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Evidence-Based Series IN REVIEW

Organizational Standards for Diagnostic Assessment Programs

Diagnostic Assessment Programs Standards Panel

*M. Brouwers, J. Crawford, P. Elison, W.K. Evans, A. Gagliardi, D. Holmes,
J. Lacourciere, D. Lo, V. Mai, S. McNair, T. Minuk, T.K. Oliver, L. Rabeneck,
C. Rand, J. Ross, J. Smylie, J. Srigley, H. Stern, and M. Trudeau*

A Special Project of the Diagnostic Assessment Standards Panel (DAP),
a Working Group Facilitated by the Program in Evidence-Based Care, Cancer Care Ontario

Report Date: June 15, 2007

An assessment conducted in September 2011 placed Evidence-based Series (EBS) Organizational Standards for DAP IN REVIEW, which means that it is undergoing assessment for currency and relevance.

The PEBC has determined that it is still appropriate for this document to continue to be available while this updating process unfolds.

This EBS is comprised of 3 sections
and is available on the CCO website (<http://www.cancercare.on.ca>)
PEBC Collaborative Projects page at:

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Section 1: Recommendations

Section 2: Systematic Review/Evidentiary Base

Section 3: Methodology of the Standards Development and External Review Process

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or contact the PEBC office at:

Phone: 905-527-4322 ext. 42822 Fax: 905-526-6775 E-mail: ccopgi@mcmaster.ca

Organizational Standards Citation (Vancouver Style): Brouwers M, Crawford J, Elison P, Evans WK, Gagliardi A, Holmes D, et al. Organizational standards for diagnostic assessment programs. Toronto (ON): Cancer Care Ontario; 2007 Jun 15 [In review 2011 Sep]. Program in Evidence-based Care Evidence-based Series Organizational Standards for DAP IN REVIEW.



program in
evidence-based care
a cancer care ontario program

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un programme de action cancer ontario

Evidence-Based Series: Section 1

Organizational Standards for Diagnostic Assessment Programs: Recommendations

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*M. Brouwers, J. Crawford, P. Elison, W.K. Evans, A. Gagliardi, D. Holmes,
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SCOPE OF STANDARDS

Improving access to better and more rapid cancer diagnosis has been identified as a priority for Cancer Care Ontario (CCO) and the Government of Ontario. A first step in realizing this objective is the development of provincial standards that define the organizational and practice-setting features expected of a diagnostic assessment program (DAP). These standards represent one of a series of strategies that are needed to achieve the overall goal of improved rapid access to diagnosis. The following standards, developed by the Diagnostic Assessment Standards Panel (Appendix I), apply to the organization of DAPs and include the full spectrum of multidisciplinary diagnostic assessment leading to treatment. These standards will be routinely updated as the evidentiary support for the recommendations, particularly as it relates to evaluation and outcome data, matures.

PURPOSE AND PRINCIPLES

The mandate of a DAP is to coordinate patient care from referral to definitive diagnosis. The guiding principles for the DAP are:

- To ensure that an environment of patient-centred care is established
 - Patients have equal access to high-quality diagnostic care regardless of where they live in the province
 - Patients are supported throughout the diagnostic process
 - Patients have a diagnosis of cancer made or ruled out in a timely fashion
- To ensure that a coordinated referral and follow-up system is established

- To ensure that indicators of quality are established and monitored to evaluate performance outcomes
- The objectives of the DAP will be enabled by the development and implementation of common evidence-based regional and/or provincial guidelines, which may include:
 - Disease-specific protocols regarding diagnostic work-ups
 - Service frameworks for primary care providers
 - Wait-time benchmarks

The DAP must be able to demonstrate compliance (alignment) with these principles.

DIAGNOSTIC ASSESSMENT PROGRAMS

The structure and organization of a DAP will be influenced by the regional and geographic realities of each jurisdiction, the diagnostic tests necessary to assess an organ system (e.g., symptom complexity or physical abnormalities), and the anticipated volume of cases. Two core organizational models are recommended including:

One-Stop Diagnostic Assessment Units

One-stop single-location units are those that provide the totality of diagnostic services in one place and, where clinically appropriate, within one patient visit, but:

- One-stop units may also provide total service across the cancer continuum (i.e., from screening to diagnosis to treatment and follow-up)
- The size of the region and the scope of care provided (i.e., diagnostic versus [vs.] total care) will determine whether there will be one or more units within a region
- For rare cancers and/or where there are existing diagnostic and treatment centres of excellence, a diagnostic assessment unit (DAU) in one region may provide services to patients from several regions
- While the organization of the DAU will typically be disease-site specific, in some cases an assessment unit may oversee multiple tumour types

Virtual Diagnostic Assessment Units

Where patient populations and geographic dispersion does not permit a single-location DAU, virtual programs should be explored.

- Within a Region or City
 - Virtual programs are systems of diagnostic services spread out geographically across the region or city but coordinated centrally
- Across Regions
 - Collaborative systems are virtual systems in which the distribution of diagnostic service crosses regional barriers. For example, for rare cancers, diagnostic expertise may be found in only a few locations in the province. Similarly, some procedures may require the use of equipment or technologies readily available in one region but not in another

The individual Regional Cancer Programs in collaboration with the Local Health Integration Networks will be responsible for determining the most appropriate organization of the assessment systems. While there is no evidence on the population-based volumes required to support any particular model, it is important to recognize that high-quality diagnostic care is not defined by having a DAP for every disease site in every region. Indeed, for rare cancers (e.g., head and neck or sarcoma), efforts to enhance the current provincial systems of diagnostic and

treatment services in a few centres is a more desirable quality goal than is the provision of such services in multiple regions. In contrast, regions should have local mechanisms to deal with the rapid diagnosis of high-volume cancers (e.g., lung, breast, colorectal, prostate).

When developing a business case for a specific DAP model, the following elements should be considered to justify the choice of model:

- how current diagnostic systems (i.e., including the organization of staff, equipment, processes, etc.) within a region can be restructured and redesigned to improve access and quality
- volume-outcome literature for specific diagnostic procedures
- cost effectiveness and clinical efficiencies of competing models
- population-based estimates of disease incidence and prevalence for each tumour type.

Regardless of the model chosen, meeting common standards for centralized access, scope of activity, team criteria, linkages and collaborations, and performance indicators is required.

REGIONAL CENTRALIZED ACCESS TO DAPS

A simple and efficient access strategy is a key mechanism for improving the health care experience of the patient and the quality of diagnostic care. Therefore, regardless of the model chosen, a coordinated, centralized, single point of entry, Central Access System (CAS), is an essential element of the DAP.

Variation in entry systems may be expected across regions: for example, low- and mid-size populations are more likely to be able to support a single entry CAS, whereas a large-size population region may require a different approach. High-quality diagnostic care can only be achieved by having coordinated points of entry, particularly for the diagnostic work-up of suspected similar cancers and by implementing systematic referral protocols that supersede existing patterns of referral and where quality and access improvements can be made. A CAS should be designed explicitly to reduce variations in demand and/or wait times across the region.

The CAS will be responsible for ensuring that eligible patients are brought into a DAP and that the diagnostic plans for patients are developed and communicated to the patients, referring physicians, other primary care providers, and local multidisciplinary care conference (MCC) coordinators, using regional and/or provincial templates. The patient version of the diagnostic plan will include the appointment schedule of all procedures, descriptions of each procedure, and the preparatory activities (if appropriate) for each procedure. The CAS will be responsible for communicating the patient version of this plan to the patient by the most appropriate method (e.g., phone, mail, e-mail, Internet). The clinician version will include the appointment schedule of all procedures booked for the patient, and the MCC version will include information about the patient and the appointment schedule of all procedures.

Entry Points to the CAS

Access to the CAS will typically be from a variety of entry points such as:

- Primary care providers or specialists
 - Patients who meet specific CAS referral criteria (see Guidelines and Standards below) will be referred
- Screening programs
 - Screening programs such as the Ontario Breast Screening Program, the emerging provincial Colorectal Screening Program, and Ontario Cervical Screening Program will

refer patients to the CAS who meet specific criteria according to appropriate protocols

- Self-referral:
 - Given the significant proportion of the public who have no access to primary care providers, a system for patient self-referral may be necessary
 - Appropriate pre-screening, following CAS protocols, by a qualified clinical coordinator will be required if self-referral is part of the DAP
 - In these instances, the DAP should ensure appropriate primary care services are available to support ongoing care. This may include development of formal linkages between the DAP and Primary Care Networks/Family Practice Teams. Where that is not possible, it may also include ensuring these services are provided within the DAP, itself.

Enabled entry by these groups into the DAP CAS must be demonstrated.

Operational Features of the CAS

There are several operational features that are essential elements of a CAS. These include:

- Entry to the CAS
 - Each DAP will determine the most appropriate modality of entry to its CAS (e.g., phone, Internet, fax). However, common across all entry strategies for all prospective patients will be the application of referral and triage criteria requirements at the intake point
- Fast-access booking
 - Protected booking slots must be accessible to the DAP for specific diagnostic procedures and specialists' clinic appointments. This will distribute patient cases more evenly, facilitate patient flow, and reduce wait times
- Priority-booking system
 - Triage should be performed by the CAS prior to the first visit to the DAP and an urgent referral mechanism must be implemented for all DAPs
- Open-access booking
 - Access to booking for specific diagnostic procedures must be open to all clinicians who adhere to predefined referral criteria and diagnostic assessment protocols (see Standards and Guidelines below)

SCOPE OF CANCER DIAGNOSTIC ACTIVITY WITHIN A DAP

Through the DAUs, each DAP will provide the spectrum of clinical diagnostic and supportive care services for the tumour type(s) that fall under the mandate of the program. Appropriate equipment, technologies, and expertise will be required to meet the scope of the diagnostic activities for each assessment unit. Where necessary diagnostic or supportive services are not available, linkages to those necessary services will need to be established in order to eliminate any gaps in care. The spectrum of diagnostic work-up must be tailored to the specific tumour type but may include any or all of the following: physical examination, imaging tests (e.g., X-rays, computerized tomography [CT], magnetic resonance imaging [MRI], positron emission tomography [PET], and ultrasound), diagnostic procedures (e.g., ultrasound-guided needle biopsy), surgical consultation, tumour-specific surgical procedures, pathological analyses, and reporting services. In addition, supportive care services that may be needed include education, psychosocial support, dietetics, genetic counselling, or other types of supportive care. Table A provides an overview of the most common diagnostic assessment service needs across the major cancer tumour types. Appendix II provides greater detail for particular tumour types.

CANCER DIAGNOSTIC ASSESSMENT TEAM CRITERIA

It is recommended that assessment units within each DAP be comprised of a dedicated multidisciplinary team, each member of which has explicit roles, responsibilities, and accountabilities. Specialists (e.g., gastroenterologists, respirologists) and surgeons will play a clinical lead in the diagnostic processes, with the assessment coordinators serving a primary communication lead. There will be common team elements across the assessment units as well as disease-specific specialists being required for each unit. See Table B, below, for details.

CANCER DAPS LINKAGES AND COLLABORATIONS

Linkages, collaborations, and communication strategies will vary across the DAPs. To facilitate patient access, each DAP should have formalized bi-directional linkages with primary care providers, other related family health teams or services (including psycho-social support), as well as any related networks and organizations. Each region will have to develop its own system to fit the specific needs of the region and the various tumour types. There will, however, be some core elements that should be common across all models of diagnostic assessment services.

Assessment Coordinator

With the assessment coordinator acting as the main source for information exchange, the assessment units will establish formal linkages, collaborations, or communication strategies with key stakeholders, including patients entering the cancer diagnostic assessment system, cancer screening programs (where applicable), primary care providers (including family/general practitioners and primary care nurse practitioners), other referral systems, multidisciplinary case conference teams, and related specialists and supportive care services.

Primary Care Provider

Formal linkages with primary care providers are essential to a successful DAP. Primary care providers must be supported with appropriate tools and products (e.g., services plans, guidelines) that provide evidence-based recommendations about appropriate criteria for the referral of patients to the DAP and committed bi-directional communication with the assessment team; beginning at point of entry, through the patient's work-up until cancer is diagnosed or ruled out, and to the development and implementation of the treatment plan with a definitive diagnosis.

Multidisciplinary Care Conference (MCC) Team/Treatment Team

A clearly identified transition protocol for the patient from the DAP to the MCC/treatment team must be established. The protocol must articulate provider accountabilities and the communication strategy for patients and providers.

Cross-DAP Collaboration

Formal collaborative linkages among the DAPs are encouraged. The formal documentation of accountabilities among the various entities and/or individuals and the DAP will be needed, as will communication strategies or protocols with clear reporting formats, to ensure common data collection and reporting, especially around the reporting of outcomes. With standardized reporting systems, and clear expectations around reporting, the focus should be on accountability and on the collection and delivery of data to enable the assessment of quality indicators and other benchmarks.

While each DAP will be responsible for developing a unique diagnostic assessment system, there are several existing models within Ontario that could help guide that development. For example, in Ottawa, the Ontario Breast Screening Program has documented the development of a Breast Assessment Program that outlines many key features on which to base a coordinated breast cancer diagnostic assessment service (see Table 8 in the Full Report).

PROVINCIAL INDICATORS OF QUALITY FOR CANCER DAPS

It is recommended that a range of process and clinical indicators of quality be developed, measured, and monitored to evaluate the performance of each DAP. These indicators should reflect the specific needs of each region or tumour type, but they should also be standardized to match provincial benchmarks developed by CCO and/or the Government of Ontario. At both levels, fundamental indicators relevant to the DAPs should be identified to drive the quality agenda at key points and must include:

- Time intervals
 - The time from abnormal screen or primary care referral to entry into the DAP
 - The time from entry into the DAP to cancer diagnosis or rule-out
- Clinical outcomes
 - Upstaging
 - Mortality
- Quality of care
 - The percentage of patients receiving the appropriate diagnostic work-up according to evidence-based guidelines, service plans, and protocols
- Patient satisfaction
 - Patient satisfaction throughout the cancer diagnostic assessment system e.g., expansion of the Ambulatory Oncology Patient Satisfaction Survey

Other indicators may include but are not limited to:

- Program efficiency indicators (avoidance of duplication)
- The completeness of cancer-stage reporting at diagnosis
- The percentage of pathology reports meeting provincial information completeness standards
- Clinician team functioning and satisfaction
- The reporting of cancer services integration through the assessment of linkages, collaborations, and communication both within and external to the DAP
- The impact on regional performance

GUIDELINES, STANDARDS, AND SERVICE FRAMEWORKS

To successfully implement a quality agenda dedicated to reducing wait times for diagnostic services and to improve the quality of these services, recommendations, benchmarks, and targets are required. These include:

- Guidelines and Service Frameworks for Primary Care Providers
 - Facilitation by CCO is recommended for the development of provincial evidence-based guidelines and service frameworks for primary care providers. A comprehensive knowledge exchange strategy should be developed and promoted for the uptake of these guidelines

- Evidence-based Investigative Algorithms and Guidance Documents
 - Facilitation by CCO is recommended for the development of provincial evidence-based algorithms that articulate the most effective diagnostic procedures and the appropriate pathways for the work-up for patients suspected of cancer. These guideline documents should be developed for all major cancer diagnoses and should serve as the foundation for the local and regional diagnostic pathway protocols and algorithms required to support the DAPs
- Wait-times Benchmarks
 - Facilitation by CCO is recommended for the development of provincial benchmark targets for various significant intervals within the diagnostic work-up

CONCLUSIONS

The standards were developed by the Diagnostic Assessment Standards Panel to guide the design, implementation, and evaluation of DAPs in Ontario. A systematic review of the literature, as well as a targeted environmental scan of the regional, provincial, national, and international literature, helped to inform the development of these standards.

An essential need is that the implementation of the DAPs be accompanied by a comprehensive evaluation framework. The standards will evolve and be refined over time as a consequence of the new information gained through the learning experience of implementing the DAPs. Future iterations will focus on the requirements for comprehensive pathway and risk assessment models for all cancer types in the ongoing effort to improve patient outcomes.

For further information about this report, please contact:

Melissa Brouwers, PhD
Director, Program in Evidence-based Care, Cancer Care Ontario
Associate Professor (PT), CE&B, McMaster University
Room 310, McMaster University Downtown Centre
mail: 1280 Main Street West, Hamilton, ON, L8S 4L8
courier/location: 50 Main Street East, Hamilton, ON, L8N 1E9
Phone: 905-527-4322 ext. 42832 Fax: 905 526-6775 E-mail: mbrouwer@mcmaster.ca

Funding

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.

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Table A. Scope of cancer DAPs diagnostic activity.

Diagnostic Assessment and Supportive Services	Type of Cancer											
	Breast	Lung	Colorectal	Gastrointestinal	Genitourinary	Gynecological	Head and Neck	Hematological	Skin	Unknown primary	Sarcoma	Neurological
Examination												
• Physical Exam	√	√	√	√	√	√	√	√	√	√	√	√
• Other Disease Site Specific	-	√	√	-	-	√	-	-	-	-	-	√
Imaging, Diagnostic and Staging Procedures												
• Ultrasound	√	-	√	√	√	√	-	√	√	-	√	-
• MRI	√	-	√	√	√	√	√	√	√	√	√	√
• X-ray	-	√	√	√	√	√	√	√	√	√	-	-
• CT scan	-	√	√	√	√	√	√	√	√	√	√	√
• PET	-	√	√	√	-	√	√	√	-	√	√	-
• Upper Endoscopy	-	-	-	√	-	-	-	√	-	√	-	-
• Colonoscopy	-	-	√	-	-	-	-	√	-	-	-	-
• Bronchoscopy	-	√	-	-	-	-	√	-	-	-	-	-
• Cystoscopy	-	-	-	-	√	-	-	-	-	-	-	-
• Bone Scan	-	-	-	√	√	√	-	√	√	-	-	-
• Mammography	√	-	-	-	-	-	-	-	-	√	-	-
• Biopsy	√	√	√	√	√	√	√	√	√	√	√	√
• Fine Needle Aspiration Cytology	√	√	-	-	-	√	-	√	-	-	-	-
• Other Disease Site Specific	√	√	√	√	√	√	√	√	√	√	√	√
Surgical Consultation And Procedures												
• Biopsy	√	-	-	-	-	√	-	√	-	√	-	√
• Other Disease Site Specific	√	√	√	√	√	√	√	-	√	-	-	√
Pathology and Laboratory Medicine ^a												
• Standardized surgical pathology requisition forms	√	√	√	√	√	√	√	√	√	√	√	√
• Routine analysis and pathology reporting	√	√	√	√	√	√	√	√	√	√	√	√
• Special pathological studies such as markers, flow, molecular, etc.	√	√	√	√	√	√	√	√	√	√	√	√
• Clinical Lab testing of tumour markers, hematology, etc.	√	√	√	√	√	√	√	√	√	√	√	√
Supportive Care												
• Education/Psychosocial Support	√	√	√	√	√	√	√	√	√	√	√	√
• Dietetics	√	√	√	√	√	√	√	√	√	√	√	√
• Genetic Counselling	√	√	√	√	√	√	√	-	√	√	√	√
• Other Supportive Services	√	√	√	√	√	√	√	√	√	√	√	√

^a The use of special pathological studies may be required, depending on the site and type of tumour. For instance, leukemia workups involve the extensive use of markers, flow and molecular. Additionally, there may be testing done in the Clinical Laboratory, depending on a given site and type of tumour (e.g., PSA, CA125).

Table B. Membership recommendations for disease-specific multidisciplinary teams.

Team Composition

- | | |
|---|--|
| Director/
Manager | <ul style="list-style-type: none"> • Provides oversight for the Assessment Centre performance • Tracks indicators and adjusts programs/services as necessary • Human resource management for Assessment Centre Staff • Oversight for resource management (equipment, staff) • Manages patient/physician concerns • Responsible for troubleshooting issues |
| Assessment
Coordinators | <ul style="list-style-type: none"> • Will ensure that appropriate patients enter the system • Will initiate the path of care where appropriate • Conducts client interviews via telephone prior to first assessment centre visit • Performs baseline clinical exam, patient history, and other related tests • Provides patient education about the assessment process and specific tests/procedures • Coordinates referrals for treatment as appropriate • Serves as a main patient contact and works with other professionals to address patient concerns • Assesses client's supportive care needs and facilitates access to services • Liaises with primary care, radiologists, surgeons and pathologists in the coordination of clients' care • Responsible for information flow, follow-up, and coordination among team members with special attention to primary care providers, specialists, and MCC team; where appropriate. Their role will be to ensure that information is comprehensive, seamless and timely • Will participate as a member of the MCC team • Will oversee data collection of provincial performance indicators |
| examples:
family/general
physicians,
advanced practice
care nurses
or equivalent | |
| Radiologists | <ul style="list-style-type: none"> • Provide imaging reports in a timely manner • If applicable, perform biopsy procedures within expected timelines • Liaise with the surgeon to plan next steps in assessment if necessary • Liaise with the Coordinator to schedule procedures as per expected timelines |
| Surgeon
Specialists | <ul style="list-style-type: none"> • Consults with patients when biopsy or imaging results suggest cancer • Works with Coordinator to provide access to timely surgical consultations • Performs biopsy or surgery to acquire a definitive diagnosis • Serves as a consultant for patients that do not have a primary care provider |
| Pathologists | <ul style="list-style-type: none"> • Provide timely pathologic diagnosis following acceptable turnaround time (TAT) standards • Determine scope of special studies that may be required to establish diagnosis • Liaise with coordinator to prioritize cases • Liaise with radiologist, surgeons and other clinicians as required to establish a diagnosis |
| Primary care
Ultrasound
Technologists | <ul style="list-style-type: none"> • Provides care to patients with health concerns when they do not have a primary care provider • Performs ultrasound • Prepares patients for ultrasound guided biopsy |
| Psychosocial
Support | <ul style="list-style-type: none"> • Consults with patients on an as needed basis • Reviews Hospital Anxiety and Depression Scale (HADS) results and follows patients proactively |
| Reception, Clerical
and Bookings | <ul style="list-style-type: none"> • Books patient appointments • Greets and registers clients in patient information system • Works with the Coordinator to secure timely follow up appointments and procedures for clients |
| Supportive Care | <ul style="list-style-type: none"> • Provides dietetics, genetic counselling, and other supportive services |

Other Disease Site-Specific Specialists

- | | |
|--|---|
| Respirologists
(Lung DAUs) | <ul style="list-style-type: none"> • Consults with patients when imaging results suggest cancer • Performs bronchoscopy and biopsy, as appropriate |
| Mammographers
(Breast DAUs) | <ul style="list-style-type: none"> • Performs diagnostic and screening mammography • Coordinates diagnostic mammography and ultrasound and prepares patients for stereotactic biopsy • Performs quality control testing as per Canadian Association of Radiologists (CAR) guidelines |
| Endoscopists
(Colorectal and
other DAUs) | <ul style="list-style-type: none"> • Meets TAT standards for reports • Liaises with the surgeon to plan assessment follow up • Liaises with the Coordinator to schedule procedures as per expected timelines |

Note: MCC, multidisciplinary care conference



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Evidence-Based Series: Section 2

Organizational Standards for Diagnostic Assessment Programs: Systematic Review/Evidentiary Base

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QUESTIONS

What are the optimal organizational and practice setting features of a cancer diagnostic assessment program for Ontario? Areas of interest included the organization, process, and evaluative measures.

INTRODUCTION

Improving access to better and more rapid cancer diagnosis is a necessary component to a high-quality cancer system. The inefficient and inappropriate use of diagnostic imaging in Ontario has been documented, including duplicated procedures and multiple imaging tests because the most appropriate test was not ordered initially (1). A recent Canadian study by Liberman et al found excessive intervals between the initial contact with a physician or the first onset of symptoms, relating to lung cancer and diagnostic surgery, with mean and median wait times of 208 and 109 days, respectively (2). Data from seven Ontario provinces measuring the time from an abnormal breast screen to diagnosis reported a median time to diagnosis of 3.7 weeks, but 10% of women waited 9.6 weeks or longer for a diagnosis (3). A reorganization of entry into the cancer system and diagnostic processes could reduce the duplication of tests, improve efficiency, reduce costs, impact waiting times, enhance the overall quality of care for patients throughout the cancer system, and conceivably improve the outcome of treatment.

This is particularly important in light of the approximately 800,000 new cases of cancer in Ontario anticipated in the next decade (4), with the majority of new diagnoses being colorectal, lung, prostate, and breast cancers (5). However, there is considerable variability in the distribution of new cases across the different regions, which serve a population of approximately 12 million people spread over more than 1 million square kilometres (6). The population size and geographic spread are important considerations when strategizing about quality improvement actions to improve access and reduce wait times to diagnosis, while acknowledging that solutions for one region may or may not be generalizable to another.

Diagnostic assessment programs (DAPs) are one component of an overall rapid-access strategy for diagnosis¹. DAPs may be either actual or virtual entities characterized by facilitated access to comprehensive diagnostic services, multidisciplinary consultative expertise, patient information resources, and psychosocial supports. DAPs have been associated with high patient satisfaction (7-10), a reduction in time from diagnosis to the initiation of treatment for various disease sites (8,11), and, potentially, improvements in clinical outcomes (12)

Less clear are the organizational and practice setting features that define a high-quality DAP, the role of a DAP in a comprehensive rapid-access strategy, the geographic regions in which a DAP is most appropriate, and the indicators that should be used to measure quality and impact. As a result, a Diagnostic Assessment Standards Panel was convened to work with the Program in Evidence-based Care (PEBC) to develop recommendations that could guide the design, implementation, and evaluation of DAPs in Ontario. These standards are directed towards practicing clinical teams and clinical and administrative leaders, including regional cancer program leaders and Local Health Integration Network (LHIN) leaders, who contribute to and are accountable for improving the access to and quality of care.

METHODS

Panel and Process

The development of DAP standards was led by the Diagnostic Assessment Standards Panel, a working group facilitated by the PEBC. The Panel comprised clinical oncology experts, regional vice presidents, clinical administrative leaders, health service researchers, and methodologists (please see Appendix I for the membership list).

A systematic review and environmental scan served as the evidentiary base. This information was assembled by methodologists and a student at the PEBC. The expert panel reviewed this evidence and made recommendations for the organizational standards for diagnostic services. The Panel met through a series of teleconferences, and meetings. The document underwent three substantive iterations, each iteration building on the feedback and comments of the panel members. The panel was invited to provide a more standardized review on the penultimate version of the document, by rating the completeness of the systematic review and environmental scan and by rating the appropriateness of the recommendations in each of the domains. Responses from the respondents ranged between '4' and '5' ('5' representing the highest rating) on a five-point scale for each item. A final review and call for comments was undertaken, and once the draft document was finalized, an internal review and data audit were performed. External validation will be conducted through a peer-review survey of relevant practitioners and administrators throughout the province.

Systematic Review

Overview

A systematic review by Gagliardi et al in 2004 (13) provided the basis for the current updated systematic review. The purpose of the update was to identify relevant studies published between 2002 and October 2006 that evaluated both clinical and economic components of DAPs for suspected cases of breast, colorectal, lung, head and neck, prostate, and other cancers and also to identify process and outcome measures utilized in their evaluation.

Literature Search Strategy

As part of the update of the Gagliardi et al (13) systematic review, the literature search reproduced their search strategy (Appendix III), using MEDLINE (OVID: 2002 through October

¹ We have chosen to use the term diagnostic assessment program (DAP) in this report although other terms have been used by other jurisdictions and in the scientific literature to represent a conceptual similar system of care. These include, but are not limited to, diagnostic assessment units, rapid access centers or units, screening and diagnostic centers, one-stop clinics, fast-stop clinics, etc.

2006), EMBASE (OVID: 2002 to October 2006), the Cochrane Library (OVID; Issue 3, 2006), the Canadian Medical Association Infobase, and the National Guideline Clearinghouse. Reference lists of related papers and recent review articles were also scanned for additional citations.

Study Selection Criteria

To be eligible for inclusion in the systematic review of the literature, studies had to be randomized control trials (RCTs), prospective or retrospective cohort studies, or case series that provided sufficient methodological detail; had to evaluate diagnostic assessment programs or units or one-stop, fast-track, or rapid-access clinics; had to focus on care provision for patients with any type of suspected cancer; had to encompass the diagnostic assessment of patients with a potential malignancy; and had to be published in English between 2002 and October 2006. Published letters, editorials, and comments were excluded from this review.

Synthesizing the Evidence

The majority of studies included for review were observational studies evaluating diagnostic assessment services for different cancer types. Therefore, combining studies for meta-analysis was not feasible due to the variations in study design and quality and the different disease-site DAUs, as well as the differences in outcomes measured.

Environmental Scan

The environmental scan sought out models, frameworks, descriptions, and evaluations of DAPs in other jurisdictions. A particular focus was to gather information that described organizational structures, practice settings, quality improvement initiatives, and process issues relevant or generalizable to DAPs in Ontario.

The environmental scan involved two processes. First, inquiries were made directly to key cancer leaders and contacts in Ontario, Canada and selected groups outside of Canada. Second, an Internet search of key sites, including professional associations, guideline registries, and health care organizations, was undertaken (see Table 1).

Table 1. Environmental scan of the literature.

Target	Source	Modality
Local Jurisdictions	Ontario regions	DI
	British Columbia	DI
	Alberta	DI
	Saskatchewan	DI
	Manitoba	DI
	Quebec	DI
	Nova Scotia	DI
	Newfoundland	DI
Guideline Directories	Ontario Guidelines Advisory Committees	IS
Other	American Society of Clinical Oncology	DI, IS
	American College of Radiologists	IS
	Canadian Association of Radiologists	DI, IS
	Canadian Strategy for Cancer Control	DI, IS
	National Health Services, UK	DI, IS
	Scottish Intercollegiate Guidelines Network, Scotland	IS
	Standards, Options, Recommendations , France	IS
	Veterans Affairs, United States	IS
	New Zealand	IS
	Australia	IS

DI – direct inquiry, IS – internet search, UK – United Kingdom

RESULTS

Overall, the evidentiary base upon which these standards were developed comprised 35 published studies (14-47) and 15 guidance documents (48-62). The results of the systematic review of the published literature and of the environmental scan are discussed separately.

Systematic Review

As seen in Table 2, 34 published studies were identified in the search of the published literature. The original systematic review by Gagliardi et al (13) included 20 articles retrieved between 1985 and October 2002 that described outcomes related to specific disease-site assessment units: 11 for breast cancer (14-24), three for colorectal cancer (25-27), and six for head and neck cancer (32-37). There were 17 case series that involved from 38 to 3,119 patients, two RCTs that included 478 and 791 patients, respectively, and one case-control study that included 177 cases and 162 controls.

As part of the update of the systematic review 237 citations and 586 citations were identified in the search of the literature. Of these citations, a total of 14 studies (Table 2) were included in the updated systematic review (28-31,38-47). Six studies were prospective cohort studies (359–3,637 patients), six were case series (69–930 patients) and one was an RCT (88 patients). Tables 3 to 7 highlight the relevant articles and summarize the data extracted (Table 3. Colorectal Cancer; Table 4. Head and Neck Cancer; Table 5. Lung Cancer; Table 6. Gynecologic Cancer; and Table 7. Neurological Cancers, Lymph Node Cancers, and Upper GI Cancers).

Elements of the Downs and Black quality assessment scale for observational studies (63) were utilized to assess the quality of studies included in the updated review. Four key domains were used in the evaluation: comparability of subjects, exposure/intervention, outcome measure, and statistical analysis (see Appendix IV for details of the studies evaluation in the updated systematic review). The quality of the studies was variable but generally modest, with approximately half the studies not using a comparative control group, thus increasing the risk for selection bias. Temporal relationships are more concrete, and multiple outcomes can be measured in prospective cohort studies, while retrospective cohort studies are prone to recall bias, measurement bias, and loss to follow-up.

Table 2. Studies identified by Gagliardi et al (13) and the systematic review update.

Disease Site	A. Gagliardi et al, (13) (Ref)	B. Update (Ref)	A + B (Ref)	Table #
Breast Cancer	11 (14-24)	0 (NA)	11 (14-24)	NA
Colorectal Cancer	3 (25-27)	4 (28-31)	7 (25-31)	3
Head and Neck Cancer	6 (32-37)	2 (38-39)	8 (32-39)	4
Lung Cancer	0 (NA)	2 (40-41)	3 (40-41)	5
Gynecological Cancer	0 (NA)	3 (42-44)	3 (42-44)	6
Neurological Cancer	0	1 (45)	1 (45)	7
Lymph Node Cancer	0	1 (46)	1 (46)	7
Upper Gastrointestinal Cancer	0 (NA)	1 (47)	1 (47)	7
			Total: 34	

Note: Ref, Reference; NA, not applicable.

Outcomes

The overall findings from Gagliardi et al (13) included the benefits of diagnostic assessment services in terms of reduced wait times for specific diagnostic procedures, increased patient satisfaction, and reduced anxiety for patients with negative findings. Most patients were diagnosed at the initial visit, and most diagnoses were confirmed by pathological determination. A number of studies reported an increased anxiety in women diagnosed with breast cancer at one-stop clinics, and one study measured clinical outcomes for breast cancer patients (see Gagliardi review for details [13]).

For the updated systematic review, all but one study were undertaken in the United Kingdom (UK) and included the National Health Service, Department of Health referral guidelines as a quality performance indicator for improving timely access (28-31,38-42,44-47). Only one study evaluated the cost of follow-up visits to general practitioners in an RCT evaluating a centralized two-stop rapid assessment unit versus conventional routine diagnostic evaluation (40). Ten studies defined cancer-specific risk criteria for general practitioners to utilize in their risk assessment and decision making to expedite high-risk referrals to rapid diagnostic units (28,29,31,39,42-47). Numerous studies evaluated or addressed a multidisciplinary team approach for the rapid diagnostic assessment of cancer (38-41,44,46).

Breast Cancer

In the Gagliardi et al (13) review, 11 studies met inclusion criteria, including two RCTs (14,18). Dey et al (14) found a reduction in patient anxiety at 24 hours for breast cancer patients randomized to a one-stop clinic versus women randomized to a dedicated clinic, but these findings were not maintained at three weeks or three months. There were additional costs associated with the one-stop clinic due to technology and staffing costs. In a second RCT, six days later, women randomized to the one-stop group had lower levels of anxiety if they were found to be cancer free and higher levels of anxiety if they were diagnosed with cancer than did women at the traditional two-visit clinic who were still awaiting diagnosis. The remaining breast cancer studies in the Gagliardi review reported on time lines and other care elements related to diagnosis and patient satisfaction. These studies generally showed favourable outcomes for multidisciplinary care, coordinated care, or one-stop diagnostic care. No additional studies met inclusion criteria in the updated review.

Colorectal Cancer

In the Gagliardi et al (13) review, studies involving two colorectal cancer assessment units (25-27) identified a reduction in wait times and increased patient satisfaction with the one-stop process. In four studies included in the updated systematic review (Table 3), the outcomes were similar and included reduced wait time from referral to first clinic visit and to first treatment, high patient satisfaction, and greater diagnostic yield (28-31).

Table 3. Studies and results for Colorectal Cancer Diagnostic Assessment Services.

Author Year (Ref)	# of Pts.	Design	Method/Protocol	Outcome and Results
Flashman 2004 (28)	2510	Design: Prospective audit and review of cases referred	Method/Protocol: Two week clinic (n=695) versus routine clinic (n=1815)	Results: The two week clinic had a greater diagnostic yield as compared to the routine clinic, 9.4% versus 2.2% respectively (p<0.001). Appointment time delays were greater in routine clinics, 27 days versus 12 days for the two week clinic (P=NS). Delays were noted before referral letter and after outpatient appointment, with less than 10% of the overall delay spent waiting for an appointment. There were no differences in time to treatment or stage of cancer at point of surgery.

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Chohan 2004 (29)	~2946	Design: Retrospective cohort study with prospective data collection Method/Protocol: Fast track clinic (n=462) versus routine clinic (n=2500) Results: The fast-track clinic wait was 12 days versus 24 days for standard referrals (P<0.001), 36.5 days versus 36 days wait respectively from first clinic to treatment (P=NS), and the medium time from referral to treatment was 49 versus 69 days for fast-track compared with standard clinics.
Rao 2005 (30)	≥359	Design: Prospective cohort study Method/Protocol: Rapid access clinic (n=319) versus routine clinic (number diagnosed = 40). Implementation of “paper clinics” with template development. Results: 92% of patients were seen within two weeks of referral through rapid access. The median wait was 13 days versus 25 days for rapid versus routine referrals (P=NR). A weekly paper clinic template designed to reduce follow-up visits and increase referrals led to an increase in referrals and median wait times were reduced from 15.9 weeks to 6.7 weeks (P<0.001). Urgent referral wait times decreased from a median of 3.4 weeks to 0.7 weeks (P<0.001). Average wait time for all categories dropped from 13.4 weeks to 3.5 weeks (P=NR) and the percentage of patients waiting in an outpatient clinic less than 4 weeks increased from 45.8% to 71.3% in a 13 month period. The overall reduction in wait times from referral to treatment was reduced from 93 days to 61.5 days.
Maruthachalam 2005 (31)	639	Design: Prospective double cohort study Method/Protocol: Direct access clinic (n=188) versus routine clinic (n=442). Patient satisfaction questionnaire sent to first 170 patients. Results: With direct access, the median time to diagnostic colonoscopy was 9 days versus 52 days for the routine clinic (P<0.001), the median time to histological diagnosis was 14 days versus 42 days (P<0.001), and the median time to treatment was 55 days versus 75 days (P=0.04). 98% of respondents (n=114) were satisfied with the rapid access or routine clinic service provided.

Note. Ref, reference; Pts., patients; NS, not significant, NR, Not Reported; n, number.

Head and Neck Cancer

In the systematic review by Gagliardi et al (13), findings from six head and neck cancer one-stop DAUs suggested there were reduced wait times between referral and first clinic visit (32-37). Similarly, two studies added in the updated review (38,39) reported improvements identified in wait times, standards of cancer care, and two-year survival rates (Table 4). In the study by Birchall et al (38), there was a significant increase in two-year survival for patients who had been seen in a multidisciplinary clinic and had a pretreatment chest x-ray. In contrast, rapid referral did not improve the detection rate of early-stage larynx cancer in the study by Moore et al (39).

Table 4. Studies and results for Head and Neck Cancer Diagnostic Assessment Services.

Author Year (Ref)	# of Pts.	Design	Method/Protocol	Outcome and Results
Birchall 2004 (38)	1293	Design: Prospective data collection with retrospective audit of notes Method/Protocol: Time 1 (year =1997) clinic (n=566) versus Time 2 (year = 2000) clinic (n=727) Results: The median number of patients treated with surgical intervention was 4 (range 1-26) for time 1, and 4 (range 1-23) for time 2; radiation consultation was 10 (range 1-51) in 1997, and 19 (range 1-70) in 2000. Wait times increased between 1997-2000; time from GP letter to first outpatient visit was 10 days for both cohorts and laryngeal cancer was 21 days for both; median times between first outpatient visit and surgery increased 26 to 28 days for laryngeal and 29 to 38 days for oral; radiation therapy waits were 56 and 64 days (larynx) and 42 and 47.5 days (oral). There were no differences between cohorts in two-year survival rates; patients in both cohorts who had pre-treatment x-ray had significantly improved survival (hazard ratio 0.7, p=0.03); being seen in a multidisciplinary clinic improved survival in both cohorts (p=0.1 and p=0.02).		
Moore 2004 (39)	930	Design: Prospective data collection with retrospective audit of notes Method/Protocol: Patients seen ≤ 2 weeks (n=652) versus > 2 weeks (n=278) Results: A mean of 70% of patients were seen within 2 weeks of referral from GPs over a four year period. The number of patients seen within 2 weeks declined from 87% in 1997 to 57% in 2000. There were no significant differences in cancer detection rates between the two cohorts		

Note. Ref, reference; Pts., patients; GP, general Practitioner; n, number.

Lung Cancer

No lung cancer-specific studies were included in the systematic review by Gagliardi et al (13). In the updated review, two studies (40-41) were available for review (Table 5). Murray et al (40) reported that, for lung cancer patients, a rapid diagnostic system produced reduced wait times from presentation to first treatment, higher overall patient satisfaction, and less follow-up visits to general practitioners when compared with the conventional system. The Salomaa et al study (41) found no association between long treatment delays and worse outcomes in the advanced stages of lung cancer; however, length of delay was not an independent risk factor related to prognosis.

Table 5. Studies and results for Lung Cancer Diagnostic Assessment Services.

Author Year (Ref)	# of Pts.	Design	Method/Protocol	Outcome and Results
Murray 2003 (40)	88	Design: Pilot Randomized controlled trial	Method/Protocol: Two stop clinic (n=43) versus routine clinic (n=45)	Results: The time from presentation to treatment was shorter in the two stop clinic arm (3 weeks versus 7 weeks, p=0.0025) as compared to the convention arm. There was no difference in time from diagnosis to start of radical treatment, or in survival between groups. Patients in the routine clinic felt that the process to diagnosis was slow, while those in the two stop arm experienced more satisfaction with care received and process of investigations. Fewer visits were made to GPs office in the two stop clinic arm, and there were no differences in GP satisfaction between the two groups.
Salomaa 2005 (41)	132	Design: Retrospective single cohort chart review	Method/Protocol: Referral process and time to diagnostic services	Results: Median patient delays = 14 days; Median GP delay before writing referral = 16 days, Median referral delay = 8 days for patients on active treatment; Median specialist's delay = 15 days; Median delay from specialist visit to treatment = 41 days. 38% of patients received treatment within 4 weeks and 75% within 8 weeks. The median treatment delay was 15 days; 22% and 61% had surgery within 4 to 8 weeks and median wait time for surgery for those with cancer was 30 days. The median symptom to diagnosis & treatment delay was 98 &122 days. A longer delay for advanced cancer patients translated into a better prognosis, however length of delay was not an independent risk factor related to prognosis. Independent predictors for survival included advanced age and type of surgery.

Note. Ref, reference; Pts., patients; n, number.

Gynecological Cancer

No gynecological specific studies were identified in the review by Gagliardi et al (13). In the updated review (Table 6), the three studies included (42-44) indicated that wait times from general practitioner referral to gynecological clinic were within a two-week time frame. Morrison et al (42), suggested that referral criteria should be reviewed with general practitioners to increase the number of referrals to the rapid access unit. The Mohamed et al study (43) reported that the majority of patients who had a diagnostic management plan at the first visit were appropriately referred, based on risk criteria, and were satisfied with the service provided.

Table 6. Studies and results for Gynecological Cancer Diagnostic Assessment Services.

Author Year (Ref)	# of Pts.	Design	Method/Protocol	Outcome and Results
Morrison 2003 (42)	297	Design: Retrospective single cohort case audit	Method/Protocol: Rapid access to fast track referral via a two-week wait bureau	Results: Of the 297 patients referred, 94% were seen within a two-week time frame with a median wait time of 8 days; 11% (33 patients) had a cancer diagnosis. 12 of 71 clinics were overbooked, and 28 clinics were underbooked.
Mohamed 2003 (43)	107	Design: Prospective single cohort	Method/Protocol: Evaluation of a one-stop post-menopausal bleeding clinic and patient satisfaction.	Results: 80 patients fulfilled referral criteria; The mean time from GP referral to consultation was 14.8 days and 87.5% of patients reported satisfaction with service provision.

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McNally 2003 (44)	242	Design: Retrospective single cohort case audit Method/Protocol: Time analysis before (n=109) and after (133) the opening of a fast track clinic Results: The confirmation of a diagnosis was reached within four weeks in most cases with the fast track clinic. Of 18 patients referred directly to the fast track clinic, 83% were seen within 4 days, and 94% seen within 14 days. The median wait time from GP referral to specialist was unchanged before and after the fast track clinic implementation (3 days), as was the GP referral to gyne-oncologist median wait time, (11 days). The median referral to diagnosis interval was significantly shorter with the fast track clinic (17.5 days versus 23 days, P=0.003).
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Note. Ref, reference; Pts., patients; n, number.

Neurological Cancer

No neurological cancer specific studies were included in Gagliardi et al review (13). In the updated review (Table 7), a rapid assessment neurological unit study (45) included in the analyses reported reduced wait times from initial referral to first clinic visit and a greater proportion of patients with a CT scan seen within a two-week time frame.

Lymph Node Cancer

No lymph node cancer-specific studies were included in the systematic review by Gagliardi et al (13). In the update, a rapid access multidisciplinary lymph node diagnostic clinic study included in the analyses (Table 7) reported reduced wait times from initial referral to first clinic visit or CT scan within a two-week time frame, as well as reduced time to cancer treatment (46).

Upper Gastrointestinal Cancer

No upper gastrointestinal cancer specific studies were included in the systematic review by Gagliardi et al (13). A single study in the update (Table 7) found that more streamlined referral criteria for upper gastrointestinal cancer might reduce the backlog of low-risk referrals made to fast-track endoscopy services (47).

Table 7. Studies and results for Neurological, Lymph Node, and Upper GI Cancer Diagnostic Assessment Services.

Author Year (Ref)	# of Pts.	Design	Method/Protocol	Outcome and Results
Neurological Cancers				
Uff 2005 (45)	69 pts. 39 GPs	Design: Retrospective single cohort study Method/Protocol: GPs sent referral letters to neurosurgeon using 2000 DOH criteria for suspected neurological cancers. If referral appropriate, patients invited within 2 weeks for CT brain scan prior to clinical review. GPs surveyed via questionnaire re: theirs and patient satisfaction, 29 responses Results: Of the 69 patients referred, 55 were scanned and 6 high priority cancers were diagnosed. The mean time from referral to scan was 8.6 days (range 2 – 14 days). The GPs had no objections to the policy of investigation before review. There was no documented suggestion of patient dissatisfaction.		
Lymph Node Cancers				
Chau 2003 (46)	550	Design: Prospective single cohort study Method/Protocol: Analysis of a rapid access multidisciplinary diagnostic clinic Results: The time between the receipt of initial referral letter and first clinic visit was within 7 days for 413 patients and within 14 days for 531 patients. The median time from first clinic visit to establishment of malignant disease was 15 days, and 98% of patients received a malignancy diagnosis within two months. The median time between date of diagnosis and date of first definitive treatment for patients with Hodgkins Lymphoma and Diffuse Large B cell Lymphoma was 14 days and 17.5 days respectively.		
Upper Gastrointestinal Cancers				
Kapoor 2005 (47)	3637	Design: Prospective double cohort validation of a predictive model Method/Protocol: Analysis before (n=1825) and after (1785) the opening of a rapid access service and the introduction of two week referral guidelines. Results: All patients were seen within a two week time period. At six months before and after introduction of the rapid access service, there was a 33% increase in total gastroscopy referrals received from primary care, and the yield of cancer diagnosed was 3% in the after group and 0.2% in the standard care group.		

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		In terms of the implementation of predictive model, of the 1785 patients in the validation group, 570 (31.2%) would have been referred to open access endoscopy (0.7% cancer yield in this group) rather than the rapid access service, thus reducing the number of referrals. There was 92.3% sensitivity, specificity and positive and negative predictive values of the criteria utilized in cancer detection for the validation cohort.
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Note. Ref, reference; Pts., patients; n, number, GPs, general practitioners.

Environmental Scan Results

As seen in Table 8, 15 guidance documents dealing with organizational matters related to DAPs were identified in the environmental scan of the literature (48-62). The documents addressed various elements of a DAP such as the mandate, centralized access, scope of diagnostic activity, team criteria, linkages, volume prerequisites, and quality indicators.

Table 8. Environmental scan results as they relate to Diagnostic Assessment Services.

Group/Region, Year (Ref)	Point of interest	Diagnostic Assessment Services Criteria						
		Mandate	Centralized Access	Diagnostic Activity	Team Criteria	Linkages	Volume Prerequisites	Quality Indicators
Lung Cancer								
NICE 2005 (48)	Diagnosis of lung cancer	√	√	√	√	√	-	√
SIGN 80 2005 (49)	Management of lung cancer	√	√	√	√	√	-	√
Colorectal Cancer								
NHS 2004, (50)	Improving outcomes in colorectal cancer	√	√	√	√	√	-	√
SIGN 67 2003 (51)	Management of colorectal cancer	√	√	√	√	-	-	√
CCO 2006, (52)	Colonoscopy standards	-	-	√	-	-	-	-
Breast Cancer								
OBSP (53)	Coordinated breast cancer services	√	√	√	√	√	√	√
NHS (54)	Cancer Services Collaborative Improvement – Breast Cancer	-	√	-	√	-	-	√
NHS 2000 (55)	Cancer Plan 2000	√	√	√	-	-	-	√
SIGN 84 2005 (56)	Management of breast cancer	√	√	√	√	√	√	√
ACR (57)	Appropriateness criteria in assessing breast cancer	-	-	√	-	-	-	-
Other								
CSCC 2002, (58)	Canadian Strategy for Cancer Control	√	√	-	√	√	-	√
ORCC 2006 (59)	Champlain model to improve access and decrease wait times	√	√	√	√	√	-	√
NHS 2006 (60)	Wait times for cancer	√	√	-	√	-	-	-
SIGN 90 2006 (61)	Diagnosis and management of head and neck cancer	-	√	-	-	-	-	√
CCO 2006 (62)	Multidisciplinary care conferences	√	-	√	√	-	-	-

Mandate

Several documents located through the environmental scan identified the following mandates or goals: a national screening programme (50), the improvement of referral systems (51) to encourage early diagnosis (51), streamlining or reducing the time from discovery of signs or symptoms suggestive of cancer to diagnosis (50,51,53,55,58,60), and advising (49) or tracking (50,53,55,58) the progress of patients through the continuum of care, with management plans (49) or pathways of care (53,55,58) for suspected or confirmed cases of cancer that are managed by clinical networks (49), DAUs (58), or multidisciplinary teams with the required expertise for each type of cancer being investigated (48-50,55,58,62). One document specifically reported that reducing wait times was an important goal, since there was some evidence to suggest poorer patient outcomes with a prolonged delay (three to six months) in referral (56). Several guidance documents reported the goals of reducing anxiety (53,55), providing high-quality services (53,55), creating a coordinated information system that could track individuals through the continuum of care (55), working more collaboratively with family/general practitioners (53), promoting education and research in various cancer areas (53), and achieving and maintaining standards of care (53,55). National groups were encouraged to develop policies, standards, and recommendations (50,58) in order to produce sustainable communities of practice (59), and to investigate other models of care such as the provision of nurse navigators or coordinators (48,58).

Centralized Access

Most of the guidance documents recommended the development of an integrated and coordinated cancer system with seamless services (50,58), realized through an urgent or rapid referral process (48-51,55,56), one-stop clinics (48,53-56,60,61), fast-track or rapid diagnostic services (48-50,53-55,61) that involve a multidisciplinary team (48-50,53-56,58-60,62), or specialized surgical units (51) with operational links to other specialty services (50), that meet regularly at one location (48) or virtually through systems such as video conferencing (54). Other documents reported the need for communication linkages between primary- and secondary-care professionals (48,50), and the need to track patients throughout the continuum of care (48,53,55), recommending that, upon referral, patients should have access to information and services through nurse specialists (48,50,51) or coordinators (50). As part of centralized access, other documents recommended an integrated network of care using common clinical guidelines, management protocols, and/or strategies of care (49,51,56,59). One document discussed the possibility of a nurse-led clinic to facilitate (54) the capture of a complete family history according to a defined protocol.

Specific aspects of centralized services suggested include the development of care pathways (55) or management plans (49), auditing systems (55), generic general practitioner referral guidance (54,60) and other approaches such as a common fax number (50), an immediate appointment service (50), pre-booking and pre-planning services (55), standardized forms (50,55), electronic forms (50,55), or electronic referral systems (54,55). One group reported that changing general practitioner referral standards and clinic rules was effective in reducing wait times (54). Several documents reported the need for patients to have access to relevant information in a variety of formats (48-51,53,54) that could be either tailored to suit the individual (48,49) or standardized (53,54), and access to supportive care services (53), patient pagers (54), or chaperone services (54).

The Ontario Breast Cancer Screening Program (53) includes referral primarily through the family/general physician but also through assessment services and/or clinics, by a surgeon, or through self-referral by women who have been appropriately screened (53).

Scope of Diagnostic Activity

The DAPs will be responsible for a spectrum of clinical diagnostic services; however, assessing and reporting on the relative merit of one diagnostic procedure over another is beyond the scope of this report. Appropriate disease site-specific equipment, technologies, and expertise will be required to provide excellence in care. Several documents listed the diagnostic care pathways (48,53,55) or investigations (48-53,55-57) that should occur upon presentation, however it was not the intent of many of the documents to list the full spectrum of diagnostic procedures. Appendix II summarizes the scope of diagnostic activities expected in a DAP as a function of the suspected disease site. These activities include examination, imaging, diagnostic and staging procedures, surgical consultation and procedures, pathology and laboratory medicine services, and supportive care services.

Team Criteria

The general understanding is that a successful DAP would be comprised of a dedicated multidisciplinary team in which each member has explicit roles, responsibilities, and accountabilities. Several documents specified the professional requirements for effective cancer services and multi-disciplinary team composition (48-50,53-56,58-60,62), with regular meetings (48,49,54,56,59,62), a team chair (50,62), coordinators (50,53,62), or nurse navigators (48).

While not DAP-specific, multidisciplinary team membership should include disease-site physician specialists (48-50); oncologists (48-50,62); specialist surgeons or surgical oncologists (48-50,53,62); breast clinicians (56); nurse specialists with appropriate training by cancer tumour type (48-51,53,62), including lung cancer nurse specialists (48,49), clinical nurse specialists (50,51,53), nurse endoscopists (50,51) or stoma nurse specialists (50,51), and breast-care nurses (54,56); radiologists (48-50,53,56,62); colonoscopists (50); pathologists (48-50,53,62); cytologists (56); pharmacists (48,49,62); family/general practitioners (48,50,53,62); mammographers (53) or radiographers (48,56) with mammography training (56); ultrasound technologists (53); patient advocates (50); identified multidisciplinary team (MDT) personnel to interact with the patient (50); clerical services (50,53); reception services, bookings personnel, and a director or manager (53); and other related professionals (49). Other documents recommended that health care providers undergo training in listening and explaining skills (49-51). One document reported that, for colorectal cancer patients, referral to a non-colorectal surgical specialist results in treatment delay (51).

If needed, multidisciplinary teams could also involve personnel from gastroenterology (50); geriatrics (48); nutrition therapy (48,50,62); physical/occupational therapy (48,62); pastoral care (50,62); pain/palliative care (50,62); mental health or psychosocial support (48,50,53,56,62), with sufficient training to perform psychosocial interventions (56); clinical trials (50,62); and nuclear medicine, genetics, dentistry, social services, and data management, as well as fellows, residents, and other health care students (62).

One Ontario document discussed the role of the multidisciplinary team coordinator. That individual was to ensure the maintenance of patient records, perform examinations and history taking, coordinate with the family/general physician, ensure timely records and the provision of information to clinicians, manage assessment timelines, provide a community link to the assessment unit, provide assessment and diagnostic test information to patients, arrange surgical consultation if needed, ascertain the need to direct patients to relevant supportive care services or resources, and offer information and support to family or friends accompanying the client (53).

Linkages and Collaboration

Several documents reported the need for linkages between health care services. Specifically, there should be linkages with system networks or trusts (50) and other relevant services, either locally or among regions, to ensure appropriate referrals and timely consultation

(50,53,59,62). Lines of communication should be established between the primary care team and the specialists (48-50,53,56,58) and primary care providers should be kept aware of the information given to patients (48,56). In areas where the population density is low, smaller units should have formal collaborative linkages with larger units (56).

Volume Prerequisites

One-stop DAUs require that patient volumes be sufficient to warrant the concentration of the required expertise and equipment in one location. There was very little evidence from the literature or the environmental scan about the appropriate volumes required. One Ontario document touched on the anticipated volume for a coordinated diagnostic service being planned but did little to inform absolute DAU volume prerequisites (53). A Scottish breast cancer guideline recommended that specialized breast units should see a minimum of 100 new cases per year to maintain their expertise and that, in areas where the population density is low, smaller units should have formal collaborative linkages with larger centres (56).

Quality Indicators

A range of process and clinical indicators of quality and benchmark targets will need to be measured to evaluate the performance of the DAPs, and provincial benchmarks will be identified to drive the quality agenda. One group developed quality indicators for breast cancer patients around the one-stop diagnostic clinic model and included the production of patient and physician questionnaire in their objectives (53). Specifically, the goal was for the institution involved to initiate phone contact within 24 hours of referral or within 72 hours of a screen-detected abnormality, ensure first assessment within one week of referral, and complete a radiology report within 48 hours, with the overall goal being that women would navigate the continuum of breast assessment investigations (including surgical procedures) in no more than seven weeks.

Several documents established wait-time benchmarks as a measure of system efficacy and efficiency. From the signs or symptoms suggestive of cancer to the diagnostic assessment, the recommended maximum wait time was two weeks for breast (53), head and neck (61), and lung (49) cancer diagnostic assessment. Other documents recommended that patients with urgent referrals should be seen within two weeks (50,60) or treated within 62 days (48). Several documents recommended that the time from the signs and/or symptoms suggestive of cancer to the diagnosis should not exceed four weeks. (55,58,60).

One document recommended timeliness standards be surveilled and that the time from health care provider referral to definitive diagnosis be no greater than two weeks when an image-directed core biopsy is performed (58), and no greater than four weeks when an open biopsy is necessary (58). Other documents recommended that quality assurance programs and audit programs should be developed (51,58,59) or that a performance measurement and monitoring process occur (60).

DISCUSSION

The findings from the updated systematic review are similar to those reported in the systematic review by Gagliardi et al (13). First, the majority of studies evaluating rapid diagnostic assessment for suspected cases of cancer demonstrated a reduced time from first referral to specialist visit and time to first treatment in that setting. Second, the studies that did evaluate patient satisfaction found greater patient satisfaction with service provision and personal care given by medical staff (31,36,43). Third, studies assessing multidisciplinary care found that it translated into a more comprehensive patient assessment and might contribute to better care overall (36,38,39,41,44,46,). Lastly, various studies reported that specific referral criteria for individual cancer types aided in decision making for general practitioners and might

assist in ensuring appropriate referral for high-risk suspected cases of cancer to rapid DAUs (28,29,31,39,42-47).

The environmental scan included fifteen guidance documents on the organization of cancer diagnostic services. While not the specific stated purpose of many of the documents, each of the guidance documents addressed some organizational element of DAPs such as the mandate, centralized access, scope of diagnostic activity, team criteria, linkages and collaborations, volume prerequisites, and quality indicators. In a majority of cases, the conclusions derived from the guidance documents were supported by consensus level evidence. Nonetheless, there was a consistent message that coordinated and organized diagnostic assessment services managed by multidisciplinary teams with operational links to other specialty services resulted in reduced wait times and improved services and possibly improved patient outcomes. Intuitively, these conclusions make sense, given the known natural history of many cancer types where delay may result in stage progression, unnecessarily increase patient anxiety, and adversely affect the quality of life.

The guidance documents also outlined many of the requirements for a DAP, including centralized access to diagnostic assessment services, as well as the multidisciplinary team criteria and the diagnostic services needed to successfully operate a DAU. Centralized access was most commonly characterized as a one-stop clinic with integrated and coordinated cancer services that provide seamless diagnostic assessment services. Given the geographic and population realities in Ontario, it is unlikely that this situation would be appropriate across the province. Nonetheless, the principles of centralized access to care can be achieved with alternative DAP models.

The composition of the disease-specific multidisciplinary team included not only the appropriate spectrum of disease-specific professionals needed to perform a diagnostic assessment, along with the appropriate disease-specific support personnel, but also coordinators and directors or chairs who were recommended to ensure the coordination of services. The purpose behind the description of the scope of the diagnostic activity was not to evaluate the relative merit of one diagnostic test or procedure over another but simply to indicate which types of diagnostic services should be offered for a specific disease site, future work that will be required in Ontario. As one would expect, the common clinical examinations, imaging, diagnostic and staging procedures, and surgical consultation and procedures were listed in the guidance documents. Also reported were the pathological services, disease-specific tests, and supportive services that might be needed as part of the spectrum of diagnostic care. There was general agreement by the authors of the guidance documents that centralized coordinated access to a multidisciplinary team and to appropriate diagnostic investigations and procedures would lead to improved services and patient outcomes.

Several of the guidance documents reported the need for linkages between primary health care providers to the coordinated diagnostic and treatment services to maintain communication as patients navigate through the system. Guidance document authors recommended that, in low-volume or under-serviced areas, smaller units should have formal collaborative linkages with larger units.

There was very little evidence from the literature or the environmental scan to suggest the appropriate patient volumes required to maintain one-stop DAUs. One DAP responsibility would be to determine the appropriate volume requirements for each type or model of DAU implemented.

Several documents established indicators of quality, with wait times being the most common indicator reported. Other documents recommended that the time from signs or symptoms suggestive of cancer to diagnosis should not exceed four weeks. A more thorough analysis of benchmarking is warranted. The development of quality assurance through performance measurement and audit programs was also recommended.

Overall, the results of the systematic review and environmental scan indicated that there is value in establishing coordinated and integrated full-service diagnostic assessment services, whether they be one-stop clinics or otherwise. The level of evidence that informed these conclusions was modest; however, the conclusions make sense intuitively, and they are concordant with the principles of best practices. Where appropriate, coordinated and integrated diagnostic assessment services should be offered to patients suspected of having cancer.

CONCLUSIONS

To ensure access to and the quality and timeliness of cancer diagnostic assessment services, CCO and the Government of Ontario identified the development of DAUs as a priority within the cancer care system. As a first step, the development of provincial standards that define the organizational and practice-setting features expected of a DAU was mandated. Initially, the focus was on standards for the organization of specific DAUs for three of the major cancer sites, breast, colorectal and lung cancer. However, it was soon realized that the organization of the assessment services would, of necessity, vary widely from region to region in Ontario. There are large variations in population density, resource availability, and geographical proximity to diagnostic services across the fourteen health networks responsible for the organization of health care in the province. The decision was made to broaden the scope of the standards to that of a conceptual framework for all cancer sites, incorporating principles for organizing diagnostic assessment programs that could be adapted to any tumour type, in any environment. DAP models may include one-stop DAUs or systems that are virtual in nature, either within or across regions. However, it is recognized that each region will need to tailor its diagnostic services to fit the specific regional circumstances.

It is clear from the literature, both published and unpublished, that organized centralized systems with multidisciplinary team membership are considered the optimum organization for the delivery of diagnostic cancer assessment services. Even though much of the available literature is limited in quality, and expert consensus opinion was often used to inform the basis of the guidance documents, both the evidence and the consensus indicate a consistent message across studies and across credible guidance organizations.

It is hoped that the organizational standards for DAPs developed by the expert panel will be a useful tool in the development of diagnostic assessment models across Ontario. It is also hoped that regardless of the model chosen, coordinated rapid access to care in a multidisciplinary team environment will result in a 'raising of the bar' in providing timely diagnostic assessment services to patients in Ontario.

JOURNAL REFERENCE

The following standards for the organization of care article has been published in *Current Oncology* (<http://www.current-oncology.com/index.php/oncology>):

- Brouwers M, Oliver T, Crawford J, Ellison P, Evans W, Gagliardi A, et al. Cancer diagnostic assessment programs: standards for the organization of care in Ontario. *Curr Oncol.* 2009;16(6):29-41.

For further information about this report, please contact:

Melissa Brouwers, PhD

Director, Program in Evidence-based Care, Cancer Care Ontario

Associate Professor (PT), CE&B, McMaster University

Room 310, McMaster University Downtown Centre

mail: 1280 Main Street West, Hamilton, ON, L8S 4L8

courier/location: 50 Main Street East, Hamilton, ON, L8N 1E9

Phone: 905-527-4322 ext. 42832 Fax: 905 526-6775 E-mail: mbrouwer@mcmaster.ca

DAP ORGANIZATIONAL STANDARDS IN REVIEW

Funding

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.

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Contact Information

For information about the PEBC and the most current version of all reports, please visit the CCO Web site at <http://www.cancercare.on.ca/> or contact the PEBC office at: Phone: 905-527-4322 ext. 42822 Fax: 905-526-6775 E-mail: ccopgi@mcmaster.ca

IN REVIEW

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Evidence-Based Series: Section 3

Organizational Standards for Diagnostic Assessment Programs: Methodology of the Standards Development and External Review Process

Diagnostic Assessment Programs Standards Panel

*M. Brouwers, J. Crawford, P. Elison, W.K. Evans, A. Gagliardi, D. Holmes,
J. Lacourciere, D. Lo, V. Mai, S. McNair, T. Minuk, T.K. Oliver, L. Rabeneck,
C. Rand, J. Ross, J. Smylie, J. Srigley, H. Stern, and M. Trudeau*

Report Date: June 15, 2007

A Special Project of the Diagnostic Assessment Standards Panel,
a Working Group Facilitated by the Program in Evidence-Based Care, Cancer Care Ontario

INTRODUCTION

The development of Diagnostic Assessment Program standards was led by the Diagnostic Assessment Standards Panel, an expert working group facilitated by Cancer Care Ontario's Program in Evidence-based Care (PEBC). The Panel comprised clinical oncology experts, regional vice presidents, clinical administrative leaders, health service researchers, and methodologists (please see Appendix I for the membership list).

The PEBC is best known for producing high-quality evidence-based reports, both practice guidelines and standards, using the methods of the Practice Guidelines Development Cycle (1,2). A typical PEBC report consists of a comprehensive evidentiary base compiled using rigorous methods including systematic review, the interpretation of and consensus agreement on that evidence, the resulting clinical recommendations, and the results of an external review by Ontario stakeholders for whom the topic is relevant. The PEBC has a formal standardized process to ensure the timeliness of each standards report, conducting routine periodic reviews and evaluations of the new evidence, and, where appropriate, integrating that evidence. The resulting recommendations document is called the Evidence-based Series.

The Evidence-based Series

This Evidence-based Series is comprised of the following three sections:

- **Section 1: Recommendations**

This section contains the standards derived by the Diagnostic Assessment Program Panel through systematic review, an environmental scan, interpretation of the clinical and scientific literature and expert consensus process, as well as through a formalized external review by Ontario practitioners and administrators.

- **Section 2: Systematic Review/Evidentiary Base**

This section presents the comprehensive systematic review of the clinical and scientific research, the environmental scan and team discussion on the topic and the conclusions drawn by the Panel.

- **Section 3: Methodology of the Standards Development and External Review Process**

This section summarizes the standards development process and the results of the formal external review by Ontario practitioners and administrators of the draft version of the systemic treatment standards and systematic review.

DEVELOPMENT OF THE EVIDENCED-BASED SERIES

Developing the Draft Standards

This Evidence-based Series was developed by the Diagnostic Assessment Program Expert Panel. The series is a convenient and up-to-date source of the best available evidence developed through systematic review, expert consensus, evidence synthesis, and input from practitioners and administrators in Ontario. Section 2 contains the evidentiary base related to the organization of diagnostic assessment cancer services. The draft standards derived from the interpretation of that evidence and the expertise of the members of the Panel are detailed in Section 1. Sections 1 and 2 have been circulated to Ontario practitioners and administrators for their feedback.

Section 3 presents the feedback process results and any resulting changes made to the draft document.

REPORT APPROVAL PANEL REVIEW

A draft of the evidence series, a report on diagnostic assessment units (DAUs) at that time, was circulated to the members of the Report Approval Panel (RAP) and the Scientific Manager of the PEBC in January 2007. Feedback was provided by one member of the RAP; however, no response from the working group was required, because of changes in the RAP review policy with respect to standards documents.

Summary of Written Comments with Modifications/Actions Taken by the DAP Standards Panel

The RAP member commented that the document provided a compelling case for the value of DAUs; however, it would be helpful if the issues of generalizability and prioritization were addressed. Specifically, there was a perceived gap between the high-level rationale for the DAUs and how the specific details would be provided. Another comment was that it might be an opportunity to advise the Local Health Integration Networks (LHINS) about the type of DAUs that might be prioritized. On a related note, the RAP member commented that, with limited evidence in some areas, the document does not thoroughly address limitations in generalizability or provide a prioritization process (perhaps by outcome measures) that might assist LHINS in implementing the DAUs. The RAP member thought that there was considerable overlap with other components and activities of the cancer care system (e.g., staging and treatment), and with general health care provision (e.g., less differentiated medical problems). It was unclear what the impact to the system would be.

Subsequent to the RAP feedback, the decision was made to broaden the scope of the standards to that of a conceptual framework for all cancer sites, incorporating principles for organizing DAPs that could be adapted to any tumour type, in any environment. In this manner, the actual specifics and prioritization of DAU implementation would fall under the mandate of the DAP. It was considered that the DAP models could include one-stop DAUs or systems that are virtual in nature, either within or across regions. However, it was recognized that each region would need to tailor its diagnostic services to fit the specific regional circumstances.

EXTERNAL REVIEW

The DAP standards were distributed to 74 Ontario stakeholders: 24 primary care providers, 17 chairs of provincial Disease Site Groups, 25 regional vice presidents of cancer programs and LHIN leaders, and eight cancer screening program experts. Responses were received from 11, 3, 12, and 3 participants in each group, respectively (overall return rate 39%). Written feedback was similar in nature for both the clinical and administrative experts.

As seen in Tables 1 and 2, feedback across participants groups was extremely positive. The majority of stakeholders agreed (with higher mean values up to 5 indicating stronger agreement) that there was a need for DAP standards (range 4.3–5.0), that the standards were clear (range 4.0–4.8), that they agreed with the draft standards as stated (4.1 and 4.5), they agreed that the standards should be formally approved (4.2 and 5.0), and importantly, they agreed that the standards reflect an effective approach that will lead to quality improvements in the cancer system (4.4 and 4.7). There was also some indication that the standards would be challenging to implement (3.0 and 4.2), but others indicated that the draft standards are achievable (4.0 and 4.0) and would reflect a more desirable system for improving the quality of patient care than current practice (4.1 and 5.0).

The written feedback was also overwhelming supportive. In support of the recommendations, additional evidence-based clinical guidance documents, educational tools to facilitate best diagnostic care and clear performance targets were identified by respondents as key components to enable improvements of quality of care. It was noted by the Panel, that evidence-based clinical guidance is likely to ease potential tensions between speciality cultures regarding investigative work-up by patients (e.g., breast assessment using imaging versus surgical open biopsy), a concern cited by some of the respondents.

The need for adequate IT systems and connectivity, particularly in regions with a large rural demographic, where the virtual program model and single central registry are particularly relevant, was identified by respondents as a key tool to enable implementation of the standards. Some respondents cited the current state of the e-health strategy and the status of e-health integration as barriers that would undermine successful application of the recommendations.

A significant and frequently cited set of challenges identified by respondents focused on confluence between cancer and non-cancer diagnostic care agendas. Specifically:

- limited ability to affect change in a system defined by multiple stakeholders representing many diseases, cancer being only one
- competition with other non-cancer programs create access barriers to clinicians and equipment
- challenges with communication and to facilitate buy-in by all providers

As a strategy to address these concerns, another respondent advocated that several recommendations in the DAP report could be used across disease sites and underpin an overall effort to improve quality of diagnostic care. CCO could play a significant leadership role in moving an agenda like this forward.

Strong and collaborative leadership among clinicians, clinical administrators, CEOs of hospitals, IT leaders, and the LHINs were identified as tools that would enable the standards to be implemented. While it was agreed that realignment of existing resources and system structures was important, there was general consensus that the implementation of these standards is not cost neutral, and additional resources (i.e., human resources, new equipment and equipment replacement, appropriate fees, and incentives) were seen to be necessary. It was further argued that efforts should be directed to strengthening existing DAPs that are working well in the province in addition to restructuring or building new DAPs.

Respondents identified some key issues relevant to the role of the primary care providers. Specifically:

- More attention is required to thinking through the role of primary care providers within the context of established family health teams, networks, and organizations. Offering to take over responsibility of primary care as part of the DAP was identified as a mistake. It was recommended, instead, that the DAP have formalized linkages with these providers and facilitate access of patients to the teams and networks.
- It was also recommended that psychosocial support within the family health team be a viable option for this care, rather than the DAP having overall responsibility.
- Finally, it was strongly recommended that assessment coordinators who are family practitioners be 'specialist designated' so as to not affect access to the bonus of primary care doctors in patient-enrolled models (family health networks, teams, or organizations), or else it is likely that referrals from these groups will not occur.

IN REVIEW

DAP ORGANIZATIONAL STANDARDS IN REVIEW

Table 1. External consultancy results. Primary Care Providers and DSG Chairs.

Item	Primary Care Providers 24 invited participants 11 returned forms, 10 completed							DSG Chairs 17 invited participants 2 returned forms, 2 completed						
	Frequencies					M	SD	Frequencies					M	SD
	1	2	3	4	5			1	2	3	4	5		
There is a need for a standards document on this topic.	-	-	2	3	5	4.3	0.8	-	-	-	1	1	4.5	0.7
The evidence (literature search and environmental scan) is relevant and complete (e.g., no key information sources or studies missed nor any included that should not have been).	-	1	4	4	1	3.5	0.9	-	-	-	1	1	4.5	0.7
I agree with the methodology used to summarize the evidence.	-	-	2	6	2	4	0.7	-	-	-	1	1	4.5	0.7
The draft standards are in agreement with my understanding of the evidence.	-	-	2	7	1	3.9	0.6	-	-	-	1	1	4.5	0.7
The draft standards in this report are clear.	-	1	1	5	3	4	0.9	-	-	-	1	1	4.5	0.7
I agree with the draft standards as stated.	-	1	1	4	4	4.1	1.0	-	-	-	1	1	4.5	0.7
The draft standards are suitable for the Ontario context.	-	-	1	6	3	4.2	0.6	-	-	-	-	2	5	0
The draft standards are too rigid to apply in the Ontario context.	1	4	2	3	-	2.7	1.1	-	2	-	-	-	2	0
When applied, the draft standards will produce more benefits for patients than harms.	-	2	-	7	1	3.7	0.9	-	-	1	1	-	3.5	0.7
The draft standards report presents a series of options that can be implemented.	-	2	-	7	1	3.7	0.9	-	-	-	1	1	4.5	0.7
To apply the draft standards will require reorganization of services/care in my practice setting.	-	1	-	5	4	4.2	0.9	-	1	-	-	1	3.5	2.1
The standards will be associated with more appropriate utilization of health care resources.	-	2	-	6	2	3.8	1.0	-	-	-	2	-	4	0
The draft standards in this report are achievable.	-	1	-	7	2	4	0.8	-	-	-	2	-	4	0
The draft report presents standards that are likely to be supported by a majority of my colleagues.	-	1	1	6	2	3.9	0.9	-	-	-	2	-	4	0
The draft standards reflect a more desirable system for improving the quality of patient care than current practice.	-	1	-	6	3	4.1	0.9	-	-	-	-	2	5	0
I would feel comfortable if patients received the care recommended in these draft standards.	1	-	-	7	2	3.9	1.1	-	-	-	-	2	5	0
These draft standards should be formally approved.	-	-	1	6	3	4.2	0.6	-	-	-	-	2	5	0
	-	-	-	-	-			-	-	-	-	-	-	-
If these draft standards were to be approved and endorsed, how likely would you be to apply the recommendations to the clinical care or organizational and/or administrative decisions for which you are professionally responsible?	-	-	3	2	5	4.2	0.9	-	-	1	1	-	3.5	0.7

* 1 = strongly disagree, 5 = strongly agree; M = mean; SD = standard deviation

DAP ORGANIZATIONAL STANDARDS IN REVIEW

Table 2. External consultancy results. Local Health Integration Network (LHIN) Leaders, Regional Vice Presidents (RVPs), Hospital CEOs, and Screening Leaders.

Item	RVPs and LHIN Leaders 28 invited participants 12 returned forms, 10 completed							Screening Leaders 10 invited participants 3 returned forms, 3 completed						
	Frequencies					M	SD	Frequencies					M	SD
	1	2	3	4	5			1	2	3	4	5		
There is a need for standards on this issue.	-	-	-	2	8	4.8	0.5	-	-	-	2	3	5	0
The standards are clear.	-	-	1	6	3	4.8	0.4	-	-	1	3	1	4.7	0.6
The standards will be challenging to implement in my institution or region.	-	1	2	4	2	4.2	0.6	-	-	1	3	1	3	1
The standards will be supported by stakeholders in my institution or region	-	2	4	2	1	3.8	1.0	-	2	2	1	-	3.7	1.2
The draft standards reflect an effective approach that will lead to quality improvements in patient care	-	-	-	6	4	3.2	1.0	-	-	-	4	1	4.7	0.6
The standards reflect an effective approach that will lead to quality improvements in the cancer system.	-	-	-	5	5	4.4	0.5	-	-	-	3	2	4.7	0.6

* 1 = strongly disagree, 5 = strongly agree; M = mean; SD = standard deviation

Action by the DAP Standards Panel

With the exception of refining the primary care role, no changes to the recommended standards were necessary. The DAP Standards Panel recommends that a letter be sent to Cancer Care Ontario's President and CEO, Terry Sullivan, summarizing the implementation-oriented feedback.

Conclusion

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

For further information about this report, please contact:

Melissa Brouwers, PhD
Director, Program in Evidence-based Care, Cancer Care Ontario
Associate Professor (PT), CE&B, McMaster University
Room 310, McMaster University Downtown Centre
mail: 1280 Main Street West, Hamilton, ON, L8S 4L8
courier/location: 50 Main Street East, Hamilton, ON, L8N 1E9
Phone: 905-527-4322 ext. 42832 Fax: 905 526-6775 E-mail: mbrouwer@mcmaster.ca

Funding

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.

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Contact Information

For information about the PEBC and the most current version of all reports, please visit the CCO Web site at <http://www.cancercare.on.ca/> or contact the PEBC office at:
Phone: 905-527-4322 ext. 42822 Fax: 905-526-6775 E-mail: ccopgi@mcmaster.ca

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IN REVIEW

Appendix I. Membership of the Diagnostic Assessment Programs Standards Panel.

<p>Dr. Melissa Brouwers (Facilitator) Director, Program in Evidence-based Care (PEBC), Cancer Care Ontario (CCO) Associate Professor (PT), Department of Clinical Epidemiology and Biostatistics, McMaster University Hamilton, Ontario</p>	<p>Ms. Joanne Crawford MSc (Nursing) Student McMaster University Hamilton, Ontario</p>
<p>Dr. Phil Elison Liaison from the Ontario College of Family Physicians to CCO Toronto, Canada <i>family medicine</i></p>	<p>Dr. William K. Evans Co-Chair, Provincial Lung Disease Site Group, PEBC, CCO Vice-President, Regional Cancer Services, CCO, Hamilton Hamilton, Ontario <i>medical oncologist, lung cancer specialist</i></p>
<p>Dr. Anna Gagliardi Scientist, Sunnybrook Research Institute Assistant Professor, Departments of Surgery; Health Policy, Management & Evaluation Faculty of Medicine, University of Toronto Toronto, Ontario</p>	<p>Ms. Donna Holmes Coordinator, Community Oncology Program Grand River Regional Cancer Centre Kitchener, Ontario</p>
<p>Ms. Joanne Lacourciere Manager, Northwest Regional Cancer Program Thunder Bay Regional Health Sciences Centre Thunder Bay, Ontario</p>	<p>Dr. Dorothy Lo Medical Oncology Resident, University of Toronto MHSc Student, University of Toronto Toronto, Ontario <i>medical oncologist</i></p>
<p>Dr. Verna Mai Director, Screening Program, CCO Toronto, Canada</p>	<p>Dr. Sheila McNair Assistant Director, PEBC, CCO McMaster University Hamilton, Ontario</p>
<p>Dr. Terry Minuk Hamilton, Ontario <i>diagnostic radiology specialist</i></p>	<p>Mr. Tom Oliver Research Coordinator, PEBC, CCO McMaster University Hamilton, Ontario</p>
<p>Dr. Linda Rabeneck Vice President, Regional Cancer Services, CCO, Toronto Toronto, Canada <i>gastroenterologist</i></p>	<p>Ms. Carol Rand Director, Regional, Systemic, Supportive and Palliative Care Juravinski Cancer Centre Hamilton, Ontario</p>
<p>Ms. Jill Ross Director, Clinical Programs, CCO Toronto, Ontario</p>	<p>Ms. Jennifer Smylie Clinical Manager, Regional Assessment Centre for Lung, Colorectal and Prostate Cancers The Ottawa Hospital Regional Cancer Centre Ottawa, Ontario</p>
<p>Dr. John Srigley Provincial Head, Laboratory Medicine/Pathology, CCO Kingston, Ontario <i>pathologist</i></p>	<p>Dr. Hartley Stern Provincial Head, Surgical Oncology, CCO Vice-President, Regional Cancer Services, CCO, Ottawa Ottawa, Ontario <i>surgeon</i></p>
<p>Dr. Maureen Trudeau Co-Chair, Provincial Breast Disease Site Group, PEBC, CCO Provincial Head, Systematic Therapy Program, CCO Toronto, Ontario <i>medical oncologist, breast cancer specialist</i></p>	

Appendix II. Clinical diagnostic assessment services by cancer disease site.

Breast Cancer

Examination	<ul style="list-style-type: none"> • Clinical Breast Examination
Imaging	<ul style="list-style-type: none"> • Screening and diagnostic mammography (Special Views) • Ultrasound • MRI
Diagnostic Procedures	<ul style="list-style-type: none"> • Ultrasound Guided Core Biopsy • Stereotactic Biopsy • Fine Needle Aspiration • Needle Localization • Galactography
Surgical Consultation and Procedures	<ul style="list-style-type: none"> • Excision Biopsy/Lumpectomy • Lymph Node Biopsy • Sentinel Node Dissection
Pathology	<ul style="list-style-type: none"> • All information to pathology provided via CCO-endorsed surgical pathology requisition forms • Analysis and Reporting using College of American Pathologists (CAP) Standards
Supportive Care	<ul style="list-style-type: none"> • Education and Psychosocial Support • Dietetics • Genetic Counselling and Other Supportive Services

Lung Cancer

Examination	<ul style="list-style-type: none"> • Percussion • Auscultation
Imaging	<ul style="list-style-type: none"> • Chest x-ray • CT scan (chest and abdomen) • PET scan (solitary nodule)
Diagnostic Procedures	<ul style="list-style-type: none"> • Bronchoscopy • Percutaneous Fine Needle Aspiration • Sputum Cytology • Video-Assisted Thoracoscopy • Anterior mediastinotomy/mediastinoscopy
Surgical Consultation and Procedures	<ul style="list-style-type: none"> • Lobectomy • Pneumonectomy • Segmental resection • Wedge resection • Thoracotomy • Sleeve lobectomy and resection
Pathology	<ul style="list-style-type: none"> • Analysis and Reporting using CAP Standards • All information to pathology provided via CCO-endorsed surgical pathology requisition forms
Supportive Care	<ul style="list-style-type: none"> • Education and Psychosocial Support • Dietetics • Other Supportive Services

Colorectal Cancer

Examination	<ul style="list-style-type: none"> • Physical examination • Digital Rectal Exam • Pelvic exam for females
Imaging	<ul style="list-style-type: none"> • Diagnostic colonoscopy • Sigmoidoscopy • Double Contrast Barium Enema • CT scan Pneumocolon
Diagnostic Procedures	<ul style="list-style-type: none"> • Excision Biopsy • Polypectomy <p>Staging may include:</p> <ul style="list-style-type: none"> • Ultrasound (abdominal, pelvic or endorectal) • Preoperative MRI • Chest x-ray • CT scan

DAP ORGANIZATIONAL STANDARDS IN REVIEW

	<ul style="list-style-type: none"> • PET scan • Tumour Markers (CEA)
Surgical Consultation and Procedures	<p>Colon</p> <ul style="list-style-type: none"> • Partial or total bowel resection (Right hemicolectomy, transverse hemicolectomy, left hemicolectomy, lower anterior resection) <p>Rectal</p> <ul style="list-style-type: none"> • Local excision • Lower anterior resection, total mesorectal excision, proctectomy with colo-anal anastomosis, abdominal perineal resection and pelvic exenteration
Pathology	<ul style="list-style-type: none"> • Analysis and Reporting using CAP Standards • All information to pathology provided via CCO-endorsed surgical pathology requisition forms
Supportive Care	<ul style="list-style-type: none"> • Education and Psychosocial Support • Dietetics • Genetic Counselling and Other Supportive Services
Other	<ul style="list-style-type: none"> • The Program in Evidence-based Care has developed Colonoscopy Standards that address physician, institution and performance standards, and should serve as the foundation for all Colorectal Cancer DAUs.

Upper Gastrointestinal Tract Cancers (esophagus, stomach, small intestine, gall bladder, pancreas, and liver)

Examination	<ul style="list-style-type: none"> • Physical examination
Imaging	<ul style="list-style-type: none"> • Ultrasound • CT scan • Upper GI endoscopy • Barium radiology • Chromoendoscopy • Percutaneous transhepatic cholangiography • Angiography • Endoscopic retrograde cholangiopancreatography • Small Bowel Enema • Arteriography
Diagnostic Procedures	<ul style="list-style-type: none"> • Structured biopsy protocol • Laparoscopy • Fine Needle Aspiration <p>Staging may include:</p> <ul style="list-style-type: none"> • Ultrasound • MRI • X-ray (chest, upper GI series, abdominal) • CT scan • PET • Endoscopic ultrasound • Laparoscopy, cytology • Bone scan • Bronchoscopy • Thoracoscopy • Neck imaging • Laboratory tests (CBC, Chemistry) • Tumour markers
Surgical Consultation and Procedures	<ul style="list-style-type: none"> • Esophagectomy • Sub-total or total gastrectomy • Small intestine surgical resection or bypass • Cholecystectomy • Whipple procedure, total pancreatectomy and distal pancreatectomy • Partial hepatectomy and Radio-frequency ablation
Pathology	<ul style="list-style-type: none"> • Analysis and Reporting using CAP Standards • All information to pathology provided via CCO-endorsed surgical pathology requisition forms
Supportive Care	<ul style="list-style-type: none"> • Education and Psychosocial Support • Dietetics • Genetic counselling and Other Supportive Services

Genitourinary Cancers (prostate, bladder and kidney)

Examination	<ul style="list-style-type: none"> Physical examination
Imaging	<p>Prostate</p> <ul style="list-style-type: none"> Transrectal Ultrasound <p>Bladder</p> <ul style="list-style-type: none"> Intravenous pyelogram (IVP) Ultrasound <p>Kidney</p> <ul style="list-style-type: none"> Intravenous pyelogram (IVP) CT scan
Diagnostic Procedures	<p>Prostate</p> <ul style="list-style-type: none"> Blood tests (PSA, testosterone) Transrectal biopsy <p>Bladder</p> <ul style="list-style-type: none"> Urinalysis Cytology Biopsy Cystoscopy <p>Kidney</p> <ul style="list-style-type: none"> Needle biopsy <p>Staging may include:</p> <ul style="list-style-type: none"> Seminal vesicle biopsy MRI Chest x-ray CT scan Bone scan
Surgical Consultation and Procedures	<p>Prostate</p> <ul style="list-style-type: none"> Prostatectomy (radical, retropubic and perineal) Transurethral resection of the prostate Pelvic lymphadenectomy <p>Bladder</p> <ul style="list-style-type: none"> Transurethral resection with fulguration Radical cystectomy Segmental cystectomy <p>Kidney</p> <ul style="list-style-type: none"> Partial, simple or radical nephrectomy
Pathology	<ul style="list-style-type: none"> Analysis and Reporting using CAP Standards All information to pathology provided via CCO-endorsed surgical pathology requisition forms
Supportive Care	<ul style="list-style-type: none"> Education and Psychosocial Support Dietetics Genetic and Other Supportive Services

Gynecological Cancers

Examination	<ul style="list-style-type: none"> Physical examination Pelvic examination
Imaging	<p>Cervical</p> <ul style="list-style-type: none"> Colposcopy <p>Endometrial</p> <ul style="list-style-type: none"> Hysteroscopy Transvaginal ultrasound <p>Ovarian</p> <ul style="list-style-type: none"> Transvaginal ultrasound Abdominal or pelvic CT or MRI scan
Diagnostic Procedures	<p>Cervical</p> <ul style="list-style-type: none"> Colposcopic biopsy Endocervical curettage Cone biopsy (cold-knife excision, LEEP, laser-excision) Sentinel node assessment (possibly) <p>Endometrial</p>

DAP ORGANIZATIONAL STANDARDS IN REVIEW

	<ul style="list-style-type: none"> • Endometrial biopsy • Endocervical curettage • Dilation and curettage (D&C) <p>Ovarian</p> <ul style="list-style-type: none"> • Laparoscopy • Laparotomy <p>Vulva</p> <ul style="list-style-type: none"> • Wide local excision • Radical vulvectomy • Groin dissection • Sentinel node assessment <p>Staging may include:</p> <ul style="list-style-type: none"> • MRI • Chest x-ray • CT scan • Bone scan • Mammogram • Lower GI series or barium enema • Intravenous pyelogram (IVP) • Cystoscopy • Sigmoidoscopy • Lymph node biopsy • Examination under anesthesia • Tumour marker tests (CA125, BHCG) • Proctoscopy
Surgical Consultation and Procedures	<p>Cervical</p> <ul style="list-style-type: none"> • Cone biopsy • Radical trachelectomy • Hysterectomy • Pelvic exenteration • Pelvic/para-aortic lymphadenectomy <p>Endometrial</p> <ul style="list-style-type: none"> • Hysterectomy (total or radical) • Bilateral salpingo-oophorectomy • Pelvic exenteration • Pelvic/para-aortic lymphadenectomy <p>Ovarian</p> <ul style="list-style-type: none"> • Oophorectomy, salpingectomy • Salpingo-oophorectomy (unilateral or bilateral) • Total abdominal hysterectomy and bilateral salpingo-oophorectomy (TAH-BSO) • Omentectomy • Pelvic/para-aortic lymphadenectomy • Intra-peritoneal catheter placement • Bowel resection
Pathology	<ul style="list-style-type: none"> • Analysis and Reporting using CAP Standards • All information to pathology provided via CCO-endorsed surgical pathology requisition forms
Supportive Care	<ul style="list-style-type: none"> • Education and Psychosocial Support • Dietetics • Genetic Counselling and Other Supportive Services

Head and Neck Cancers

Examination	<ul style="list-style-type: none"> • Clinical examination
Imaging	<ul style="list-style-type: none"> • MRI • Chest x-ray • CT scan • PET scan • Ultrasound
Diagnostic Procedures	<ul style="list-style-type: none"> • Fibre optic endoscopy • Fine needle aspiration cytology (FNAC)

DAP ORGANIZATIONAL STANDARDS IN REVIEW

	<ul style="list-style-type: none"> • Core biopsy • Ultrasound guided fine needle aspiration (USFNA) <p>Staging may include:</p> <ul style="list-style-type: none"> • Symptom-directed endoscopy • Direct pharyngolaryngoscopy • Esophagoscopy • Bronchoscopy
Surgical Consultation and Procedures	<ul style="list-style-type: none"> • Corpectomy, supraglottic laryngectomy, hemilaryngectomy, total laryngectomy • Total Thyroidectomy • Wide local excision, neck dissection
Pathology	<ul style="list-style-type: none"> • Analysis and Reporting using CAP Standards • All information to pathology provided via CCO-endorsed surgical pathology requisition forms
Supportive Care	<ul style="list-style-type: none"> • Education and Psychosocial Support • Dietetics • Genetic Counselling and Other Supportive Services

Hematological Cancers (ALL, AML, CLL, CML, Hodgkins and Non-Hodgkins Lymphoma, Multiple Myeloma)

Examination	<ul style="list-style-type: none"> • Physical examination
Imaging	<p>Leukemia</p> <ul style="list-style-type: none"> • Ultrasound • MRI • Chest x-ray • CT scan <p>Non-Hodgkins Lymphoma</p> <ul style="list-style-type: none"> • Ultrasound • MRI • Chest x-ray • CT scan • PET scan • Bone Scan • Gallium scan <p>Hodgkins Lymphoma</p> <ul style="list-style-type: none"> • Chest x-ray • CT scan • PET scan • Gallium scan <p>Multiple Myeloma</p> <ul style="list-style-type: none"> • MRI scan • X-ray • CT scan • PET scan
Diagnostic Procedures	<p>Leukemia</p> <ul style="list-style-type: none"> • Blood tests: CBC, Lactate Dehydrogenase (LDH), fibrinogen, PT, INR, cell and tissue analysis, cytochemistry, histochemistry, immunohistochemistry, immunofluorescence, cytogenetics (chromosome analysis) and molecular analysis • Blood chemistry (creatinine, liver enzymes, calcium, etc.) • Bone marrow aspiration, lumbar puncture or spinal for CSF fluid • Fluorescence in situ hybridization (FISH) • Direct antiglobulin test <p>Non-Hodgkins Lymphoma</p> <ul style="list-style-type: none"> • CBC, Lactate dehydrogenase (LDH), urine test, HIV test • Blood chemistry (creatinine, liver enzymes, calcium, etc.) • Bone marrow aspiration, lumbar puncture or spinal for CSF fluid • Direct antiglobulin test • Serum protein electrophoresis <p>Hodgkins Lymphoma</p> <ul style="list-style-type: none"> • CBC, sedimentation rate, blood chemistry • Bone marrow

DAP ORGANIZATIONAL STANDARDS IN REVIEW

	<ul style="list-style-type: none"> • Direct antiglobulin test <p>Multiple Myeloma</p> <ul style="list-style-type: none"> • 24 hour urine, Bence-Jones protein • Serum protein electrophoresis and cytogenetic analysis • Bone marrow aspiration <p>Staging may include:</p> <ul style="list-style-type: none"> • Bone marrow biopsy, biopsy of lymph nodes, other organs • Chest x-ray • CT scan • PET scan • Bone scan • CSF fluid • Paracentesis • Thoracentesis • Gallium scan
Surgical Consultation and Procedures	<ul style="list-style-type: none"> • Lymph node biopsy (all) • Incisional, excisional and core biopsy, needle biopsy or fine needle aspiration (usually not sufficient to make a diagnosis), immunophenotyping—(Hodgkins)
Pathology	<ul style="list-style-type: none"> • Analysis and Reporting using CAP Standards • All information to pathology provided via CCO-endorsed surgical pathology requisition forms
Supportive Care	<ul style="list-style-type: none"> • Symptom management • Education and Psychosocial Support • Dietetics • Other Supportive Services

Skin Cancer (melanoma and non-melanoma)

Examination	<ul style="list-style-type: none"> • Physical examination
Imaging	<ul style="list-style-type: none"> • High magnification dermatoscopy
Diagnostic Procedures	<ul style="list-style-type: none"> • Biopsy (incisional, excision, shave and punch biopsy) • X-ray • Fine needle aspiration • Cauterization or freezing • Mohs microsurgery <p>Staging may include:</p> <ul style="list-style-type: none"> • Sentinel lymph node biopsy • Lymph node dissection • Chest x-ray • Liver function tests • Ultrasound of the liver • MRI • CT scan • Bone scan
Surgical Consultation and Procedures	<ul style="list-style-type: none"> • Simple excision • Re-excision
Pathology	<ul style="list-style-type: none"> • Analysis and Reporting using CAP Standards • All information to pathology provided via CCO-endorsed surgical pathology requisition forms
Supportive Care	<ul style="list-style-type: none"> • Education and Psychosocial Support • Dietetics • Other Supportive Services

Cancer of unknown primary origin

Examination	<ul style="list-style-type: none"> • Complete physical examination
Imaging	<ul style="list-style-type: none"> • MRI • Chest x-ray • CT scan • PET scan • Endoscopy

DAP ORGANIZATIONAL STANDARDS IN REVIEW

	<ul style="list-style-type: none"> • Mammography
Diagnostic Procedures	<ul style="list-style-type: none"> • Biopsy, FNA or CT guided depending on site of tumour • Immunohistochemical markers • Tumour markers (CEA, CA125) • Molecular diagnostics • PSA (males) and estrogen and progesterone receptors (females) • Fecal occult blood test
Surgical Consultation and Procedures	<ul style="list-style-type: none"> • Surgical resection
Pathology	<ul style="list-style-type: none"> • Analysis and Reporting using CAP Standards • All information to pathology provided via CCO-endorsed surgical pathology requisition forms
Supportive Care	<ul style="list-style-type: none"> • Education and Psychosocial Support • Dietetics • Genetic Counselling and Other Supportive Services

IN REVIEW

Soft Tissue Sarcoma

Examination	<ul style="list-style-type: none"> • Complete physical examination
Imaging	<ul style="list-style-type: none"> • Ultrasound • MRI • CT scan • PET scan • Radiography • Magnetic resonance angiography
Diagnostic Procedures	<ul style="list-style-type: none"> • Imaging-guided biopsy • Fine needle aspiration biopsy • Incisional biopsy • Core biopsy
Surgical Consultation and Procedures	<ul style="list-style-type: none"> • Wide local excision • Lymphadenectomy • Limb sparing surgery • Amputation
Pathology	<ul style="list-style-type: none"> • Analysis and Reporting using CAP Standards
Supportive Care	<ul style="list-style-type: none"> • Education and Psychosocial Support • Dietetics • Other Supportive Services

Neuro-oncology

Examination	<ul style="list-style-type: none"> • Physical examination • Neurological assessment
Imaging	<ul style="list-style-type: none"> • CT scan • MRI • Skull, spine radiographs • Gadolinium-DTPA enhanced MRI (Gd-DTPA) • CT myelography
Diagnostic Procedures	<ul style="list-style-type: none"> • Biopsy • Image-guided percutaneous needle techniques
Surgical Consultation and Procedures	<ul style="list-style-type: none"> • Biopsy • Surgical excision
Pathology	<ul style="list-style-type: none"> • Analysis and Reporting using CAP Standards • All information to pathology provided via CCO-endorsed surgical pathology requisition forms
Supportive Care	<ul style="list-style-type: none"> • Education and Psychosocial Support • Dietetics • Genetic Counselling and Other Supportive Services

Appendix III. Literature search strategy.

<i>Literature Search Strategy</i>			
Database	Search Strategy	Resulting Citations	Eligible Citations
Ovid MEDLINE(R) 1996 to October Week 3, 2006	<p>Medical Subject Headings Ambulatory Care Facilities/ Community Health Centers/ outpatient clinics, hospital/ambulatory or cancer care facilities.mp. [mp=title, original title, abstract, name of substance word, subject heading word] 1 or 2 or 3 Breast Neoplasms/di [Diagnosis] Prostatic Neoplasms/di [Diagnosis] Lung Neoplasms/di [Diagnosis] exp Colorectal Neoplasms/di [Diagnosis] exp "Head and Neck Neoplasms"/di [Diagnosis] 5 or 6 or 7 or 8 or 9 4 and 10 limit 11 to (english language and yr="2002 - 2006") limit 12 to (comment or editorial or letter) 12 not 13</p> <p>Subject headings and key word search (prostatic neoplasms/di or breast neoplasms/di or lung neoplasms/di or exp. colorectal neoplasms/di or exp "head and neck neoplasms"/di) and (rapid or same day or one stop or multidisciplinary) and clinic or diagnosis Keyword search ONLY (as above)</p>	36	2
HealthSTAR, 2002-current (October Week 3, 2006)	Same search strategy as for MEDLINE above and limit to nonMEDLINE	225	3
EMBASE, 2002 to current (October Week 3, 2006)	Same search strategy as for MEDLINE above and limit to nonMEDLINE	0	0
EMBASE, 1996 to Week 42	<p>Medical Subject Headings Outpatient Department/ Exp Neoplasm/di [Diagnosis] 16 and 17 limit 18 to (english language and yr="2002 - 2006") limit 19 to (editorial or letter) 19 not 20</p> <p>Subject headings and key word search (prostatic neoplasms/di or breast neoplasms/di or lung neoplasms/di or exp. colorectal neoplasms/di or exp "head and neck neoplasms"/di) and (rapid or same day or one stop or multidisciplinary) and clinic or diagnosis and limit to non-MEDLINE Keyword search ONLY (as above)</p>	28	0
Cochrane Database of Systematic Reviews (3 rd Quarter 2006)	<p>Medical Subject Headings Ambulatory and Neoplasms</p>	161	6
		71	0
		12	0

Appendix IV. Quality evaluation scale for observational studies (adapted from Downs and Black, 1999).

Study	Domains			
	Comparability of subjects	Exposure /Interventions	Outcome Measures	Statistical Analysis
<u>Colorectal Cancer</u>				
Chohan et al, 2005	Y	Y	Y	Y
Flashman et al, 2004	Y	Y	Y	Y
Maruthachalam et al, 2005	Y	Y	Y	Y
Rao et al, 2006	P	Y	Y	Y
Upper Gastrointestinal cancer				
Kapoor et al, 2005	Y	Y	Y	Y
<u>Head and Neck</u>				
Birchall et al, 2004	Y	Y	Y	Y
Moore et al, 2004	N	Y	Y	P
<u>Lung Cancer</u>				
Murray et al, 2003 (RCT-randomization, no blinding)	Y	Y	Y	Y
Salomaa et al, 2005	N	N	Y	Y
Gynecological Cancer				
McNally et al, 2003	N	Y	Y	Y
Mohamed & Nair, 2003	N	Y	Y	P
Morrison et al, 2003	N	Y	Y	P
Lymph node cancer				
Chau et al, 2003	N	Y	Y	Y
Neurological cancer				
Uff et al, 2005	N	Y	Y	N

****Y: yes (met domain of utilizing a comparative group) N: no (no comparative group) P: partial (did not fully meet domain for valid comparisons to be made or performed statistical analysis to reduce confounders)**