over the Age of 70 (15)

The one meta-analysis identified was used to form the basis of an age-specific recommendation for the use of altered fractionated radiotherapy in patients over the age of 70. Bourhis et al (15) reported a significant age-by-treatment effect interaction whereby altered fractionation radiotherapy might become a less effective treatment to improve overall survival, death related to cancer, local control, and locoregional control outcomes, as compared with conventionally fractionated radiotherapy, as patients approached 70 years of age. Furthermore, as patients exceeded the age of 70, altered fractionation radiotherapy was associated with a greater risk of death as compared with conventionally fractionated radiotherapy.

The HNMWG recommendation pertaining to altered fractionation in patients with HNSCC over the age of 70 is:

- 1) Altered fractionation regimens should be individualized for patients over the age of 70.

Induction Chemotherapy with Docetaxel (16, 17)

Recommendations addressing first-line treatment of patients with locoregionally advanced HNSCC were based on the findings of the two identified phase III open-label RCTs (16, 17). Survival results from these two studies are found in Table 6.

Table 6. Survival results.

Study	Posner, 2007 (17)			Vermorken, 2007 (16)		
	PF Arm	TPF Arm	Comparison [HR (95% CI)]	PF vs. TPF	TPF Arm	Comparison [HR (95% CI)]
Overall Survival (m)	30	71	0.70 (0.54 - 0.90) p = 0.006	14.5	18.8	0.73 (0.56 - 0.94) p = 0.02
Progression-Free Survival (m)	13	36	0.71 (0.56 - 0.90) p = 0.004	8.2	11.0	0.72 (0.57 - 0.91) p = 0.007
Locoregional Failure (#, (%))	93 (38)	77 (30)	0.73 (0.54 - 0.99) p = 0.04	NR		
Distant Metastases (#, (%))	21 (9)	14 (5)	0.60 (0.30 - 1.18) p = 0.14	NR		

Abbreviations: CI: confidence interval; HR: hazard ratio; m: months; NR: not reported; vs.: versus.

The adverse effects of the addition of docetaxel to induction chemotherapy was similar between trials, with grade 3 or 4 neutropenia and febrile neutropenia more common and thrombocytopenia less common in the patients receiving TPF as compared with those receiving PF (16, 17). However, while the incidence of anemia was similar between treatment groups in one study (17) it was less common in the TPF group in the other study (16). Likewise, the incidence of lethargy was similar between groups in one study (16), whereas in the other study it was less common in patients receiving TPF as compared with those receiving PF (17).

The HNMWG recommendations pertaining to the addition of docetaxel to induction chemotherapy in patients with HNSCC are:

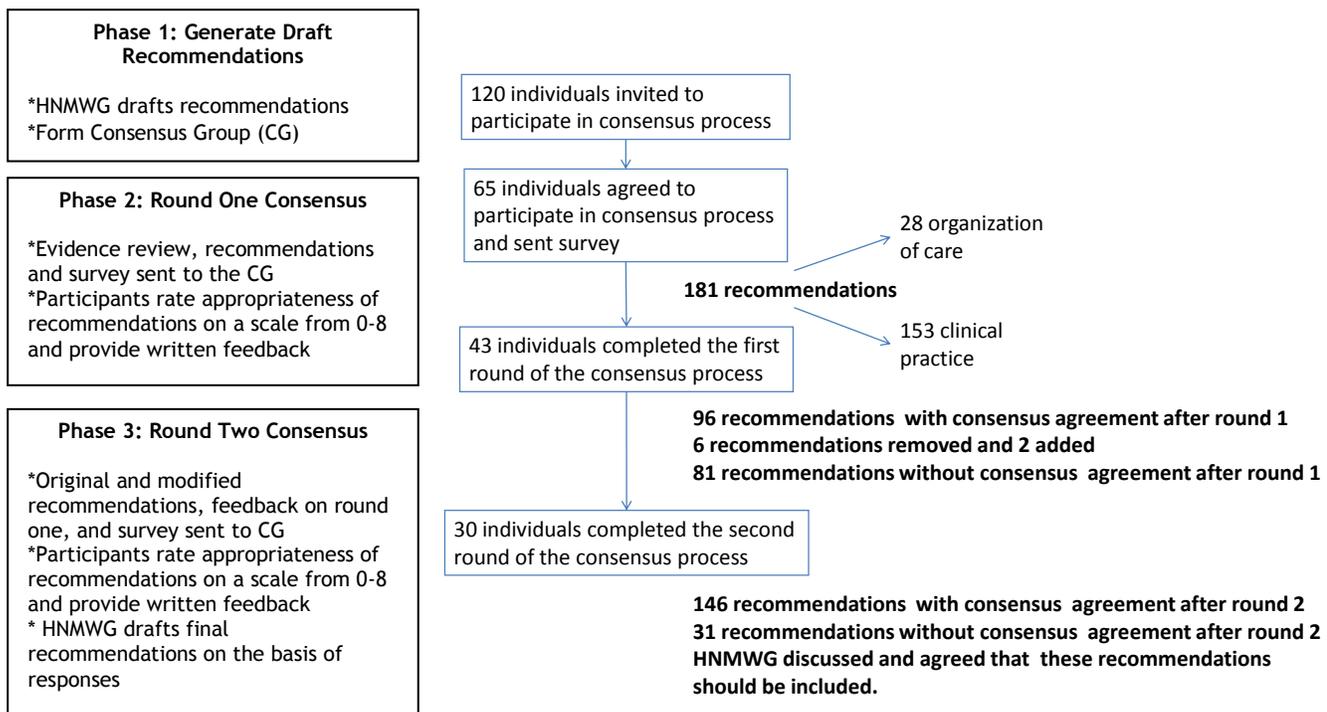
- 1) Concurrent chemoradiotherapy should only be administered where there are appropriate facilities for monitoring toxicity, with rapid access to appropriate outpatient and inpatient support for the treatment of acute radiotherapy and chemotherapy toxicity.
- 2) If neoadjuvant chemotherapy is used, docetaxel/cisplatin/5-fluorouracil (TPF) is recommended.

Consensus-Based Guideline Development Process

Methods and Results

The HNMWG used a modified Delphi consensus process to develop draft recommendations for the organization of care and for clinical practice in the management of head and neck cancer. The steps in the process are outlined in Figure 1.

In the first phase, the HNMWG drafted 181 recommendations for the management of head and neck cancer (28 recommendations for the organization of care and 153 recommendations for clinical practice). The recommendations were adapted from (using the adaptation process described above), and informed by, two previously published guidelines (3,4), by evidence identified in a supplementary literature search for areas not covered by either guideline (i.e., IMRT), and by the clinical expertise of the HNMWG. Discussions were conducted through teleconference, email, and in-person meetings. The HNMWG also nominated practitioners from various disciplines to participate in the consensus process, and an invitation letter was sent to 117 individuals, requesting their participation as members of the consensus group. This group consisted of medical oncologists, radiation oncologists, surgical oncologists, nurses, social workers, registered dietitians, and speech language pathologists from across Ontario (Table 7), including 13 members of the PEBC Head and Neck DSG. Of the 117 invited participants, 63 respondents agreed that they would take part in the consensus process. Additionally, three more names were suggested (two speech language pathologists and one social worker), and two of these individuals also agreed to participate in the consensus process (one speech language pathologist and the social worker).

Figure 1. Schematic drawing showing the steps of the consensus process.

In the second phase, the first of two rounds of consultations were conducted between May 2 and June 10, 2008, using a Web-based software program WebSurveyor (©2009 Vovici; version 4.1). The draft recommendations were sent to the 65 members of the consensus group (Table 7), including nine members of the Head and Neck DSG. Within the survey, links were provided to the source guidelines and evidence that were the basis for each recommendation. In the survey, the respondents were asked to rate their level of agreement with each recommendation on a nine-point Likert scale, ranging from ‘strongly agree’ at 0, through “strongly disagree” at 8. Additionally, if the respondents felt that they were unqualified to rate the recommendation, they were able to choose “not applicable” as their response. For each recommendation, a comment box was provided. For the interpretation of responses from the consensus group, an a priori decision was made by the HNMWG that a recommendation would be accepted if 75% or more of respondents submitted a rating of 0 (strongly agree) or 1 (agree). Of the 65 individuals who originally agreed to participate in the consensus process, 43 completed the survey (response rate = 66%) as outlined in Table 7.

Table 7. Types of practitioners participating in each phase of the consensus process.

Practitioner	Invited to Participate (N=120)	Agreed to Participate (N=65)	Responded Round 1 (N=43)	Responded Round 2 (N=30)
Medical Oncologist	9	4	3	2
Radiation Oncologist	16	12	5	4
Surgical Oncologist	12	10	6	4
Nurse	27	9	7	6
Social Worker	28	13	8	6
Registered Dietitian	11	6	5	3
Speech Language Pathologist	18	11	8	5
Unknown specialty	0	0	1	0

Due to the size and complexity of this survey, several delays were experienced in making the survey available to consensus participants. For example, the original expected start date for the first consensus round was March 2008, but the survey was not actually launched until May 2008.

Upon receipt of completed surveys, the HNMWG realized that in several instances respondents did not rate their level of agreement with a recommendation. In those cases, the methodologist contacted each respondent to determine whether they left the recommendation with no response because the recommendation was not applicable to them or because they did not know how to respond to the recommendation as written. In cases where the respondent indicated that a blank response meant “not applicable,” their response was changed from “did not respond” to “not applicable.” In cases where the respondent indicated that they did not know how to respond to the recommendation or no response was received from the respondent with regard to the meaning of a blank response, the methodologist logged their response as “did not respond.”

The first-round feedback was analyzed and distributed to the HNMWG, and the members revised the initial recommendations as appropriate. Of the 181 recommendations proposed in the first round of consensus, 97 recommendations received consensus of agreement (greater than 75% of respondents strongly agreed with the recommendation as written), 55 recommendations did not receive consensus, and 23 were edited as a result of respondent feedback. Two recommendations that received consensus of agreement were merged into one recommendation for round 2; thus, 96 recommendations went forward as “has consensus” in round 2. One recommendation that did not achieve consensus agreement was split into two recommendations for the second round of the consensus process. Additionally, two recommendations were added to the survey, based on respondent feedback, and six recommendations were removed prior to the second round of consensus (and not included in the count above).

In phase three of the consensus process, a second consensus round was conducted via WebSurveyor (©2009 Vovici) between October 21 and January 21, 2009. The survey included 177 recommendations and was sent to those 43 participants who had completed the survey in the first round. Links to the original source guidelines and other evidence were again provided. The participants were also provided with both the recommendations that met the criteria for acceptance in the first round (75% or higher strongly agreed) and the recommendations that did not (see example in Appendix 3). For those recommendations that were modified based on respondent feedback, participants were provided with both the original and revised versions of the recommendation. Respondents were asked to review and rate both the recommendations with and without consensus; however, respondents were informed that if they did not respond to the recommendations that achieved consensus agreement in the first round, their response would be taken as strongly agree. In cases where two versions of the recommendation were presented, respondents were asked to choose which version of the recommendation they felt was most appropriate and then use the 9-point Likert scale to rate their level of agreement. Of the 43 individuals who were sent the survey for the second round of consensus, 30 completed the survey, as outlined in Table 7 (response rate = 70%). Of the 13 individuals who completed the first round but not the second round of the survey, three were accounted for (one had retired, one was away, and one felt it was beyond their scope of practice). At the end of the second round of consensus, 144 recommendations received consensus agreement, while 33 recommendations did not (less than 75% consensus agreement).

The second round feedback was distributed to the HNMWG. The HNMWG discussed the results of those recommendations that did not achieve consensus agreement by examining the

distribution of the replies and agreed that 33 of these recommendations should be included in this document because either a) no one disagreed with the recommendation or b) due to the multidisciplinary nature of the consensus group, some recommendations were misinterpreted by some respondents. although specialists whose jurisdiction the recommendation fell under agreed with the recommendation. It is the expert opinion of the HNMWG that all 177 recommendations should be implemented, including those that did not achieve the specified a priori level of consensus agreement. The consensus process demonstrated that some diversity of opinion exists for specific topics but that there is general agreement with these recommendations. Of the 33 recommendations without a clear consensus agreement, the level of agreement was 65% or greater for 23, and none of the respondents registered any disagreement with these 23 (some of the 23 recommendations had both). (The complete consensus results for Rounds 1 and 2 are contained in a separate file that is available online at <http://pebc.mcmaster.ca/pdf/5-3results.pdf>).

DISCUSSION

The province of Ontario and Cancer Care Ontario have embarked on a program to develop new regional cancer centres, with the goals of increasing the capacity for patient treatment and providing care closer to home. In this environment, the Head and Neck DSG has recognized the need for a comprehensive document describing the optimal organization and delivery of healthcare services for patients with head and neck cancer. In addition, the DSG has elected to provide evidence-based recommendations detailing the best treatment approaches for the variety of mucosal malignancies affecting patients with head and neck cancer.

For this project, the core methodology used to develop the evidentiary base was adaptation, supplemented by a literature search to update the evidence from the adapted guidelines. In order to establish consensus and develop the organizational and practice recommendations, the authors utilized a modified Delphi approach. This document therefore represents an evidence-based consensus statement on the organization of care, infrastructure, and optimal treatment approaches for patients with head and neck cancer being treated in Ontario.

There are a number of limitations to this document. There is minimal direct, high-quality evidence on the organization and delivery of cancer services. Given this, the organizational standards are largely based on expert opinion gleaned from the NICE and SIGN documents (3,4). The estimates of minimal volumes and expertise are adapted from the NICE document (3) and represent the opinion of the authors augmented by a modified Delphi approach to consensus development. The treatment recommendations are based on evidence where available, but a significant portion of these recommendations are based on expert opinion and consensus.

While the DSG and HNMWG place particular emphasis on a high-quality evidentiary-base, the paucity of such evidence necessitates consideration of other sources. A consensus-based guideline development approach is well established and allows for the systematic and transparent development of recommendations that reflect the expert opinions of clinicians participating in the process. In such instances, the combination of expert opinion and consensus is a critical tool, acting as a bridge between the literature and clinical practice.

The HNMWG also acknowledges that the response rate to the consensus survey was less than ideal. It is believed that a number of factors played a role in the suboptimal response and substantial dropout rate. Chief among these was the delay in initiating the survey. Some practitioners, initially agreeing to participate, were no longer available to do so once the survey was finally launched. Additionally, the time commitment to complete the survey proved to be too onerous for many. Nevertheless, the sample of responses was still

substantial and was obtained from a wide range of leading experts in the field, thus providing credibility for and confidence in the resulting recommendations. Despite these limitations, each step in the guideline development process was systematic and has been made transparent, with all results reported in detail. This guideline represents a significant advance in the organization and delivery of healthcare services to head and neck cancer patients.

The authors, the DSG, and this document endorse the concept that patients afflicted with head and neck mucosal malignancies are best treated in regional centres with highly trained and experienced multidisciplinary teams and comprehensive supportive programs. The question arising from this document is, given the complexity of care and resource requirements for head and neck patients, how do small evolving cancer programs develop services and treatment programs? A number of options are available, the most attractive of which is to develop virtual or collaborative programs partnering small, evolving cancer programs with established high-volume centres. This approach would serve to balance the objective of providing care close to home with the need of providing multidisciplinary care in centres having the appropriate infrastructure and clinical expertise.

CONCLUSIONS

- Patients with head and neck mucosal malignancy are best treated in regional cancer centres with the appropriate infrastructure, human resources, and clinical volumes to manage and support this complex group.
- A review of the currently published organizational and treatment standards and an evidence-based review of the current literature, the ADAPTE protocol and the AGREE instrument, and a modified Delphi approach were utilized to develop a consensus document addressing the organizational standards and treatment approaches for patients with head and neck mucosal malignancy.

CONFLICT OF INTEREST

No conflicts of interest were declared.

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For a complete list of the Head and Neck DSG members, please visit the CCO Web site at <http://www.cancercare.on.ca/>

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For information about the PEBC and the most current version of all reports, please visit the CCO website at <http://www.cancercare.on.ca/> or contact the PEBC office at:
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Appendix 2. MEDLINE literature search strategy.

1. exp Radiotherapy, Intensity-Modulated/
2. exp "Head and Neck Neoplasms"/
3. 1 and 2
4. 3
5. limit 4 to (humans and english language and yr="2005 - 2008")
6. comparative stud\$.mp.
7. exp "clinical trial [publication type]"/
8. clinical trial\$.tw.
9. exp Randomized Controlled Trials/
10. randomized controlled trial.pt.
11. clinical trial\$.mp.
12. or/6-11
13. 2 and 12
14. 1 and 13
15. 14
16. limit 15 to (humans and english language and yr="2005 - 2008")
17. exp "Review Literature"/
18. exp Meta-Analysis/
19. exp "Review [Publication Type]"/
20. or/17-19
21. 2 and 20
22. 1 and 21
23. 16 or 22

Appendix 3: Diagrammatic representation of survey questions from round 2 of the consensus process.

Figure 1: Representative survey question when two recommendation options were available for voting. The diagram shows the a and b recommendation options, the voting options used to choose which recommendation was most appropriate, the 9 point Likert scale used to rate the recommendation, the results from the first round of the consensus process and the comment box.

130) Intensity Modulated Radiotherapy (IMRT)

Recommendation: For most cases of head and neck cancer, which require significant volumes of tissue to be irradiated to high dose in close proximity to multiple organs at risk, radiation delivery with IMRT is the treatment of choice given superior dose conformality and avoidance.

Please rate your level of agreement:

Strongly agree				Neither agree nor disagree				Strongly disagree	Not Applicable
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>				

Grade of recommendation **

Results from the first round:

Strongly agree				Neither agree nor disagree				Strongly disagree	N/A
9	0	0	0	4	0	0	0	1	26

3 people did not respond

Comments:

Figure 2. Representative survey question when only one recommendation option required voting. The diagram shows how the recommendation was presented along with the 9 point Likert scale used to rate the recommendation, the results from the first round of the consensus process and the comment box.

102) Registered Nurses and Advanced Practice Nurses

a) Recommendation: Baccalaureate degree in Nursing and is registered with the College of Nurses of Ontario (CNO), as well as, a member of the Canadian Association of Nurses in Oncology (CANO <http://www.cano-acio.org>).

b) Recommendation: All entry to practice nurses shall have a Baccalaureate degree in Nursing and be registered with the College of Nurses of Ontario (CNO). Ideally, all nurses will be Certified Oncology Nurses in Canada (CON C), as well as, members of the Canadian Association of Nurses in Oncology (CANO <http://www.cano-acio.org>).

Please choose which recommendation is most appropriate:

- a
- b
- N/A

Please rate your level of agreement with the recommendation you chose:

Strongly agree				Neither agree nor disagree				Strongly disagree	Not Applicable
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>				

Results from the first round:

Strongly agree				Neither agree nor disagree				Strongly disagree	N/A
22	0	0	0	1	0	0	0	1	16

3 people did not respond

Comments:



Evidence-Based Series 5-3: Section 3

The Management of Head and Neck Cancer in Ontario: EBS Development Methods and External Review Process

*R Gilbert, M Devries-Aboud, E Winquist, J Waldron, M McQuestion,
and the Head and Neck Disease Site Group*

A Quality Initiative of the
Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)

Report Date: December 15, 2009

THE PROGRAM IN EVIDENCE-BASED CARE

The Program in Evidence-based Care (PEBC) is an initiative of the Ontario provincial cancer system, Cancer Care Ontario (CCO) (1). The PEBC mandate is to improve the lives of Ontarians affected by cancer, through the development, dissemination, implementation, and evaluation of evidence-based products designed to facilitate clinical, planning, and policy decisions about cancer care.

The PEBC supports a network of disease-specific panels, termed Disease Site Groups (DSGs), and other groups or panels called together for a specific topic, all mandated to develop the PEBC products. These panels are comprised of clinicians, other healthcare providers and decision makers, methodologists, and community representatives from across the province.

The PEBC is well known for producing evidence-based guidelines, known as Evidence-based Series (EBS) reports, using the methods of the Practice Guidelines Development Cycle (1,2). The EBS report consists of an evidentiary base (typically a systematic review), an interpretation of and consensus agreement on that evidence by our Groups or Panels, the resulting recommendations, and an external review by Ontario clinicians and other stakeholders in the province for whom the topic is relevant. The PEBC has a formal standardized process to ensure the currency of each document, through the periodic review and evaluation of the scientific literature and, where appropriate, the integration of that literature with the original guideline information.

The Evidence-Based Series

Each EBS is comprised of three sections:

- *Section 1: Guideline Recommendations.* Contains the clinical recommendations derived from a systematic review of the clinical and scientific literature and its

interpretation by the Group or Panel involved and a formalized external review in Ontario by review participants.

- *Section 2: Evidentiary Base.* Presents the comprehensive evidentiary/systematic review of the clinical and scientific research on the topic and the conclusions reached by the Group or Panel.
- *Section 3: EBS Development Methods and External Review Process.* Summarizes the evidence-based series development process and the results of the formal external review of the draft version of Section 1: Guideline Recommendations and Section 2: Evidentiary Base.

DEVELOPMENT OF THIS EVIDENCE-BASED SERIES

Development and Internal Review

This EBS was developed by the Head and Neck DSG of the CCO PEBC. The series is a convenient and up-to-date source of the best available evidence on the management of head and neck cancer, developed using the methods of guideline adaptation (3), updating of evidence, and formal consensus. The body of evidence in this review is primarily comprised of guidelines from credible organizations or government bodies, as well as mature RCT data. That evidence, combined with the consensus opinion of individuals working with head and neck cancer patients, forms the basis of the organizational and clinical recommendations for the optimal delivery of the management of head and neck cancer in Ontario. Input from external review participants in Ontario was also sought and incorporated.

Report Approval Panel

Prior to the submission of this EBS draft report for external review, the report was reviewed and approved by the PEBC Report Approval Panel, which consists of two members, including an oncologist, with expertise in clinical and methodology issues. Key issues raised by the Report Approval Panel and the modifications made by the Head and Neck DSG (indicated by ➤) are listed below:

- 1) Add to the “source” component, the % consensus for each recommendation and whether it was achieved in first or second round.
 - The percentage agreement and in which round consensus was achieved was added for each recommendation.
- 2) In addition to NICE and SIGN, you indicate other data, but they are never really acknowledged in the “source”.
 - All evidence has now been acknowledged and clearly referenced.
- 3) Discussion is thin. Come back and have statements about quality and quantity of evidence; why is there no evidence to support the vast majority of the recommendations.
 - Discussion about the lack of evidence, the quality of existing evidence, and the usefulness of expert opinion and consensus was specified.
- 4) We are never really told about the contents of the two source documents as it relates to the evidence base - what did they do (systematic review) - what sort and kind of evidence did they find, etc.
 - A description of the quality of the NICE and SIGN guidelines, the methodology used, and the evidence included was added.
- 5) As an overall principle, the methodologic processes for reaching recommendations for the different component sections addressed are expected to vary. For instance, recommendations addressing personnel requirements and infrastructure are more likely to use health service data base-driven research in conjunction with a consensus process where as recommendations about specifics of therapy are more likely to be

based on randomized controlled trials / meta-analyses (again in conjunction with a consensus process). In this document, it is not consistently clear what form of “evidence” is being used to generate recommendations. As a result, for several recommendations, there appears to be a risk that recommendations may have resulted from a disproportionate use of opinion and consensus as opposed to a use of evidence. It is not clear whether this risk results from the process or from the presentation (i.e., the process having been robust). Selected examples to illustrate the above include:

- a. The FTE personnel needs could be regarded as an example of a “standard”. It is unclear how these conclusions were reached. Some recommendations refer to NICE; a description of that process would be helpful. Most recommendations relate to the authors; was their determination supported by evidence or largely opinion?
 - The driving force behind each recommendation is listed as the source. In the instances where NICE and SIGN are the source, adaptation methodology was used. Recommendations listing HNMWG as the source were developed from the collection of expert opinion. A modified Delphi process was used to review and come to consensus on each draft recommendations regardless of the driving force behind the recommendation. This process has been described in more detail in Section 1.
 - b. Most treatment specifics refer to the SIGN document. While it is understandable that ADAPTE would be used to make recommendations rather than redoing this work, there is a lack of clarity about the quality of evidence that has led to individual recommendations (e.g., recommendations based on homogeneous results of well done RCTS included in a meta-analysis cannot be separated from recommendations based on observational data).
 - The guideline development process utilizing ADAPTE proceeds under the assumption that the original recommendations are reasonable and supported by the evidence. It is beyond the scope of the guideline development process and this document to make the connection between the recommendations and the original key evidence. Readers who wish to do so are referred back to the NICE (3) and SIGN (4) guidelines.
- 6) Given the reservations in #5 above, there are potential issues with the consensus process. First, a more detailed description of the initial cohort “invited to participate” would be helpful. Second, the dropout rate was substantial - are there reasons for this that can be provided? Third, and importantly, it is not clear how this process proportionately “drove” the final recommendations. The document reads as if great weight is being placed on this consensus process in leading to and legitimizing the recommendations. However, the process in large part resembles the “practitioner feedback” process of other PEBC guidelines, which is a process that is predominantly one of supplementary validation after a review of best evidence. Without understanding the quality of the evidence (i.e., #5 above), it is unclear whether this consensus process provides the same type of validation (let alone being perceived as the driving force for the recommendations).
 - A consensus-based guideline development approach is well established and allows for the systematic and transparent development of recommendations that reflect the expert opinions of clinicians participating in the process. The limitations of this approach, including the dropout rate, are now outlined in the discussion in Section 2 of this document.
 - 7) From a formatting perspective, understanding the evidentiary base, which is provided in the second part of the document, is helpful in understanding the recommendations

that are in the first part of the document. While I understand why the documents have been arranged in this order, in this instance, having a better understanding of the foundation of the recommendations prior to reviewing the details of the recommendations would be helpful.

- An overview of the key evidence and the adaptation and consensus methods has now been included in Section 1 to offer readers a better understanding of the document development process upfront.
- 8) Finally, as indicated, some clarity about the consensus process and comments about its robustness (i.e., sampling/dropouts) would be helpful.
- Limitations of the consensus process have been added to the discussion in Section 2 of the document.

External Review by Ontario Clinicians and Other Experts

The PEBC external review process is normally two-pronged and includes a targeted peer review that is intended to obtain direct feedback on the draft report from a small number of specified content experts and a professional consultation that is intended to facilitate dissemination of the final guidance report to Ontario practitioners. In this case, because the consensus process included all professionals interested in head and neck cancer in our database, the professional consultation step was omitted.

Methods

During the guideline development process, five targeted peer reviewers from North America considered to be clinical and/or methodological experts on the topic were identified by the HNMWG. Several weeks prior to completion of the draft report, the nominees were contacted by email and asked to serve as reviewers. Four reviewers agreed and the draft report and a questionnaire were sent via email for their review. The questionnaire consisted of items evaluating the methods, results, and interpretive summary used to inform the draft recommendations and whether the draft recommendations should be approved as a guideline. Written comments were invited. The questionnaire and draft document were sent out in October 2009. Follow-up reminders were sent at two weeks (email) and at four weeks (telephone call). The HNMWG reviewed the results of the survey.

Results

Three responses were received from four reviewers. Key results of the feedback survey are summarized in Table 8.

Table 8. Responses to nine items on the targeted peer reviewer questionnaire.

Question	Reviewer Ratings (N=3)				
	Lowest Quality (1)	(2)	(3)	(4)	Highest Quality (5)
1. Rate the guideline development methods.				2	1
2. Rate the guideline presentation.				1	2
3. Rate the guideline recommendations.				2	1
4. Rate the completeness of reporting.			1		2
5. Does this document provide sufficient information to inform your decisions? If not, what areas are missing?			1	1	1
6. Rate the overall quality of the guideline report.				2	1
	Strongly Disagree (1)	(2)	Neutral (3)	(4)	Strongly Agree (5)
7. I would make use of this guideline in my professional decisions.				1	2
8. I would recommend this guideline for use in practice.				1	2
9. What are the barriers or enablers to the implementation of this guideline report? <ul style="list-style-type: none"> • Lower volume centers and surgeons may contest these suggestions. The exclusion of Oral and Maxillofacial surgeons will be controversial. • The report is comprehensive but long. You could consider a condensed document regarding treatment. This would be more user friendly. I would recommend adding salivary tumour guidelines and advanced skin cancer. • As always local resource limitations are a barrier to implementing some of the guidelines. Such documents, if well supported and generally accepted, are very useful instruments to lobby institutions and governments for additional resources. 					

Summary of Written Comments

The majority of the comments received from external review were positive and complimentary. There was, however, a recurring concern about the length of the document and a suggestion to remove any unnecessary material. Conversely, someone suggested more comprehensive coverage of nasopharynx, paranasal sinus, salivary gland, and unknown primary tumours. The addition of advanced skin cancer was also put forward.

Modification/Actions and Response to Comments

After reviewing the feedback and comments, the Head and Neck Cancer DSG decided that no further action was required in terms of guideline modification. No material included in this guideline was felt to be unnecessary and, while it is recognized that the document is lengthy, our attempt was to be comprehensive, thorough, and systematic. Feedback suggests the document is orderly and user friendly. The focus of the document is what the Head and Neck DSG believes constitutes optimal management of head and neck cancer.

Conclusion

This EBS report reflects the integration of feedback obtained through the external review process with final approval given by the Head and Neck Cancer DSG and the Report Approval Panel of the PEBC. Updates of the report will be conducted as new evidence informing the question of interest emerges.

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