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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:
http://www.cancercare.on.ca/toolbox/qualityguidelines/other-reports/collaborative-pr-ebs/

Section 1: Recommendations
Section 2: Systematic Review/Evidentiary Base
Section 3: Methodology of the Standards Development and External Review Process

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Evidence-Based Series: Section 1

Organizational Standards for Diagnostic Assessment Programs: Recommendations

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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.

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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	• 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 examples: family/general physicians, advanced practice care nurses or equivalent	• 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
Radiologists	• 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	• 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	• 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	• Provides care to patients with health concerns when they do not have a primary care provider
Ultrasound Technologists	• Performs ultrasound • Prepares patients for ultrasound guided biopsy
Psychosocial Support	• Consults with patients on an as needed basis • Reviews Hospital Anxiety and Depression Scale (HADS) results and follows patients proactively
Reception, Clerical and Bookings	• 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	• Provides dietetics, genetic counselling, and other supportive services

Other Disease Site-Specific Specialists

Respirologists (Lung DAUs)	• Consults with patients when imaging results suggest cancer • Performs bronchoscopy and biopsy, as appropriate
Mammographers (Breast DAUs)	• 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)	• 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