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Target Wait Times for Cancer Surgery in Ontario

A quality improvement collaboration of the Provincial Surgical Oncology Program, the Surgical Access to Care and Wait Times Subcommittee and the Program in Evidence-based Care.

FINAL REPORT

REVISED – April 2006

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EXECUTIVE SUMMARY

In November 2004, Ontario's Ministry of Health and Long-Term Care (the Ministry) announced Ontario's Wait Time Strategy. The strategy was designed to reduce wait times by December 2006 by improving access to healthcare services for adult Ontarians in five areas of care including cancer surgery.

As part of this strategy, the Ministry asked for the development of prioritization tools and benchmarks. Specifically, the Ministry asked Cancer Care Ontario (CCO) to identify wait time targets for cancer surgery. CCO's Surgical Access to Care and Wait Times Subcommittee (the Committee) worked with the Program in Evidence-based Care and a panel of experts to develop the targets.

THE COMMITTEE'S MANDATE

The Committee was asked to develop target wait times from the decision-to-treat[1] to surgery that could be used to monitor and evaluate the relationship between system capacity and the demand for surgery, as well as to plan for appropriate capacity. These targets will be used as a system management tool to identify resource needs to meet the implied service levels. The scope of the Committee's work involved operating room procedures for known or suspected invasive cancer.

The targets are not intended to guide decisions about the urgency of the need for surgery for an individual patient. Those decisions require careful consideration of the clinical presentation, patient values and preferences and will continue to be made at the discretion of the surgeon, in consultation with the patient.

METHODS

The overall approach to the development of target wait times had four major elements:

1. A systematic review of published literature to examine the impact of diagnostic and/or surgical delay on patient outcomes and to find published reports defining acceptable or excessive wait times.
2. A review of selected work related to surgical oncology wait time targets that has been undertaken in other jurisdictions.
3. The development of consensus recommendations by the Committee and the documentation of the Committee's work in a draft report informed by steps 1 and 2.
4. Submission of the draft report and recommendations to an Expert Panel for review and comment. Participants were asked to review the report and complete an on-line survey requesting feedback on the methodology, recommendations, and implementation issues. Responses were received from 55 of the 128 physicians and cancer care administrators on the expert panel, yielding a response rate of 43%.

The surgical wait time report was the first of three reports prepared by CCO. After this report was submitted to the Ministry, CCO began work on wait time reports for radiation treatment and

[1] For the purpose of preparing these targets, the decision-to-treat date has been defined as the date on which the surgeon makes the decision to operate and that decision is agreed to by the patient. This date is distinct from, and may precede, the date on which all pre-operative investigations are complete.

systemic therapy. CCO also continued to work with the Wait Time Information Office (WTIO) in developing the provincial approach to measuring and reporting surgical wait times. Based on deliberations and decisions made in these subsequent processes, this surgical wait time report was revised to ensure consistency with recommendations from these other initiatives.

FINDINGS

Role of Clinical Evidence

Fifty-three studies were identified that met the inclusion criteria for our literature review. While the literature provided context, it was subject to a number of limitations:

- No literature was found for some types of cancer.
- The wait time interval being measured was inconsistent from study to study. Only 11 studies explicitly reported on recommended wait times from diagnosis to surgery.
- None of the studies were randomized controlled trials, and two-thirds of the studies were retrospective.
- There was little evidence on the relationship between wait times and outcomes.

The recommended target wait times reflect consensus expert opinion informed by the findings of the literature review.

Broad Support for Targets

Using the evidence as a contextual framework, the Committee recognized the importance of having a broad consultation process to establish target wait times and to build consensus around those targets. The Committee received detailed feedback on the draft report and preliminary recommendations from 55 physicians and cancer care administrators. The draft report and recommendations were adjusted based on this feedback.

The Expert Panel provided strong feedback confirming the Committee's purpose of the recommendations that it would be inappropriate to use the proposed urgency categories and target wait times for clinical assessment of individual patients. The Committee agreed that these targets should be used only for ex-post evaluation of system performance against these wait time targets.

Need for Targets from Consultation to Diagnosis

Much of the evidence reviewed suggested that a delay in diagnosis affects patient outcomes more than a delay between diagnosis and surgery. In most studies, delays between diagnosis and surgery were relatively short compared with the delays occurring prior to a diagnosis of cancer.

From a patient's perspective, the real wait time in the system starts long before the decision to treat. By adding a second target for the period from the first consult to diagnosis, the Committee has implicitly created a third target (from first consult to surgery) that better reflects the patient's experience.

Measurement Issues

A challenge in implementing these target wait times is the need to ensure that the key dates (i.e., first consult, decision-to-treat, surgery) are consistently defined among the various

stakeholders. As well, there must be processes in place to collect data at these milestone dates.

Until recently, there has been no way to measure the decision-to-treat date. In distributing the Wait Time Strategy incremental volume funding, CCO required funded hospitals to submit the time interval from decision-to-treat to surgery for every cancer surgery case. This measure is very new. It will take time to work out operational processes to identify the time interval and assess the validity of this measurement. In contrast to the decision-to-treat data issues, the interval of first consultation to surgery is clearly defined, readily available from administrative data sets, and is already reported publicly by CCO.[2]

Dynamic Target-setting Process

At this time, consensus informed by the clinical evidence provides our best estimate of what these target wait times should be. The importance of this exercise has been to establish a first estimate in what will be an iterative process. Over time, new literature will be published to provide a better understanding of the science behind the targets and clinical practice patterns will change, resulting in additional refinements to the original targets. For example, we may eventually have the evidence to support:

- Target wait times that vary by tumour site.
- Changes in the expected proportion of surgeries that should be completed within the target wait times.

The recommended target wait times in this report are not an end point for the system, but rather a starting point for ongoing continuous quality improvement.

RECOMMENDATIONS

The Committee determined that most cancer surgery patients would fall into a single priority category and that the most practical approach was to set a target for the majority of cases and then identify exceptions. Therefore, it was agreed that patients with suspected or confirmed invasive cancer would be assigned to a single urgency category (category III), unless otherwise indicated. The Committee agreed on three additional urgency categories (category I for emergent cases, category II for very aggressive tumours and category IV for indolent tumours) to reflect the heterogeneity of tumour biology.

There was acknowledgement that there are legitimate clinical or patient circumstances for which these broad-based targets would not be applicable. For example, the patient's age, existing comorbidities, and patient choice can all contribute to a delay in the time from decision-to-treat to the surgical procedure. For that reason, it was agreed that Ontario should not be attempting to ensure 100% of patients meet the time targets.

Therefore, the Committee recommended that:

- Wait times for surgery for known or suspected invasive cancer be evaluated using four urgency categories.
- Emergent patients will be assigned to urgency category I and will receive care immediately.

[2] http://www.cancercare.on.ca/qualityindex/access/surgeryWaitTimes/index.html#.

- All other cancer surgeries be classified as category III, unless otherwise indicated.
- The wait time for 90% of all cancer surgeries measured by tumour site be less than or equal to 14 days from consult to decision-to-treat and 14 days from the ready-to-treat date to the date of surgery for category II, 28 days for category III and 84 days for category IV.

The reader is reminded that the targets are not intended to guide decisions about the urgency of the need for surgery for an individual patient.

These target wait times do not apply to surgeries to remove non-invasive or pre-malignant tumours (even if there are major or urgent health issues). These targets also do not apply to procedures for reconstruction or rehabilitation, palliative operations or operations for metastatic disease. In addition, the target interval from consult to decision-to-treat is not applicable to surgeries that are delayed because the surgeon and the patient have agreed on a "watchful waiting" strategy for treatment.

Table 1: Recommended Target Wait Times (days)

Urgency Category	Clinical Conditions	Consult to Decision-to-treat*	Ready-to-treat to Operation
		Target wait time (Days)	
I	Patients requiring surgery to remove known or suspected cancers that have immediately life-threatening conditions (e.g., airway obstruction, hemorrhage, neurological compromise)	Immediate	Immediate
II	Patients diagnosed with very aggressive tumours, such as central nervous system (CNS) cancer.	14	14
III	All patients with known or suspected invasive cancer that does not meet the criteria of urgency category II or IV.	14	28
IV	Patients diagnosed with indolent tumours.	14	84

A survey of a surgery Expert panel indicated that only 33% of the respondents believed that these targets are achievable. In general, the respondents described a surgical system that is constrained by human, physical and financial resources. Respondents cautioned that because cancer surgery shares resources with other surgeries, care must be taken to ensure that an increase in priority for cancer surgery does not result in increased delays for other surgeries. CCO is committed to working with the Ministry to begin to measure performance against these targets, to identify specific constraints and how they may be addressed, and to refine the targets as new information becomes available.

* From the date of the patient's first visit to the operating surgeon for this specific problem until the decision-to-treat date. The decision-to-treat date is the date on which sufficient pre-treatment testing is complete, the physician can reasonably assume that the patient will be treated, and the patient has agreed to the treatment. By this date, sufficient assessment will have been completed in order to reasonably assume that the procedure will go ahead, and an operating room booking is requested. This date is distinct from, and may precede, the date on which all pre-operative investigations are complete.

1.0 INTRODUCTION

1.1 THE ONTARIO WAIT TIME STRATEGY

In November 2004, Ontario's Ministry of Health and Long-Term Care (the Ministry) announced Ontario's Wait Time Strategy. The strategy was designed to reduce wait times by December 2006 by improving access to healthcare services for adult Ontarians in five areas: cancer surgery, selected cardiac procedures, cataract surgery, hip and knee total joint replacements, and magnetic resonance imaging (MRI) and computed tomography (CT) scans.

In the first phase of this strategy, the Ministry allocated $10 million to 20 hospitals in Ontario to fund an additional 1,700 cancer surgeries by March 31, 2005. This funding was intended to reduce the backlog in cancer surgeries and reduce the overall wait time for these surgeries.

Within the second phase of the strategy, the Ministry has asked for the development of prioritization tools and benchmarks. Specifically, the Ministry asked Cancer Care Ontario (CCO) to identify wait time targets for cancer surgery. CCO's Surgical Access to Care and Wait Times Subcommittee (the Committee) worked with the Program in Evidence-based Care and a panel of experts to develop the targets. The Committee includes members from regional cancer centres across Ontario representing a variety of subspecialties within oncology and representatives from CCO. It is a multidisciplinary panel of clinicians, managers, administrators, social and behavioural scientists, and health research methodologists. The membership of the Committee is provided in Appendix A.

1.2 THE IMPORTANCE OF WAIT TIME TARGETS FOR CANCER SURGERY

Surgery is a key component of curative treatment for most cancers. Because cancer may grow and spread to other parts of the body over time, an inappropriate delay in initiating treatment may result in the loss of an opportunity for a cure. In Ontario, some amount of waiting is inevitable, and in fact, desirable. The only way to prevent waiting for treatment is by having excess capacity in the system. Too much capacity creates an inefficient system. The challenge is to establish a reasonable wait time that balances the medical risk with the cost-effective availability of resources to deliver the needed surgery.

In addition to the medical risks of waiting for surgery, there are psychological impacts on the patient. Waiting for surgery, especially to treat a potential life-threatening condition, results in a great deal of anxiety for the patient. The longer the wait, the greater this anxiety becomes.

While there is a broad public perception that Ontarians wait too long for cancer surgery, the ideal target waiting times for cancer surgery are not known.

1.3 THE COMMITTEE'S MANDATE

The Committee's mandate was to recommend target wait times from the decision-to-treat to the date the surgery is performed. For the purpose of preparing these targets, the decision-to-treat date has been defined as the date on which sufficient pre-treatment testing is complete, the physician can reasonably assume that the patient will be treated, and the patient has agreed to the treatment. By this date, sufficient assessment will have been completed in order to reasonably assume that the procedure will go ahead, and an operating room booking is

requested. This date is distinct from, and may precede, the date on which all pre-operative investigations are complete.

The target wait times were to be developed based on clinical evidence and expert opinion from a wide range of surgical stakeholders regarding a safe waiting period for surgery. In reality, there will be many barriers, including the availability of sufficient human resources, to meeting the recommended targets. These targets are based only on the best evidence and have not been adjusted to reflect the capacity of the system to meet these targets.

1.3.1 Targets Will be Used for System Management

The Committee was asked to develop target wait times that could be used to monitor and evaluate the relationship between system capacity and the demand for surgery, as well as to plan for appropriate capacity. These targets will be used as a system management tool to identify resources required to meet the implied service levels and to direct resources where they are needed most urgently to meet these service commitments. These targets will allow planners and administrators to know how and when to intervene at a system level to improve cancer care for patients.

The recommended targets are not intended to guide decisions about the urgency of the need for surgery for an individual patient. Those decisions require careful consideration of individual clinical presentation and patient values and preferences and will continue to be made at the discretion of the surgeon in consultation with the patient. The heterogeneity of the many diseases that are cancer would make such a tool very complex, and there is insufficient scientific evidence to support development of such a tool at this time.

The development of target wait times is a dynamic process. As the system gains experience with the implementation of the targets and evaluates its performance and the impact on patient outcomes and quality of care, the targets can be refined to reflect this new knowledge. Over time, new literature will be published to provide a better understanding of the science behind the targets and clinical practice patterns will change, resulting in additional refinements to the original targets.

The recommended target wait times in this report are not an end point for the system, but rather a starting point for ongoing continuous quality improvement.

1.3.2 Maximum versus Ideal Wait Times

The Committee was asked to develop targets for maximum wait times. These maximums should be interpreted as the longest that any patient should have to wait, recognizing that some will require surgery sooner and some later within that time interval, based on the specific tumour biology. Surgeons will continue to have the flexibility to assign a longer or shorter wait time for individual patients as they do now.

1.3.3 Inclusion of Surgeries only for Known and Suspected Cancers

In addition to definitive surgical procedures aimed at removing a known invasive cancer, there are many surgeries performed for suspected cancer. Some surgical procedures can be both definitive and diagnostic (e.g., thyroidectomy, oopherectomy). For this reason, the Committee set targets for procedures for both suspected and known cancers.

The following types of surgery were not within the Committee's scope of work:

- Surgeries to remove benign tumours, even if there are major or urgent health issues.
- Surgeries to remove non-invasive or pre-malignant tumours.
- Procedures for reconstruction or rehabilitation.
- Palliative operations or operations for metastatic disease.

The wait time targets apply only to cases where it has been decided that surgical treatment is required. Where the surgeon and patient have agreed on a "watchful waiting" approach to care, these targets do not apply.

1.3.4 Inclusion of Time from Consult to Decision-to-Treat

In addition to providing advice on the time interval from decision-to-treat to date of operation, which is the focus of the Ministry's Wait Time Strategy, the Committee felt there would be value in deliberating on the time interval between the date of consult and decision-to-treat.

The date of consult is more easily measured with current data sets than is the date of the decision-to-treat. CCO is currently able to track the time from consult to surgery using administrative data sets, allowing immediate evaluation of province-wide performance against target times from the first consult to the date of treatment. In addition, CCO has recently implemented a process with those hospitals that have agreed to increase cancer surgery incremental volume activity to measure the time interval from decision-to-treat to surgery. Monitoring of this time interval will not be feasible until the needed indicators are collected from surgical centres. By introducing a second target wait time from first consult to decision-to-treat, CCO can begin to monitor the total period from first consult to surgery.

1.4 ORGANIZATION OF THE REPORT

The remainder of this report is organized as follows:

- Chapter 2 describes the methodology used by the Committee to develop the target wait times.
- Chapter 3 provides a summary of the key findings from the literature review. A copy of the full documentation of the literature review is provided in Appendix B.
- Chapter 4 describes the deliberations that shaped the Committee's development of a consensus expert opinion on target wait times.
- Chapter 5 outlines briefly the implications of implementing these targets.
- Chapter 6 provides the key conclusions of our report and the final recommendations.

2.0 METHODS

The overall approach to the development of target wait times had four major elements:

1. A systematic review of published literature.
2. A review of selected work related to surgical oncology wait time targets undertaken in other jurisdictions.
3. The development of consensus recommendations by the Committee and the documentation of the Committee's work in a draft report informed by steps 1 and 2.
4. Submission of the draft report and recommendations to an Expert Panel for review and comment.

2.1 SYSTEMATIC REVIEW

A working group of the Committee comprising clinicians and representatives of the Program in Evidence-based Care conducted a systematic review of the research evidence regarding diagnostic and surgical wait times. This review was undertaken to:

- Examine the impact of diagnostic and/or surgical delay on patient outcomes, and
- Find published reports defining acceptable or excessive wait times.

A search of the published literature regarding the prioritization of patients was not included. The Committee made an a priori decision to use consensus methods, informed by the evidence related to the other questions, to determine prioritization recommendations.

Published literature was searched using the medical databases MEDLINE (OVID; 1994 through April 4, 2005), the Cochrane Library, and the National Guideline Clearinghouse. Article bibliographies and personal files were also searched for evidence relevant to this report. The full MEDLINE literature search strategy can be found in Appendix B.

The working group identified 7,153 citations. After full-text screening and assessment for the inclusion criteria, 53 articles remained for review. Reports were selected for inclusion in this systematic review of the evidence if they met the criteria described below:

(i.) Reported on at least one of the following outcomes:
- Impact of diagnostic or surgical delay on patient survival, tumour size, recurrence, staging, quality of life, or adverse events. Due to time and resource constraints, evidence regarding psychological distress associated with delay was not considered in this review. The Committee acknowledges this is a common and important outcome for patients.
- An explicit time interval defining excessive diagnostic or surgical delay.
- An explicit time interval defining acceptable diagnostic or surgical delay.

Studies that reported delay data across more than one modality of care were included as long as part of the combined modality included surgery.

(ii.) Reported on at least one of the following cancer diagnoses: bladder, breast, cervical, colorectal, head and neck, esophagus, kidney, liver, lung, melanoma, ovarian, pancreatic, prostate, sarcoma, stomach, thyroid and uterine.

(iii.)Publication types encompassed in this review included evidence-based practice guidelines, standards documents, systematic reviews, randomized controlled trials, and observational studies. Fully published reports were preferred but abstract data were also considered. Publications in languages other than English were not considered. Where a high quality systematic review existed, the Working Group considered it and any reports that met inclusion criteria beyond the publication of the review.

Selection of the studies included in this review followed a two-step screening process.

- Abstracts of the identified studies were screened against inclusion criteria by at least one member of the working group.
- Full texts were obtained for all studies that met this first level of screening. Full texts were reviewed by at least one member of the working group, and data were extracted for those that met the criteria.

The full literature review can be found in Appendix C.

2.2 WAIT TIME INITIATIVES IN OTHER JURISDICTIONS

Work related to surgical oncology wait time targets has been undertaken in other jurisdictions in Canada. The Committee also considered reports, briefing notes, and recommendations from those jurisdictions.

2.3 CONSENSUS OPINION

The limited available evidence provided a general model of wait time intervals. The consensus discussions of the Committee members, based on their clinical experience and expertise, played a vital role in framing the details of the recommendations.

From these discussions, the Committee developed draft urgency categories and target wait times that were reached by a consensus process. These preliminary targets were documented in a draft report for further review.

2.4 EXPERT REVIEW

The Committee's draft report was circulated to an expert panel comprising:

- All surgical oncologists in Ontario (as provided by CCO's Surgical Oncology Program),
- All Regional Vice Presidents for cancer services,
- Members of the Committee, and
- Representation from the Ontario Medical Association (OMA) (e.g., OMA chairs in general surgery, otolaryngology, gynaecology, thoracic, and urology).

Participants were asked to review the report and complete an on-line survey requesting feedback on the methodology, recommendations, and implementation issues. Responses were received from 55 of the 128 physicians and cancer care administrators on the expert panel, yielding a response rate of 43%.

Based on the responses from the expert panel, the Committee revised the proposed urgency categories and target wait times.

A summary of the survey responses is provided in Appendix D.

2.5 FINAL REVISIONS

The surgical wait time report was the first of three reports prepared by CCO. After this report was submitted to the Ministry, CCO began work on wait time reports for radiation treatment and systemic therapy. CCO also continued to work with the Wait Time Information Office (WTIO) in developing the provincial approach to measuring and reporting surgical wait times. Based on deliberations and decisions made in these subsequent processes, this surgical wait time report was revised to ensure consistency with recommendations from these other initiatives.

Specifically, the following changes were made to ensure consistency with the Ministry's Wait Time Strategy:

- The terminology "target maximum wait time," which was the original terminology used by the Surgical Subcommittee, was changed to "target wait time."
- The percentage of patients who were expected to be treated within the target wait time was changed from 80% to 90%.

In addition, the definitions of the wait time events and wait time intervals were revised during the development of the radiation treatment and systemic therapy reports. This report has been updated to incorporate these revisions.

3.0 THE EVIDENCE BASE

This chapter provides a summary of the key findings from the literature review and work related to surgical oncology wait time targets in other jurisdictions that informed the target-setting process. The full literature review is presented in Appendix C.

3.1 THE LITERATURE BASE

The literature search identified 7,153 citations. Of those, 53 articles met the inclusion criteria and comprise the body of the evidence for this report. All of the articles reviewed were published within the past ten years.

Common reasons for excluding studies were:

- The failure to report on one of the outcomes of interest, and
- The reporting of data on a modality of care other than surgery or diagnosis.

There were many studies examining either reasons for the delay in diagnosis and surgery or strategies to reduce delay. While important, those questions were beyond the scope of this review and were not included. In addition, there were many reports summarizing delays found within a specific institution or jurisdiction. Unless those reports also provided data on patient outcomes or concluded with recommendations regarding specific time intervals of acceptable or excessive delay, they were not included.

Across the disease sites, the number of relevant studies ranged from no studies (i.e., esophagus, kidney, liver, thyroid and uterus) to 12 (breast cancer), as shown in Table 1.

Table 1: Profile of the Evidence, number of studies

Cancer Type	Total Studies	By Study Design				
		RCT[3]	Retrospective	Prospective	Standards	Unspecified
Bladder	4		3	1		
Breast	12		11		1	
Cervical	7		6	1		
Colorectal	11		5	5	1	
Head and Neck	4		1	2	1	
Lung	9		6	1	1	1
Melanoma	3		1	2		
Ovarian	1		1			
Pancreatic	1		1			
Prostate	2		1		1	
Sarcoma	2		1			1
Stomach	1		1			
Total studies	57[4]	0	38	12	5	2

[3] Randomized controlled trials.
[4] There were 53 articles. Some articles provided information on more than one disease site.

The quality of the studies reviewed was modest and subject to a number of limitations:

- There was little evidence on the relationship between wait times and outcomes. Acceptable delay rates were reported, but there often was little evidence demonstrating superior clinical outcome if the interval was met or inferior clinical outcome if it was not met. No studies reported on the relationship between delay (diagnostic or surgical) and disease recurrence, quality of life, or the risk of adverse events.
- None of the studies were randomized controlled trials, and two-thirds (38 out of 57) of the studies were retrospective. Therefore, the body of evidence available to inform deliberations was prone to biases that limit their ability to provide valid estimates of the effects of diagnostic or treatment delay on cancer outcome. This is perhaps most apparent in the reports of some retrospective studies that suggest the seemingly counter-intuitive conclusion that longer delays are better than shorter delays.

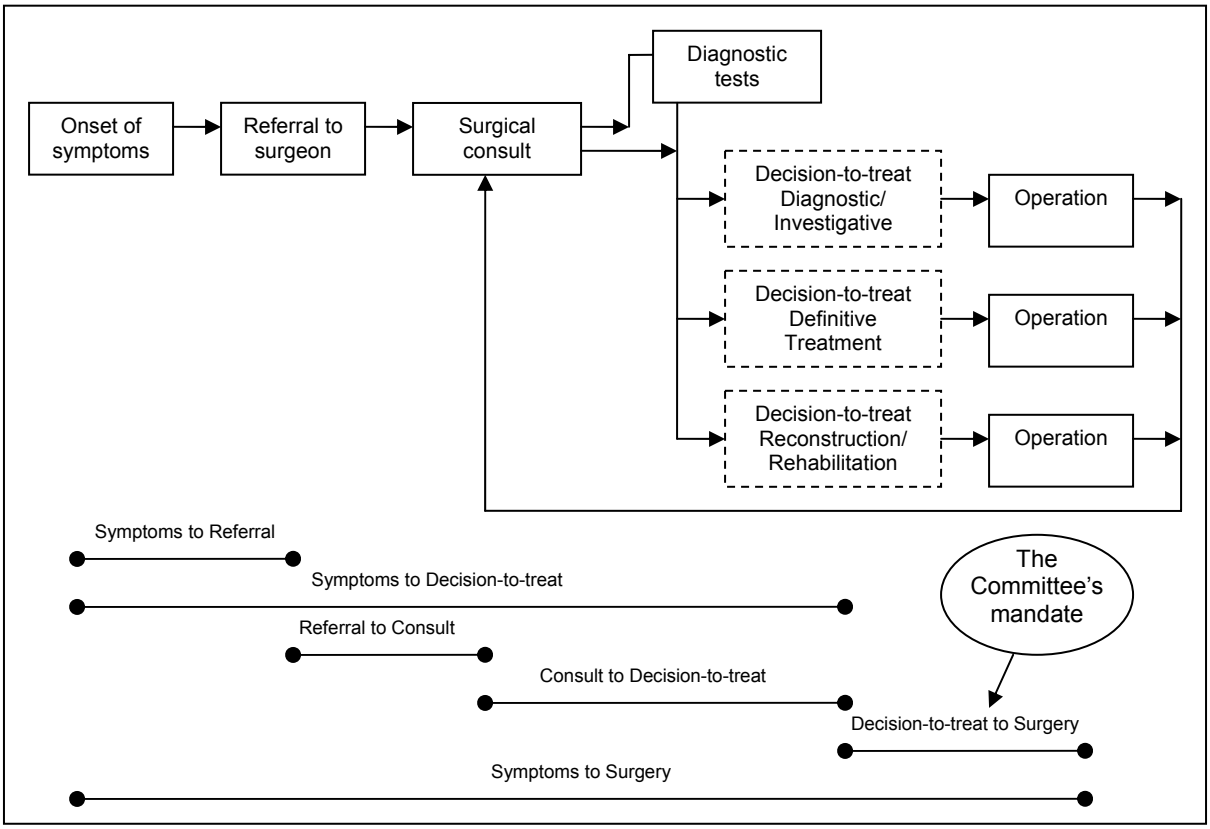
Drawing conclusions from the data in the literature was also difficult because of the many different definitions of the interval of delay that were used. For example, the interval may begin when:

- Symptoms are first identified,
- The referral is made to a surgeon,
- The first consultation with the surgeon, or
- The decision is made to operate (i.e., decision-to-treat).

Similarly, the interval being measured may stop at any point on the continuum. These relationships are shown graphically in Figure 1. As also shown in the figure, the patient may be referred for different types of surgery (i.e., the surgery may be diagnostic or definitive, or sometimes both at the same time) and may also be scheduled for a second surgery.

The Committee's mandate was to look at the time interval from the decision-to-treat to surgery. Few studies specifically commented on wait times from symptoms to diagnosis and only 11 explicitly reported on recommended wait times from diagnosis to surgery. Further, clinical data to support these intervals was missing. Therefore, it was very challenging to isolate this portion of the overall wait time and comment on data specifically related to it and to interpret it in a clinically meaningful fashion.

Figure 1: Key Dates in the Patient's Cancer Surgery Experience



3.2 SUMMARY AND INTERPRETATION OF THE EVIDENCE

Despite the limitations noted in the previous sections, the evidence that was identified does provide important context and structure to the target-setting process.

Much of the evidence reviewed suggested that a delay in diagnosis affects outcome more than a delay between diagnosis and surgery. In most studies, delays between diagnosis and surgery were relatively short compared with the delays occurring prior to a diagnosis of cancer.

Further, other factors such as the stage of disease, aggressiveness of the tumour, and comorbidities appear to have a stronger impact on survival than does the delay from the decision-to-treat to surgery. Nonetheless, among studies or standards documents that presented target wait times we found that:

- The shortest recommended waiting time was 14 days.
- The more common recommended target for maximum waiting time from the date of decision-to-treat to surgical treatment was one to two months.
- All studies recommended a target waiting time for surgical treatment of less than three months from the date of diagnosis.

Although we were not specifically looking for maximum or acceptable wait times from the onset of symptoms to the date of surgery, many studies did report wait times using this time interval.

The relevance of these times for our work is that the maximum wait time between diagnosis and surgery must, by definition, be shorter than the maximum wait time from the onset of symptoms to the surgical procedure. Four studies were reviewed that provided a recommended maximum wait time between the first symptoms and surgery. Two of these studies recommended one month or less, and two others recommended three months or less.

3.3 Generalizability of the Evidence

The literature review was designed to find relevant studies for 17 types of cancer. Only 53 relevant studies were found, of which only 11 recommended maximum or acceptable wait times from diagnosis to surgery, for only four types of cancer.

It is important to note that the evidence to substantiate recommendations regarding acceptable or excessive delays were often insufficient, unclear, or incomplete. It also important to note that there is unlikely to be significant advancements or improvements in the body of evidence in the short term.

3.4 Other Evidence

The Committee identified two urgency scoring systems that are used in Canada to assign an urgency score to all surgical disciplines:

- Kingston General Hospital Urgency Scale
- Saskatchewan Surgical Care Network.

Both of these systems assign a surgery to one of five (Kingston) or six (Saskatchewan) priority categories. Both were developed through clinical consensus.

Based on these two scoring systems, cancer surgeries would be classified as follows:

- In Kingston, most cancer patients are designated as priority level II[5], with a target wait time of 28 days to surgery.
- In Saskatchewan, all cancer patients are designated as priority level II, with a target of 95% of surgeries to be completed within 3 weeks (21 days).

These two jurisdictions have, through a consensus process, determined that 21 days (Saskatchewan) or 28 days (Kingston) is an acceptable maximum wait time for most cancer surgeries.

3.5 Summary Findings

There is little medical evidence on which to base recommendations regarding target wait times for cancer surgery. However, the literature does provide some useful context and data to guide the development of a consensus opinion. Specifically, the existing evidence does support the concept of three general categories of urgency for cancer surgeries. It also provides insights into which procedures have a higher or lower urgency than the majority of cases.

[5] With the exception of thyroid disease patients (in the absence of proven malignancy) who are designated as priority level III with a target time of 84 days).

4.0 THE CONSENSUS OPINION

4.1 CONSENSUS PROCESS

The development of a consensus opinion on urgency categories and target wait times was an iterative process involving three major steps:

- First, the Committee reviewed the literature and the urgency scoring systems in other jurisdictions. Based on this information and their clinical experience and expertise, the Committee members agreed on preliminary recommendations.
- The Committee's preliminary recommendations were documented in a draft report that was circulated to an Expert Panel of 128 physicians and cancer care administrators in Ontario. Each member of the Expert Panel was asked to review the draft report and provide comments through a web-based survey. Responses were received from 55 of the 128 invitees, yielding a response rate of 43%.
- After the results of the survey had been compiled, the Committee met again to consider this feedback and to revise the report and the recommendations based on the Expert Panel's comments.

Throughout the discussions, Committee members reinforced the idea that these target wait times are system management tools and are not intended to guide individual patient care or clinical decisions which, in contrast, require careful consideration of clinical presentation and patient values and preferences.

4.2 ENDORSEMENT OF COMMON WAIT TIME DEFINITIONS

The Wait Times Steering Committee asked the chairs of the three wait time subcommittees (i.e., surgery, radiation treatment and systemic therapy) to develop common definitions of wait time events and intervals that could be used by all three modalities. Once this process was completed, the Surgical Subcommittee adopted the definitions common to all three modalities in January 2006.

The relevant definitions for the wait time intervals described in this report are provided in Appendix E.

The Committee endorsed revised definitions for two key wait time events:

- The decision-to-treat (DTT) date will be defined as the date on which sufficient pre-treatment testing is complete that the physician can reasonably assume that the patient will be treated, and the patient has agreed to the treatment. If there is no planned delay, the DTT date is the same as the ready-to-treat (RTT) date.
- If a patient is not proceeding directly to radiation treatment but has a planned delay (i.e., other cancer treatment first, patient choice or physician choice), then the RTT date will be defined as the date on which any planned delay is over, and the patient is ready to begin treatment from both a social/personal and medical perspective.

Another significant change is for the Referral to Specialist Date, which is now defined as the date on which a request for consultation with a specialist is received in the specialist's office. If

the specialist does not accept the referral at this time (e.g., referral form incomplete, workup not complete), this date does not change.

4.3 Adoption of Common Wait Time Intervals

In its original report, the Committee recommended that the primary of interval of interest be the interval from the decision-to-treat date to the date of the operation. However, during the deliberations of the radiation treatment and systemic therapy subcommittees, it was found that the ready-to-treat date was a more informative starting point for measuring wait times because it excluded any planned delays (i.e., other cancer treatment first, patient choice or physician choice). The Committee members felt it was important to remove these waits because they were not within the control of the cancer treatment system.

This report has been updated to replace the interval from the decision-to-treat date to the operation date with the interval from the ready-to-treat date to the operation date. This interval is now consistent with the intervals reported within CCO by the other two modalities, and is more consistent with the Ministry's Wait Time Information System (WTIS).[6]

4.4 Urgency Categories

Cancer is a highly heterogeneous disease. A malignant tumour can be aggressive and fast growing, or slow growing, with few symptoms. In addition, some cancers cause symptoms that need very urgent attention (e.g., spinal cord compression, bleeding). There are also patient factors, economic, practical, and psychological, that contribute to what may be an ideal wait time for any given patient.

However, the Committee agreed that it would be both impractical and unnecessary to attempt to identify a wait time target for individual diseases and patient circumstances. The lack of scientific evidence relating wait times to outcomes further reinforced the limited value of developing highly detailed urgency ratings.

The Committee also considered its mandate to develop a system management tool rather than a tool to help inform decisions by clinicians. If such a tool is to be useful, the categories must be measurable. Having a single category for most cancer surgeries allows planners to monitor the system with relative ease.

Sixty-nine percent of the Expert Panel respondents agreed or strongly agreed that having three major categories was reasonable and appropriate.[7] The concept of a single urgency category for most cancer surgeries is also consistent with the urgency rating scores developed in Kingston and Saskatchewan.

Based on these considerations, the Committee agreed that grouping patients into a limited number of urgency categories would facilitate the identification of practical, measurable, system-level targets.

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[6] The Wait Time Information System excludes the dates that the patients is not available for surgery, is another wait to identify planned delays. However, the methodology for excluding these delays is slightly different than the methodology for calculating the ready-to-treat date. It is unclear at this time how much, if any, impact the difference will have on reported wait times for cancer surgery.

[7] The reader is reminded that the Expert Panel was asked about three urgency categories in addition to emergent cases.

The Committee also agreed that most cancer surgery patients would fall into a single category and that the most practical approach was to set a target for the majority of cases and then identify exceptions. Therefore, it was agreed that patients with suspected or confirmed invasive cancer would be assigned to a single urgency category (category III), unless otherwise indicated. Emergent cases were to be assigned to urgency category I.

4.4.1 Exceptions to the Common Category

Given the above decisions, the next set of deliberations was around which cancers were the "exceptions" that should be placed in categories II and IV. Based on feedback from the Expert Panel, it was decided to keep the number of exceptions small and generic in nature.

The Committee agreed on two additional urgency categories:

- Urgency Category II. For some cancers, it is critically important to have the surgery in a very short time period to reduce the risk of the disease advancing beyond the point where it can be effectively treated or because permanent disability may occur without timely surgery. The types of cancers that would be classified as urgent cases include, for example, central nervous system (CNS) cancer and other very aggressive tumours.
- Urgency Category IV. At the other extreme, some cancers are less aggressive and the risk of the tumour becoming more dangerous in the short term is lower.

Having two additional categories to capture cancers that are more or less urgent than most other cancers provides a degree of flexibility needed to recognize the heterogeneity of this disease.

4.5 TARGET WAIT TIMES

There was considerable discussion within the Committee and from the Expert Panel that within each category there will be patients that should be seen sooner than the target wait time. It was agreed that these groupings and targets represented a service goal within which most cancer patients would have surgery and are sufficient to be used to assess the overall health of the cancer care system. The importance of the intent of these targets – they are not intended to cover all situations, nor to inform individual case decision-making – was strongly emphasized.[8]

The Expert Panel provided strong feedback that it would be inappropriate to use the proposed urgency categories and target wait times for clinical assessment of individual patients.

4.5.1 Urgency Category I

Surgeries to remove known or suspected cancers that have immediately life-threatening conditions (e.g., airway obstruction, hemorrhage, neurological compromise) are expected to be treated on an emergent basis.

[8] The Subcommittee defined three categories (1, 2 and 3) in June 2005, and noted that emergency situations would be dealt with immediately. To be consistent with the Ministry's Wait Time Strategy, an emergent category was added, and the categories were renamed as I, II, III and IV, with the emergency category being category I.

4.5.2 Urgency Category II

The time interval that has been use in Kingston for two years was presented to the Committee as a starting point. For category II, this interval was seven days. It was noted that there was no scientific evidence to suggest one week was preferable to two weeks for these more urgent surgeries, which made Committee members reluctant to endorse this timeline. It was felt there were many legitimate practical barriers to meeting a one-week target and that a two-week timeframe was reasonable.

This decision was further influenced by debate about Category III. There were several cancers for which 28 days was felt to be too long, but one week was an unnecessarily aggressive target.

Based on these discussions and feedback from the Expert Panel, the Committee agreed that the target wait time for Category II should be 14 days.

4.5.3 Urgency Category III

The 28-day time interval used in Kingston was put before the Committee as a draft and was accepted. This time interval is also supported in the literature.

There was some discussion about a three-week (21-day) target, based on Saskatchewan's urgency scoring system. However, the Committee agreed that two weeks for Category II and four weeks for Category III addressed the perceived needs for all clinical scenarios discussed.

The Committee members agreed that the target wait time for the majority of cancer cases (i.e., cancers in Category III) should be 28 days, as long as the surgeon has the authority to prescribe a higher urgency and shorter wait time for an individual patient subject to the specific case.

4.5.4 Urgency Category IV

The literature suggested that three months was an appropriate wait time in a select grouping of other clinical scenarios. In no cases did the literature recommend a longer time interval.

The Committee agreed that three months (i.e., 84 days) would be an appropriate target wait time for these less urgent surgeries. The psychological impact of a cancer diagnosis was a significant factor in this recommendation.

4.5.5 Target Percentages

Given the lack of data or evidence to inform an ideal percentage, the Saskatchewan goal of 95% was put forward as a starting point. However, both the Committee and the Expert Panel believed that the proportion of cases that would be delayed due to clinical and patient considerations was considerably higher than 5%.

There was no literature or other evidence to support a definitive estimate of surgeries that are legitimately delayed. Therefore, the Committee originally adopted an estimate of 80% based on clinical experience and feedback from the Expert Panel. This percentage was later increased to 90% for two reasons:

- First, by changing the definition of the wait time interval to start at the ready-to-treat date instead of the decision-to-treat date, planned waits were excluded from the calculation.

Therefore, a higher percentage of patients (i.e., 95%) could be expected to have their operation within the target maximum wait time.
- The target percentage of 95% was changed to 90% in April 2006 to be consistent with the Ministry's Wait Time Strategy.

This percentage applies to all categories and should be applied to each tumour site. For example, this means that 90% of all breast cancers in category II should have a wait time from ready-to-treat to surgery of no longer than 14 days, in category III no longer than 28 days and in category IV no longer than 84 days.

4.6 CONSULT TO DECISION-TO-TREAT

The Committee was mandated by the Ministry to develop targets for the interval between the decision-to-treat and the operative procedure. However, the literature suggested that the length of time leading up to diagnosis had a much stronger relationship to outcomes than did the wait time from the decision-to-treat to the surgery. Therefore, as noted earlier in this report, the Committee felt there was value in also identifying a target for the interval from first consultation to decision-to-treat. Furthermore, administrative data for the time interval from consultation to surgery is readily available. This will allow immediate assessment of performance while the data on decision-to-treat date is being collected and validated.

The discussion of an appropriate wait time centred on how quickly one could reasonably expect to complete the full range of diagnostics required to support a definitive decision-to-treat. These diagnostic tests might include, for example:

- An assessment of fitness for surgery (e.g. cardiac and pulmonary function).
- Investigations for staging the disease (e.g., PET scan, CT scan, bone scan, systemic imaging, tissue biopsy, bronchoscopy).

The Committee felt it was not appropriate to require all pre-operative investigations to be complete in order to make a decision-to-treat. The Committee considered and accepted the definition of decision-to-treat as the date on which sufficient pre-treatment testing is complete, the physician can reasonably assume that the patient will be treated, and the patient has agreed to the treatment. The Committee felt that the definition needed additional clarification to ensure that this date is distinct from, and may precede, the date on which all pre-operative investigations are complete. For the purpose of this target-setting exercise, the definition has been refined to note that the decision-to-treat date is when sufficient assessment has been completed in order to reasonably assume that the procedure will go ahead and an operating room booking is requested.

In general, the Committee felt that a target wait time of two weeks was appropriate for most cancers. Although some tests may take longer than the two weeks to complete, the total target wait time of six weeks (e.g., two weeks from consult to decision-to-treat and four weeks to surgery) would still be an appropriate target for the overall wait time for most cancer patients.

4.7 TERMINOLOGY FOR THE TARGETS

The Committee initially elected to refer to its recommendation as "target maximum wait times."

Some Committee and Expert Panel members were uncomfortable with the concept of a "maximum" wait time. Although these wait times will be used to monitor the system and not to

manage individual patient care, there was still concern that a patient might mistakenly interpret the maximum wait time as defining the period of time before an adverse event is likely to occur. Further, members were concerned about the physician's, hospital's and CCO's liabilities if the maximum wait time were exceeded for an individual patient.

Other Committee members felt it was important to retain the concept of a maximum wait time as it was consistent with the terminology used in clinical practice.

The Committee ultimately decided to use the term "target maximum wait times," with the following clarifications:

- The recommendation that 90%[9] of all patients should be treated within the target wait time suggests that there are exceptions in which a patient might safely wait longer than the target interval.
- The inclusion of the word target captures the concept that these wait times are intended to be used as a measure of the system's performance, which is consistent with the Ministry's intentions.

In April 2006, this report was revised to use the term "target wait time" instead of "target maximum wait time" to be consistent with the terminology used by the Ministry in its Wait Time Strategy.

4.8 THE IMPORTANCE OF CONTINUOUS REFINEMENT

As noted frequently in this report, there is a paucity of clinical evidence to support specific target wait times. Therefore, these targets should be viewed as a starting point in the development of a rigorous monitoring and evaluation system for the delivery of timely cancer care.

Over time, we will need to reassess these targets to determine whether they achieve the desired impact on the system, or whether there are special considerations where tumour biology and the outcomes we measure will change. We will need to observe practice and use these observations to inform the revision of these targets.

[9] The Subcommittee initially recommended that the target be 80% of patients. The target was changed to 90% in April 2006 to be consistent with the target percentage used in the Ministry's Wait Time Strategy.

5.0 CONCLUSIONS AND RECOMMENDATIONS

5.1 CONCLUSIONS

5.1.1 Role of Clinical Evidence

Only 53 studies were identified that met the inclusion criteria for our literature review. While the literature provided context, it was subject to a number of limitations:

- No literature was found for some types of cancer.
- The wait time interval being measured was inconsistent from study to study. Only 11 studies explicitly reported on recommended wait times from diagnosis to surgery.
- None of the studies were randomized controlled trials, and two-thirds of the studies were retrospective.
- There was little evidence on the relationship between wait times and outcomes.

The recommended target wait times reflect consensus expert opinion informed by the findings of the literature review.

5.1.2 Broad Support for Targets

Using the evidence as a contextual framework, the Committee recognized the importance of having a broad consultation process to establish target wait times and to build consensus around those targets. The Committee received detailed feedback on the draft report and preliminary recommendations from 55 physicians and cancer care administrators. The draft report and recommendations were adjusted based on this feedback.

The Expert Panel provided strong feedback confirming the Committee's purpose of the recommendations that it would be inappropriate to use the proposed urgency categories and target wait times for clinical assessment of individual patients. The Committee also believes that these targets should only be used for ex-post evaluation of system performance against in meeting these wait time targets.

5.1.3 Need for Targets from Consultation to Diagnosis

Much of the evidence reviewed suggested that a delay in diagnosis affects patient outcomes more than a delay between diagnosis and surgery. In most studies, delays between diagnosis and surgery were relatively short compared with the delays occurring prior to a diagnosis of cancer.

From a patient's perspective, begins long before the decision-to-treat is made. By adding a second target for the period from the first consult to diagnosis, the Committee has implicitly created a third target (from first consult to surgery) that better reflects the patient's experience.

5.1.4 Measurement Issues

A key challenge in implementing these target wait times is the need to ensure that the key dates (i.e., first consult, decision-to-treat, ready-to-treat, surgery) are consistently defined among the

various stakeholders. As well, there must be processes in place to collect data at these milestone dates.

CCO has recently implemented a process with those hospitals that have agreed to increase cancer surgery incremental volume activity to measure the time interval from the ready-to-treat date to the date of surgery. Monitoring of this time interval will not be feasible until the needed indicators are collected from all surgical centres.

In addition, by introducing a second target wait time from first consult to decision-to-treat, CCO can begin to monitor the total period from first consult to surgery and compare it against the target wait times. The introduction of this target interval facilitates measurement, given that consult date and surgical date are readily available in administrative data sets.

5.1.5 Dynamic Target-setting Process

As described in this report, there is little quality data to support evidence-based target wait times for cancer surgery. The Committee believes that such evidence is not likely to become available in the medium term. However, the Ministry, CCO and the Committee all recognize the value of having system targets.

At this time, clinical consensus informed by the clinical evidence provides our best estimate of what these target wait times should be. The importance of this exercise has been to establish a first estimate in what will be an iterative process. As we collect data on performance against these targets, they can be refined to reflect this new knowledge. For example, we may eventually have the evidence to support:

- Target wait times that vary by tumour site.
- Changes in the expected proportion of surgeries that should be completed within the target wait times.

5.2 RECOMMENDATIONS

The reader is reminded that the following recommended targets are not intended to guide decisions about the urgency of the need for surgery for an individual patient. Those decisions require careful consideration of individual clinical presentation and patient values and preferences and will continue to be made at the discretion of the surgeon in consultation with the patient.

The Committee recommended that:

- Wait times for surgery for known or suspected invasive cancer be evaluated using four urgency categories.
- Emergent patients will be assigned to urgency category I and will receive care immediately.
- All other cancer surgeries be classified as category III, unless otherwise indicated.
- The wait time for 90% of all cancer surgeries measured by tumour site be less than or equal to 14 days from consult to decision-to-treat and 14 days from the ready-to-treat date to the date of surgery for category II, 28 days for category III and 84 days for category IV.

Table 2: Recommended Target Wait Times (days)

Urgency Category	Clinical Conditions	Consult to Decision-to treat[10]	Ready-to-treat to Operation
		Target wait time (Days)	
I	Patients requiring surgery to remove known or suspected cancers that have immediately life-threatening conditions (e.g., airway obstruction, hemorrhage, neurological compromise)	Immediate	Immediate
II	Patients diagnosed with very aggressive tumours, such as central nervous system (CNS) cancer.	14	14
III	All patients with known or suspected invasive cancer that does not meet the criteria of urgency category II or IV.	14	28
IV	Patients diagnosed with indolent tumours.	14	84

These target wait times do not apply to:

- Surgeries to remove benign tumours, even if there are major or urgent health issues.
- Surgeries to remove non-invasive or pre-malignant tumours.
- Procedures for reconstruction or rehabilitation.
- Palliative operations or operations for metastatic disease.
- Surgeries that are delayed because the surgeon and the patient have agreed on a "watchful waiting" strategy for treatment.

[10] From the date of the patient's first visit to the operating surgeon for this specific problem until the decision-to-treat date. The decision-to-treat date is the date on which sufficient pre-treatment testing is complete, the physician can reasonably assume that the patient will be treated, and the patient has agreed to the treatment. By this date, sufficient assessment will have been completed in order to reasonably assume that the procedure will go ahead, and an operating room booking is requested. This date is distinct from, and may precede, the date on which all pre-operative investigations are complete.

5.3 IMPLEMENTATION CONSIDERATIONS

The assessment of implementation considerations was not within the Committee's mandate. However, the Expert Panel was asked for input on implementation, and this report would not be complete without a description of some of the key challenges in meeting the recommended targets.

The Expert Panel's comments are best understood within the context of current wait times for cancer surgery. CCO has wait time data from surgical consultation to procedure for four of the most common cancer surgeries in Ontario.[11] According to these statistics, the actual wait times vary significantly by tumour site, as shown in Table 3.

These statistics also show that 75 percent of surgeries are performed within 6.7 weeks for large bowel resection and 7.4 weeks for mastectomy, which puts these two tumour sites close to the target time of 80% of surgeries being completed within six weeks (i.e., two weeks from consult to diagnosis and four weeks from diagnosis to surgery). However, the 75th percentile wait times for hysterectomy (11.3 weeks) and radical prostatectomy (17.1 weeks) are significantly longer than the recommended target wait times.

Table 3: 75th Percentile Waits from Surgical Consultation to Procedure, Ontario, 2001-2003 (weeks)

	Number of Weeks		
	2001	**2002**	**2003**
Large bowel resection	6.1	6.4	6.7
Mastectomy	7.1	7.1	7.4
Hysterectomy	10.0	9.9	11.3
Radical Prostatectomy	17.1	17.6	17.1

Source: http://www.cancercare.on.ca/qualityindex/access/surgeryWaitTimes/index.html#. Accessed May27, 2005.

The Expert Panel was asked a number of questions about whether the proposed target wait times were achievable and what additional resources would be needed to meet the targets.

Most respondents (87%) believed that additional human resources would be required to deliver these services. The specific professions mentioned included:

- Surgeons,
- Anesthesiologists,
- Nurses, and
- Pathologists.

Respondents also indicated a need for additional physical resources to meet these targets, including operating room (OR) time, and ICU, step down and ward beds.

[11] These data are from the Ontario Cancer Registry, the Canadian Institute for Health Information Discharge Abstract Database, and the Ontario Health Insurance Plan database. Compiled by ICES.

Similarly, 84% of respondents believed that additional financial resources were also required. Some also mentioned improved accountability frameworks for the administration of existing or incremental funding.

Only 33% of the respondents believed that these targets are achievable. In general, the respondents described a surgical system that is constrained by human and financial resources. Because cancer surgery shares resources with other surgeries, any increase priority for cancer surgery could result in increased delays for other surgeries.

APPENDIX A: Surgical Access to Care and Wait Times Subcommittee Membership

Jon Irish (chair)*, MD, University Health Network, Mount Sinai Hospital
Michael Sherar, PhD, London Regional Cancer Program
Ralph George, MD, Kingston Regional Cancer Centre
Marko Simunovic, MD, Hamilton Regional Cancer Centre
Jillian Ross,* RN, Cancer Care Ontario
Lee Fairclough, University Health Network
Janice Skot, Royal Victoria Hospital
David Urbach,* MD, University Health Network
Sandra Bennett,* Cancer Care Ontario
Victoria Welch,* Cancer Care Ontario
Hartley Stern, MD, Ottawa Regional Cancer Centre
Tom Song, MD, Niagara Health System
John Rowsom, MD, Peterborough Regional
Bish Bora, MD, Sudbury Regional Cancer Centre

Program in Evidence-based Care (PEBC) Participants

Melissa Brouwer,* PhD, Director, PEBC
Laurie Cocking, PEBC
Helen Massfeller, PhD, PEBC
Bryan Rumble, BSc, PEBC
Tom Oliver, BSc, PEBC
Tricia Waldron, MA, PEBC
Denise Stys Norman, BSc, PEBC
Manya Charette, BSc, PEBC
Carol DeVito, MA, PEBC

Additional Invited Experts

Barry Rosen, MD, University Health Network
Jason Dodge, MD, University Health Network
John Miller, MD, St. Joseph's Healthcare, Hamilton

* *Member of the surgical wait times working group.*

APPENDIX B: Search Strategy

Date: April 4, 2005
Database: Ovid MEDLINE(R) <1966 to March Week 4 2005>
Search Strategy:
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1 exp breast neoplasms/ (120328)
2 exp colorectal neoplasms/ (81576)
3 exp colorectal surgery/ (757)
4 exp prostate neoplasms/ (44888)
5 exp lung neoplasms/ (99491)
6 exp "head and neck neoplasms"/ (151599)
7 exp carcinoma, non-small-cell lung/ (11999)
8 or/1-7 (472288)
9 pediatric.tw. (69320)
10 "watchful waiting".mp. (600)
11 menstrual$.ti. (6076)
12 exp Fusion Proteins, gag-pol/ (227)
13 mice/ (713125)
14 muscles/ or adipose tissue/ or transcription factors/ (232828)
15 rats/ or membrane proteins/ or carrier proteins/ or tissue.mp. (1770815)
16 nerve tissue proteins/ (46062)
17 or/9-16 (2495910)
18 8 not 17 (393772)
19 exp health care rationing/ (8014)
20 delay$.ti. (28507)
21 wait$.ti. (3015)
22 timing.ti. (6383)
23 time.ti. (71168)
24 exp time factors/ or time interval.mp. (665562)
25 waiting lists.mp. or exp waiting lists/ (4065)
26 time.ti. and (prognosis/ or survival/ or recurrence/ or morbidity/ or mortality/ or treatment outcome/ or fatal outcome/) (2752)
27 or/19-26 (747050)
28 18 and 27 (21985)
29 randomized controlled trial.pt. (197506)
30 controlled clinical trial.pt. (67658)
31 random allocation/ (52441)
32 double blind method/ (80347)
33 single blind method/ (8692)
34 clinical trial.pt. (398766)
35 exp clinical trials/ (162257)
36 (clin: adj trial:).ti,ab. (83554)
37 ((singl: or doubl: or tripl: or trebl:) adj (mask: or blind:)).ti,ab. (76939)
38 random:.ti,ab. (301576)
39 research design/ (39871)
40 exp cohort studies/ (517396)
41 ((control: adj3 (group: or condition:)) or (control: adj2 (trial: or study or studies))).tw. (301977)
42 (cohort adj (study or studies or trial or trials)).tw. (21007)

43 intervention studies/ (2872)
44 clinic: trial:.tw. (83513)
45 case control:.tw. (29989)
46 exp case control studies/ (274408)
47 retrospective:.tw. (146742)
48 controls.tw. (315420)
49 prospective:.tw. (189063)
50 (observational adj (study or studies or trial or trials)).tw. (9422)
51 case series.tw. (8007)
52 meta-analysis.sh,pt. or meta-analy:.tw. or metaanaly:.tw. or metanaly:.tw. (19244)
53 ((systematic: or quantitative: or methodologic:) adj (review: or overview:)).tw. (7480)
54 clinical trial?, phase III.sh,pt. (4818)
55 clinical trial?, phase IV.sh,pt. (306)
56 clinical trial?, phase I.sh,pt. (8344)
57 clinical trial?, phase II.sh,pt. (12221)
58 phase III.mp. (9261)
59 phase IV.mp. (742)
60 phase 3.mp. (2179)
61 phase 4.mp. (1036)
62 phase four.mp. (242)
63 exp randomized controlled trials/ (35968)
64 rct.tw. (1456)
65 controlled clinical trials/ (2799)
66 exp practice guidelines/ (26925)
67 exp guidelines/ (44178)
68 guideline?.tw,pt,sh. (86542)
69 (practice guideline or guideline?).mp,pt. (105351)
70 consensus.sh,tw,pt. (46079)
71 or/29-70 (1882659)
72 28 and 71 (9726)
73 limit 72 to (humans and english language and yr=1994 - 2005) (4675)

APPENDIX C: The Literature Review

SYSTEMATIC REVIEW

A systematic review of the research evidence was undertaken to examine the impact of surgical delay on patient outcomes and to find published reports defining acceptable or excessive wait times. A search of the published literature regarding the prioritization of patients was not included; an a priori decision was made to have the Committee use consensus methods, informed by the evidence related to the other questions, to determine prioritization recommendations.

The working group identified 7,153 citations. After full-text screening and assessment for the inclusion criteria, 53 articles remained for review.

Questions

Four series of questions were asked for each of the following cancers: bladder, breast, cervix, colorectal, head and neck, esophagus, kidney, liver, lung, melanoma, ovary, pancreas, prostate, sarcoma, stomach, thyroid, and uterine.

I. Impact of Delay on Patient Outcomes

- What is the impact of delayed cancer diagnosis on patient outcomes?
- What is the impact of delayed surgical treatment on patient outcomes?

For each of the questions, the outcomes of interest included survival, tumour size, stage, recurrence, quality of life, and risk of adverse events.

II. Definition of Acceptable and Excessive Delay

- How are maximum-acceptable and excessive delay defined in the published literature for the diagnosis of adult patients suspected of having cancer?
- How are maximum-acceptable and excessive surgical delay defined in the published literature for adult patients diagnosed with cancer?

The outcome of interest is a metric of time.

Search Strategy

Published literature was searched using the medical databases MEDLINE (OVID; 1994 through April 4, 2005), the Cochrane Library, and the National Guideline Clearinghouse. Article bibliographies and personal files were also searched for evidence relevant to this report.

Reports were selected for inclusion in this systematic review of the evidence if they met the criteria described below:

(i.) Reported on at least one of the following outcomes:

- Impact of diagnostic or surgical delay on patient survival, tumour size, recurrence, staging, quality of life, or adverse events. Due to time and resource constraints, evidence regarding psychological distress associated with delay was not considered

in this review. The Committee acknowledges this is a common and important outcome for patients.
- An explicit time interval defining excessive diagnostic or surgical delay.
- An explicit time interval defining acceptable diagnostic or surgical delay.

Studies that reported delay data across more than one modality of care were included as long as part of the combined modality included surgery.

(ii.) Reported on at least one of the following cancer diagnoses: bladder, breast, cervix, colorectal, head and neck, esophagus, kidney, liver, lung, melanoma, ovary, pancreas, prostate, sarcoma, stomach, thyroid, and uterine.

(iii.)Publication types encompassed in this review included evidence-based practice guidelines, standards documents, systematic reviews, randomized controlled trials, and observational studies. Fully published reports were preferred but abstract data were also considered. Publications in languages other than English were not considered. Where a high quality systematic review existed, the Working Group considered it and any reports that met inclusion criteria beyond the publication of the review.

The full MEDLINE literature search strategy can be found in Appendix B.

Selection of the studies included in this review followed a two-step screening process. Abstracts of the identified studies were screened against inclusion criteria by at least one member of the working group. Full texts were obtained for all studies that met this first level of screening. Full texts were reviewed by at least one member of the working group, and data were extracted for those that met the criteria.

OTHER EVIDENCE

Work related to surgical oncology wait time targets has been undertaken in several jurisdictions throughout Ontario. The Committee also considered reports, briefing notes, and recommendations from those regions.

OVERVIEW OF LITERATURE RESULTS

Seven thousand one hundred fifty-three citations emerged from the literature search, and screening of the abstracts yielded 172 that met the criteria for full-text screening. Of those, 53 met inclusion criteria and comprise the body of the evidence for this report.

The overall quality and quantity of the evidence is modest. There is considerable variability in the number of relevant studies across the disease sites, ranging from 0 to 12.

Common reasons for excluding studies were the failure to report on one of the outcomes of interest and reporting of data on a modality of care other than surgery or diagnosis. There were many studies examining either reasons for the delay in diagnosis and surgery or strategies to reduce delay. While important, those questions were beyond the scope of this review. In addition, there were many reports summarizing delays found within a specific institution or jurisdiction. Unless those reports also provided data on patient outcomes or concluded with recommendations regarding specific time intervals of acceptable or excessive delay, they were not included.

No studies reported on the relationship between delay (diagnostic or surgical) and disease recurrence, quality of life, or the risk of adverse events.

It is important to note that the evidence to substantiate recommendations regarding acceptable or excessive delays were often insufficient, unclear, or incomplete. Acceptable delay rates were reported, but there often was little evidence demonstrating superior clinical outcome if the interval was met or inferior clinical outcome if it was not met.

There were no studies meeting the inclusion criteria for cancers of the esophagus, kidney, liver, thyroid, or uterus. The recommended target wait times for those conditions were based exclusively on the consensus of expert opinion. For each of the remaining disease sites, a summary of the evidence is provided.

Bladder Cancer

A total of four studies met the inclusion criteria (1-4). Of those studies, one report (1) was a prospective study, and three reports (2-4) were retrospective studies.

In a retrospective study, Liedberg et al (3) evaluated whether delay in diagnosis of invasive bladder cancer affected the risk of bladder cancer death. The median diagnostic delay was 144 days (range 12-2866) for the total cohort of patients. A significantly longer diagnostic delay ($p = 0.02$) was detected for more advanced tumour stages (T1 = 124 days; T2-T4 = 157 days). Tumour stage correlated strongly ($p < 0.001$) with the cumulative incidence of bladder cancer mortality. For T1 tumours, there was a trend towards a better disease-specific survival for patients with a shorter diagnostic delay (<6 months versus [vs.] > 6 months). An inverse relation between diagnostic delay and bladder cancer death was found in muscle-invasive bladder cancer. That latter finding was attributed to more aggressive tumour growth.

In a prospective study of 1537 patients, Wallace et al (1) found that there was significantly better survival for patients referred to a hospital by the general practitioner (GP) within 14 days of the onset of symptoms than those referred after 14 days. Patients with a shorter interval between the onset of symptoms and the GP referral had a lower tumour stage and 5% better five-year survival. There was a trend towards a better prognosis for patients with T1 tumours with a shorter diagnostic delay of < 6 months. The total delay time, from the onset of symptoms to surgery, had no effect on survival in that study.

Sanchez-Ortiz et al (2) recommended that patients should undergo a radical cystectomy in less than 12 weeks from the diagnosis of muscle invasion due to bladder cancer. They found that a delay in surgery of more than three months was associated with advanced pathological stage (84% patients; Stage pT3a or N+ or greater) compared to those patients (43%) who underwent surgery within 12 weeks. Surgical delay also increased the risk of lymph node metastases alone, independent of pathological T stage ($p = 0.04$). The three-year estimated survival was lower (34.9% $\pm$ 13.5%) for those with a surgical delay >12 weeks compared to those with a shorter interval (62% $\pm$ 4.5%; hazard ratio [HR] 2.51 95% confidence interval [CI] 1.30-4.83, $p = 0.006$).

Similarly, May et al (4) recommended that the interval from muscle invasion to radical cystectomy should be < 3 months. They also found that a delay of > 3 months was associated with advanced pathological stage and poorer progression-free survival.

Breast Cancer

A total of 12 reports were obtained (5-16). Results from retrospective studies demonstrate a positive correlation between time to diagnosis and tumour size (5-10; 15), risk of metastases to lymph nodes (5;7-9), stage of disease (11-13), and death (8;12). Those findings, however, are not consistent with other studies finding no relationship between delay and the clinical outcomes (7;12;13).

There is a range (<1 month to < 6 months) of recommended acceptable/excessive diagnostic delays reported in the literature. However, the interval of three months has been a common time frame used, and studies have demonstrated poorer clinical and prognostic outcomes for women with breast cancer that exceed this time (12;13).

In 1999, Richards published a comprehensive high-quality systematic review of 87 observational studies, published between 1907 and 1996 and involving 101,954 breast cancer patients, examining the relationship between the time from onset of symptoms to start of treatment (all modalities) and clinical outcomes (13). In three separate comparisons, 5 year survival rates were significantly lower (statistically and clinically) for patients with longer delays. Richards found that patients with delays of > 3 months had 12% lower 5-year survival rates than those with delays < 3 months (OR 1.47, 95% CI 1.42-1.53); patients with delays of 3 to 6 months had 7% lower 5-year survival than those with delays < 3 months (OR 1.24, 95% CI 1.17-1.30); and patients with delays < 6 months had 12% lower 5-year survival rates than those with delays > 6 months (OR 1.45, 95% CI 1.40-1.50). These findings were true with studies published before 1960, studies published after 1960, studies with unrestricted samples, and studies that included only operable women. In addition, thirteen studies in the review found that larger delays were associated with a more advanced stage of disease and worse survival, and eight studies in the review showed a significant relationship between delay and tumour size. Richards concluded that a delay exceeding three months between symptom onset and the start of treatment could be considered excessive. Specific data regarding surgical wait times were not provided separately. Since this study, three studies (7;10;14) addressing surgical delay in breast cancer patients have been found.

Montella et al (10;14) published two reports on one study that assessed the determinant factors for diagnostic delay in a cohort study of women (n = 644) with operable breast cancer. In delay intervals of three to six months (95% CI 1.4-3.7, p = 0.001) and > six months (OR 2.4, 95% CI 1.5-3.7, p < 0.005), women were more likely to present with tumours > 2 cm than with tumours < 2 cm.

Ganry et al (7) investigated the influence of abnormal screens results on diagnostic delay and the prognostic indicators (tumour size, axillary lymph node metastasis) of women with screen-detected breast carcinoma. Women with high-suspicion screens (n=979) were investigated more promptly, presented with larger tumours (62% vs. 42%, p = 0.03), and were more likely to be lymph-node positive (36% vs. 17%, p = 0.02) compared to women with intermediate-suspicion screens (n = 1,008). A delay of > three months and ≤ six months was associated with a 1.4-fold increase in the risk of lymph node metastases. While a delay of > six months was associated with a 2.0-fold increase. Longer delay to diagnosis was also associated with increasing tumour size. Compared with the reference interval (≤ 1 month), the odds ratio for tumour size greater than 10 mm was 1.4 (95% CI 0.90-1.90) for a delay of one month to ≤ 6 months, and 1.8 (95% CI 1.02-2.85) for a delay > 6 months. However, Ganry et al (7) indicated that the interval from diagnosis to treatment did not show any significant differences. Their

findings showed that a delay to treatment was not correlated with the screening results but rather with the results of further investigations.

Finally, quality-indicator standards for breast cancer were published by the RAND group (16). That panel recommended (i) wait times no greater than three months for the time interval between the detection of a palpable breast mass to the assessment procedure, (ii) wait times no greater than three months for the time interval between a second visit to detect a breast mass to biopsy, fine needle aspiration (FNA), or ultrasound, (iii) wait times no greater than six weeks for the time interval from suspicious mammography or persistent palpable mass not cystic on ultrasound to biopsy or FNA, and (iv) wait times no greater than six weeks for the time interval from when FNA cannot rule out malignancy to biopsy.

Cervical Cancer

Seven studies met the inclusion criteria; five reported results on the delay of surgery for cervical cancer with the intent of achieving fetal maturity, and two reported outcomes associated with diagnostic delay. However neither study reported whether definitive treatment included surgery, nor were patient survival outcomes reported.

In a prospective study (17), eight patients with stage IB cervical cancer delayed treatment for a median of 16 weeks (range 3 to 40 weeks) prior to cesarean section and radical hysterectomy. No clinical progression of disease was detected in any of the patients and all were alive and disease-free after a median follow-up of 33 months (range 13-68 months).

A planned delay to achieve fetal maturity was reported in one retrospective study of 12 patients with early-stage (IA1 to IB2) invasive squamous cell carcinoma of the uterine cervix (18). Eight patients had stage IA1 disease, while the stage of disease ranged from IA2 to IB2 in the remaining four patients. All 12 patients were successfully treated after a planned delay ranging from six weeks to 25 weeks with no evidence of disease at follow-up (range 52 to 156 months). The authors concluded that for patients with early stage disease, a planned treatment delay of up to 25 weeks was acceptable.

One retrospective study (19) reported a median delay of 3.5 weeks (range 2-10 weeks) of planned delay to treatment for six pregnant women diagnosed with cervical cancer (stage IB to stage IIB). Five of the six women received a radical hysterectomy, with or without radiotherapy, and one patient received radiotherapy alone. Of the five women who received surgery, one died of relapse at 12 months, and four were disease-free after a median follow-up of 82 months (range 16 to 142 months).

A retrospective study by Sood et al. (20) reported results for 11 patients with stage IA1 to IB1 squamous cell carcinoma who had a median planned delay of 16 weeks (range 3-32 weeks) prior to treatment with surgery. All 11 patients were alive and disease-free after a mean follow-up of 118 months (range 12-360 months).

One trial (21) reported two patients with stage IB squamous cell cervical cancer who delayed treatment for 18 and 19 weeks respectively to achieve fetal viability. After a follow-up of 62 and 69 months respectively, both patients were alive with no evidence of disease. The authors reported that one other patient in the review elected to delay surgery for 13 months prior to treatment with caesarean section, radical hysterectomy, and pelvic lymphadenectomy. No patient outcome data were reported for that one patient.

To assess the delay between diagnostic procedures and patient impact, one study retrospectively compared 388 patients who had undergone loop electrosurgical excision procedure (LEEP) within 12 weeks of diagnosis to 68 patients with LEEP performed > 12 weeks from diagnosis (22). The authors report an 87% agreement between biopsy and LEEP histopathology to within 1 degree ($k = 0.81$, $p=0.01$) indicating that a time delay of 12 weeks did not adversely affect patient outcomes. In another retrospective review of 72 patients with high-grade squamous intraepithelial lesions (23), the elimination of colposcopy-directed biopsy before LEEP was significantly associated with a shorter time interval from Papanicolaou (Pap) testing to definitive treatment (98 days versus 49 days, $p<0.001$).

In summary, regarding the delay of treatment to achieve fetal viability, five studies with a combined total of 39 patients reported that surgical delay was feasible for women with early stage disease. One prospective study reported eight women who declined the recommendation of immediate surgery in favour of delayed treatment. In this study, there was no evidence of clinical progression of disease with a planned delay to surgery, even in one woman with a delay of 40 weeks. While the remaining retrospective reports did not report differences in stage of disease from diagnosis, all but one patient was alive and disease-free at the time of follow-up reviewed by the investigators. The small number of patients precludes any definitive conclusions; however, it would appear that patients with early-stage disease could reasonably choose between immediate treatment, with termination of the pregnancy, or delayed treatment until fetal viability.

While the time to diagnostic delay does not directly address the question of delay to surgery and negative patient outcomes, one retrospective study reported that a delay of 12 weeks between diagnostic testing did not negatively change clinical diagnoses, and another retrospective review reported that the time to definitive treatment could be reduced by the elimination of colposcopy-directed biopsy before LEEP.

Colorectal Cancer

A total of ten reports were obtained (16;24-32) and one standards document (16). Of the ten reports, five were retrospective studies (24;25;27;30, 33), five were prospective studies (26,28;29;31,32), and one was a standards document (16). Seven reports examined colorectal-cancer-combined patients (24;25;27,30-33), two reports examined rectal cancer patients only (28;29), one report examined colon cancer patients only (33), and the cross-sectional survey report (34) was not applicable as it did not involve the treatment of any cancer patients. The number of patients included in those reports ranged from a low of 72 (29) to a high of 1,457 (25).

Within the reports obtained, the definition of an acceptable delay varied and was measured using different intervals (e.g., development of symptoms to surgery or first physician visit to surgery). Three reports (30-33) stated an acceptable time period from the appearance of the initial symptoms to surgery, two studies recommended a time interval of no more than three months (30,31), and one study recommended a time interval of no more than one month (32). Two reports (25;28) stated an acceptable time period from the initial visit to a GP to treatment (all modalities combined), which varied from no more than two months (28) to no more than three months (25). One report stated an acceptable time period from the initial GP visit to surgery as being no more than two months (24). Three reports (24;26;27) identified an acceptable period of time from the initial GP visit to specialist referral as being no more than two weeks. This Two-week Rule (TWR) is current policy in the UK. One report (29) stated that an acceptable period of time between the completion of neoadjuvant treatment with

chemoradiotherapy and surgery should be no more than eight weeks (6-8 weeks was the stated range). Clinical data supporting any of those recommendations were not provided.

Only one study, by Roncoroni et al (31), provided overall survival data. In that prospective study, 100 patients with colorectal cancer (modified Duke's stages A,B,C, and D) were stratified into three different groups, according to the length of delay between the onset of symptoms and surgery, as follows: Group A–less than 12 weeks (the stated standard); 31 patients, Group B–more than 12 weeks but less than 20 weeks; 31 patients, and Group C–more than 20 weeks; 38 patients. All patients underwent surgery within two weeks of diagnosis. Five-year survival results were Group A–75%, Group B–46%, and Group C–41% (all estimated from the survival curve). Statistically significant ($p<0.05$) differences were detected in the five-year survival rates between Group A and Group B and between Group A and Group C, favouring the patients with the shorter (less than 12 weeks) delay. No five-year overall survival difference was detected between Groups B and C. That overall survival advantage favouring a less-than-12–week delay was detected at five years only. Univariate analysis revealed delay to be a factor in five-year overall survival ($p<0.03$), but that finding was not confirmed in a subsequent multivariate analysis that detected five-year overall survival and disease-free survival benefits for pathological stage (earlier being better) and preoperative complications (fewer and less severe being better) only.

The RAND quality indicator report provides recommendations regarding diagnostic and surgical delays for patients with colorectal cancers (16). All patients with positive screening sigmoidoscopy tests should be offered a diagnostic colonoscopy within three months. They also advise that patients diagnosed with a malignant polyp should be offered a wide surgical resection within six weeks if any of the following are true: the colonoscopy report states that (i) the polyp was not completely excised, (ii) the margins are positive, (iii) lymphatic or venous invasion is present, or (iv) histology is grade 3 or poorly differentiated. Patients who are diagnosed with colon cancer and who do not have metastatic disease should be offered a wide resection with anastamosis within six weeks of diagnosis. Finally, patients who are diagnosed with rectal cancer that appears clinically to be Stage II or III should be offered one of the following surgical resections within six weeks of diagnosis or completion of preoperative therapy (or be enrolled in a clinical trial with documentation of informed consent): (i) low anterior resection or (ii) abdominal perineal resection.

Head and Neck Cancer

Four reports met the inclusion criteria for delays related to head and neck cancers (35-38). Primary outcomes reported in the identified literature included delay from first symptoms to first medical consultation or diagnosis (patient delay), delay from diagnosis to primary treatment (professional delay), or delay from first symptoms to primary treatment (total delay). It should be noted that data on delay to primary treatment included radiotherapy, chemotherapy, and/or surgery, and specific data on delay to surgery were not available in any of the reports. With the exception of one standard document, acceptable versus excessive delay criteria were not explicitly defined in the identified studies.

Data related to delay (patient delay, professional delay, and total delay) were extremely sparse. In the two studies reporting data, no association between increased patient delay and negative patient or tumour outcomes (35,36) was found. Three studies reported on patient outcomes related to professional delay. One study reported the upstaging of 69 patients due to a median professional delay of 5.5 months (37). That study reported significant reductions in overall survival for patients who were upstaged when compared to historical-matched controls, but

surgery was only performed in 34% of patients, and surgery-specific outcome data were not reported. One study reported that professional delay greater than three months was associated with an increased risk of late-stage disease when compared to delays less than one month, but, again, surgery-specific outcome data were not reported (36). One study also reported an association between small tumour presentation and greater professional delay (35). Finally, in one report, there was an increased risk of late-stage disease among all categories of total delay greater than one month (36).

Minimum standards in delay developed through consensus by the British Association of Head and Neck Oncologists were reported in one study (38). The consensus of that group was that the total time from first symptoms to surgical treatment should be approximately 2.5 months. Specifically, the standards recommended that the patient delay from first symptoms to seeking medical consultation should be no greater than one month, the professional delay from general practitioner to the time of diagnoses be no greater than 28 days, and the time from diagnoses to surgery be no greater than 14 days. Those recommendations were not substantiated with data demonstrating superior clinical outcomes for patients in circumstances where targets were met in comparison with patients in circumstances where targets were not met.

Lung Cancer

A total of nine reports met the inclusion criteria (16;39-46): six were retrospective studies (40-43;45,46), one was a prospective study (39), one did not specify the type of design (44), and one was a standards document (16). The size of the patient groups studied ranged from 39 (43) to 1,277 (40). At the time of diagnosis, one study (42) focused on lung cancer in general, four (39;40;43;44) examined lung cancer and provided a synopsis of the types of cancer that were diagnosed (i.e., squamous cell, adenocarcinoma, and large cell and small cell), and three studies focused on non-small cell lung cancer (NSCLC) (41;45;46).

Although there were several studies that reported on mean and median delays experienced by patients in specific institutions or jurisdictions, six studies reported data associating delay with clinical outcomes (41-46) and two studies commented on acceptable or excessive delay times (39;40).

Six studies provided evidence on the impact of diagnostic or surgical delay on clinical outcomes. The results of those studies were decidedly mixed. Myrdal (41) examined the relationship between delay and prognosis in 466 patients with NSCLC to investigate impact of delay time from first symptoms and from first hospital visit to the start of treatment. In patients with symptom-to-treatment delay of less than three months, three-year survival was 11%, whereas for patients whose delay was greater than six months, the three-year survival was 35%. Similarly, three-year survival for patients with the shortest hospital delay (<1 month) was worse compared to those with long delays (> 3 months), 19% versus 43%, respectively. Those seemingly counterintuitive findings were accounted for by prognostic factors: the patients seen first and treated first were more ill and at later stages of the disease than were those seen later.

In contrast to those findings, Christensen (42) reported a significantly shorter median delay emerged for stage I and II compared to stage III and IV in the time interval between the appearance of first symptoms and surgery ($p < 0.037$). Similar findings emerged in the time interval from first contact with the health care system to surgery ($p < .01$).

Finally, in four other studies, no relationship was found between surgical delay and the stage of disease (43;44) or survival (44-46).

Two studies reported perspectives on acceptable or excessive intervals of delay (39;40). Koyi measured time to various points on the disease-treatment trajectory for 154 Swedish lung cancer patients (39). Koyi concluded that a seven-month delay between the signs of first symptoms and treatment (all modalities) was excessive. Koyi also stated a median delay of nine days or a mean of one month was appropriate from the appointment with a specialist until diagnosis. However, in neither instance were patient outcome data supporting those recommendations provided.

Buccheri and colleagues examined diagnostic delay for 1,277 lung cancer patients (40). Here, a survival advantage was found in favour of those patients whose referral delays (time from symptoms to appointment with specialist) was less than two months compared to those with a referral delay greater than two months. No data regarding the delay to definitive diagnosis or surgery were provided.

Finally, the RAND report makes recommendations regarding the diagnosis and surgical treatment of patients with lung cancer (16):

- Patients with Stage I and II NSCLC be offered a lung resection (pneumonectomy, lobectomy, or wedge resection) within six weeks of diagnosis, unless contraindicated.
- Patients with Stage III non-small cell lung cancer with good performance status be offered at least one of the following within six weeks of diagnosis (unless contraindicated or enrolled in a clinical trial with documentation of informed consent): (i) thoracotomy with surgical resection of the tumour; or (ii) radiation therapy to the thorax with chemotherapy.

Melanoma

Three reports regarding two studies were obtained (47;48;49). Of those studies, one study was retrospective (47) and one, reported in two papers, was prospective (48;49).

In two reports of a prospective study, Richards et al (48;49) examined the role of patients and doctors on the diagnostic delay of melanoma. Acceptable delay was defined as less than two months for patients seeking medical attention after noticing a suspicious lesion. Furthermore, an acceptable time interval between the diagnosis and surgical removal of the lesion was defined as less than one month. There was no survival data reported.

Bennett et al (47) examined the impact of diagnostic delay on the clinical outcome in melanomas of the foot. Delays in diagnosis (mean delay = 14 months) had no demonstrable effect on clinical outcome. Instead, the inherent aggressiveness of the tumour growth accounted for poor clinical outcomes.

Ovarian Cancer

One retrospective study (50) of 135 women was considered in the review of the evidence. Kirwan and colleagues found that, while age of the patient, stage of disease, and other clinical symptoms were significant predictors of survival at 18 months, delay in referral or diagnosis was not found to adversely affect survival. No additional evidence emerged.

Pancreatic Cancer

One retrospective study of 146 pancreatic cancer patients was found (51). Gilliam found the presence of patient jaundice was associated with significantly shorter waits to diagnosis. They concluded that 14 days was an acceptable delay in the diagnosis of pancreatic carcinomas. However, there were no data presented to support superior patient outcomes if that target was met.

Prostate Cancer

One study presenting original data and one standards document met the inclusion criteria (16;52). Nam et al (52) retrospectively assessed the impact of delayed time to surgery (radical prostatectomy) in patients (n=645) with clinically localized prostate cancer (stages T1-2) who were treated between 1987 and 1997. Delay to surgery was defined as being greater than or equal to three months after diagnosis. An acceptable time-to-surgery was considered to be less than three months after diagnosis (referred to as early surgery). The effect of delay was also assessed by categorizing wait time into quartiles (i.e., <43, 43-68, 69-97, and >97 days from diagnosis). The primary endpoint of the study was biochemical recurrence, which was defined by the authors as a prostate-specific antigen (PSA) elevation of at least 0.2ng/ml on two consecutive measurements. Metastasis-free survival was also an outcome of interest. The mean follow-up time for all patients was four years. Four hundred fifty-six patients (70.7%) and 189 patients (29.3%) underwent early versus delayed surgery, respectively. There were no statistically significant differences in the distribution of important prognostic variables (i.e., stage, Gleason score, and PSA level at diagnosis) between the two groups, with the exception of PSA level. More patients in the delayed surgery group had a PSA level of >10ng/ml at diagnosis (p=0.003). The crude hazard ratio (HR) for biochemical recurrence was 1.58 (95% CI, 1.0-2.4; p=0.04) for delayed surgery compared to early surgery. However, after adjusting for all prognostic variables using multivariate analysis, the benefit with early surgery was no longer statistically significant (HR=1.46; 95% CI, 0.9-2.3; p=0.09). Stage, Gleason score, and PSA level at diagnosis (>20ng/ml) were all statistically significant predictors of biochemical recurrence in the multivariate model. The 10-year actuarial estimates for recurrence-free and metastasis-free survival for delayed versus early surgery were 61.3% versus 74.6% (p=0.05) and 88.1% versus 97.5% (p=0.0009), respectively. There were no differences in the risk for biochemical recurrence between the different surgical wait time quartiles.

The RAND group offers recommendations regarding diagnostic and surgical treatment of men with prostate cancer. Men without any previously known diagnosis of cancer who has have an x-ray or radionuclide bone scan with blastic or lytic lesions, or with a notation that the findings are consistent with metastases, should be offered a digital rectal exam and TSA test within the 12 months prior to or the 3 weeks following the date of the x-ray or bone scan. Further, men with a new diagnosis of prostate cancer, who have not had a serum PSA in the prior three months, should have serum PSA checked within one month after diagnosis or prior to any treatment, whichever comes first. Finally, men with a new diagnosis of prostate cancer who have a PSA > 10mg/ml should be offered a radionuclide bone scan within one month or prior to initiation of any treatment, whichever is comes first.

Men under age 75 with localized prostate cancer (Stage I or II/A2 or B) and a Gleason score >=7 should be offered both of the following treatment options within three months of diagnosis (unless contraindicated or enrolled in a clinical trial with documentation of informed consent):

- radiation therapy;
- radical prostatectomy**.**

With respect to surgical treatment, the RAND group recommends men with metastatic prostate cancer (Stage IV/D) should be offered bilateral orchiectomy as one of many androgen-blockade treatment options, within three months of staging (16).

Sarcoma

Two studies were obtained that examined the impact of diagnostic delay on the stage of disease of bone sarcoma. In a retrospective study, Wurtz et al (53) examined the data on 68 patients (mean age = 41 years; range, 8-34 years) with symptoms arising from primary bone sarcoma of the pelvic girdle. An excessive delay in diagnosis was regarded as greater than or equal to one month. The average duration of symptoms before an accurate diagnosis was made was 10 months (range, 1 month to 4 years; median 6 months). There were no significant associations between the duration of symptoms before an accurate diagnosis and grade or stage of the tumour. No significant associations between the duration of symptoms reported by the patients and survival ($p = 0.54$) were detected. No significant differences were found between the overall survival of the patients ($n = 30$; 44%) who had a delay in diagnosis of at least one month and that of the remaining patients ($p = 0.62$). However, a low tumour grade proved to be a favourable prognostic indicator for survival ($p = 0.006$). Thus, patients who had a high-grade bone sarcoma of the pelvis had a poor prognosis regardless of any delay prior to a definitive diagnosis.

One study, available in abstract only, was available for review. Bacci et al (54) examined the delay in diagnosis of high-grade osteosarcoma of the extremities in 965 patients. They concluded that a shorter interval between the onset of symptoms and diagnosis observed in patients with disseminated disease at the time of diagnosis was indicative of aggressive tumour behaviour and metastatic disease at presentation.

Stomach Cancer

One retrospective study met the inclusion criteria. Maconi et al (55) measured the delay from the first onset of symptoms to diagnosis in 92 young gastric patients (mean age = 40 years). The mean delay was 16.8 ± 13.9 weeks in patients with alarm symptoms and 29.3 ± 39.9 weeks in patients without alarm symptoms. There were no significant differences between patients with alarm symptoms and patients without alarm symptoms for mean time to diagnosis and also mean time to surgery. Despite the delay in diagnosis, patients without alarm symptoms had a better outcome than those with alarm symptoms.

OTHER EVIDENCE

In addition to the published literature, three other evidence sources related to wait times were uncovered including (i) two comprehensive urgency scales with associated wait times that are in use for all surgeries at the Kingston General Hospital in Ontario and in the Province of Saskatchewan and (ii) one case study summarizing Ontario wait times for cancer surgeries.

Kingston General Hospital Urgency Scale

At the Kingston General Hospital (KGH), an urgency level scale as been applied for non-emergent surgical cases (see Table 1). It is a five-point scoring system with each score having an associated target waiting time. It was developed on the basis of clinical consensus and is now universally applied across all surgical disciplines.

The targets have been in use for two years and were readily accepted as they were rolled out across all disciplines. Many of the disciplines have provided clinical examples for each urgency score to assist in guiding their assignment.

Cancer patients are designated as priority level II (target time of 28 days), with the exception of thyroid disease patients (in the absence of proven malignancy) who are designated as priority level III (target time of 84 days).

KGH has a wait list management tool (Axcess.Rx) that allows individual physicians or divisions or departments to view real time wait list management. As a result, the active lists of individual physicians are routinely reviewed at divisional meetings, which is particularly important in that it has led to normalization of urgency scoring.

Table 1: Kingston General Hospital Urgency Scoring System

Urgency	Description	Target Time in days
1	Conditions with threat to life or limb within one week. i.e. large (> 8 cm) AAA, daily TIAs, obstructing or slowly bleeding malignancies. These conditions are not yet true emergencies but may quickly progress to a true emergency.	7
2	Conditions with threat to life over next few weeks or having a profound effect on the patient physically or psychologically, i.e. most major malignancies - breast, lung, gi tract, neurologic gynaecologic or urologic., mid-large aneurysms (> 6 cm but < 8 cm), symptomatic cerebrovascular disease, many coronary artery diseases - left main disease, severe triple vessel disease with impaired ventricle, some neurosurgical cases - intracranial aneurysm. These conditions have significant urgent impact on health.	28
3	Conditions with less impact on health due to pain, suffering, loss of time from work with some or minor risk to life i.e. biliary tract disease, diverticular disease, thyroid disease, inflammatory bowel disease, coronary artery disease	84
4	Conditions identical to 3, but with no risk of life to patient i.e. hernia surgery, parathyroid surgery, benign anorectal surgery, joint replacement, hand surgery, back surgery.	168
5	Conditions with little impact on health and minimal effect on suffering or loss of work time i.e. cosmetic surgery, varicose vein surgery.	364

No published data are available yet examining the impact of this urgency scale on patient and organizational outcomes.

Saskatchewan Surgical Care Network

Saskatchewan recently implemented a standardized, two-step process of assessing and classifying patients' need for surgery:

- Step 1: Patient assessment questionnaire. The surgeon discusses the patient's situation and reviews any test results. Based on this process, the physician fills out a new patient questionnaire that has a standard set of questions to determine the urgency of the patient's condition. These questionnaires produce an "assessment score".
- Step 2: Urgency profiles for surgical procedures. The process also takes into account the "urgency" of patient's procedure.

The assessment score, combined with the urgency profile of the procedure, gives a final urgency score that places the patient into one of six priority levels, as shown in Table 2. All known or suspected cancer surgeries are classified as priority II.

Table 2: Saskatchewan Surgical Care Network Urgency Scoring System

Priority Classification Level	Scoring Range	Target Level of Surgeries Completed within Target Time Frame
Priority I	95 to 100	95% within 24 hours
Priority II	80 to 94	95% within 3 weeks
Priority III	65 to 79	90% within 6 weeks
Priority IV	50 to 64	80% within 3 months
Priority V	30 to 49	80% within 6 months
Priority VI	1 to 29	80% within 6 months
All cases		Within 18 months

Source: http://www.sasksurgery.ca/. Accessed May 2, 2005.

No published data are available yet to examining the impact of this urgency scale on patient and organizational outcomes. Please refer to http://www.sasksurgery.ca/ for further information.

Ontario Wait Times Case Study

While not directly related to the criteria of this report, the literature search included a case study examining wait times in Ontario. Simunovic et al (155) evaluated waiting times for 1,456 cancer patients (gynecology, colorectal, head and neck, thoracic, and urologic cancer) treated by one of 66 surgeons affiliated with one of eight regional cancer centres in Ontario in 2000. The median wait times for referral to first visit was 11 days, from first visit to treatment decision was zero days, from treatment decision to surgery 20 days, and from surgery to receipt of the pathology report eight days. Overall, the median times from referral to surgery and from referral to receipt of the pathology report were 37 and 48 days respectively. Across disease sites treated, the range in interval from time from referral to surgery was 29 days (colorectal cancer) to 64 days (urology cancers).

The surgeons in their study marked as inappropriate 37.2% of cases and 46.1% of cases of waits from referral to surgery and referral to receipt of the pathology report, respectively. Contributing factors to delay reported by the surgeons included shortage of operating room time, lack of diagnostic tests, lack of allied health personnel and patient preferences.

INTERPRETATION OF THE EVIDENCE

There is little medical evidence on which to base Cancer Care Ontario's recommendations regarding target wait times for cancer surgery. The number of published studies is small. For each cancer site reviewed, the number ranged from 0 to 12 (breast cancer). The quality of the studies was modest; most studies were retrospective and prone to biases that limit their ability to provide valid estimates of the effects of diagnostic or treatment delay on cancer outcome. This is perhaps most apparent in the reports of some retrospective studies that suggest the seemingly counter-intuitive conclusion that longer delays are better than shorter delays. Furthermore, across the studies, varying definitions and intervals of delay were used, such as symptoms to first physician consult, symptoms to confirmatory diagnosis, diagnosis to surgery, symptoms to surgery. This lack of consistency poses a challenge in the application of the findings to inform recommendations. Despite these limitations, the evidence is useful to provide context and structure to a deliberative process of target development.

Much of the evidence reviewed suggested that the delay in diagnosis affects outcome more than the delay between diagnosis and surgery. In most studies, delays between diagnosis and surgery were relatively short compared with the delays occurring prior to a diagnosis of cancer. Further, other factors such as the stage of disease, aggressiveness of the tumour, and comorbidities appear to have a stronger impact on survival than does the delay from the decision-to-treat to surgery. Nonetheless, among studies or standards documents that presented target wait times, the shortest recommended waiting time was 14 days. The more common recommended target for maximum waiting time from the date of decision-to-treat to surgical treatment was one to two months. All studies recommended a target waiting time for surgical treatment of less than three months from the date of diagnosis.

While data in the studies reviewed is probably generalizable to Ontario, the data offer little information to guide Cancer Care Ontario's recommendations regarding target wait times for cancer surgery.

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APPENDIX D: Expert Panel Survey Feedback

Respondents were asked to indicate their level of agreement with the following questions on a scale of 1 (Strongly Agree) to 5 (Strongly Disagree): Respondents were also invited to write in comments for each question and general comments after questions 4 and 15.

	Strongly Agree				Strongly Disagree	Response Average	N=	% who responded	
	1	2	3	4	5	(exc NA)		1 or 2	4 or 5
1. The concept of grouping all cancer surgeries into three major categories is reasonable and appropriate.	7	27	5	6	4	2.4	49	69%	20%
2. The assignment of clinical conditions into the three categories as shown is reasonable and appropriate.	5	19	6	13	5	2.9	48	50%	38%
3. The proposed target maximum wait times for each of the three categories are reasonable and appropriate.	4	22	7	9	5	2.8	47	55%	30%
4. A target of 95% of all patients being within the proposed target maximum wait times is reasonable and appropriate.	13	23	6	5	2	2.2	49	73%	14%
5. The methods used by the committee to develop the provincial cancer surgery target maximum wait times were transparent.	8	18	6	6	3	2.2	45	58%	20%
6. The methods used by the committee to develop the provincial cancer surgery target maximum wait times were appropriate.	7	20	10	2	2	2.1	45	60%	9%
7. The draft report is clear.	9	19	4	7	1	2.0	45	62%	18%
8. I am satisfied with my opportunities to participate in the development of the provincial cancer surgery target maximum wait times.	10	18	8	7	1	2.3	45	62%	18%
9. The proposed provincial cancer surgery target maximum wait times will improve services for patients.	13	16	11	5	1	2.2	46	63%	13%
10. The proposed provincial cancer surgery target maximum wait times are achievable.	4	11	15	10	5	3.0	45	33%	33%
11. The proposed provincial cancer surgery target maximum wait times will require reorganization of services/care in my practice setting.	15	15	4	8	2	2.2	46	65%	22%
12. Meeting the proposed provincial cancer surgery target maximum wait times will require additional financial resources in my practice setting.	28	10	3	0	2	1.5	45	84%	4%
13. Meeting the proposed provincial cancer surgery target maximum wait times will require additional human resources in my practice setting.	23	16	3	0	1	1.5	45	87%	2%
14. There are barriers other than financial and human resources limitations to meeting the proposed target maximum wait times in my setting.	20	9	1	9	3	2.1	44	66%	27%

SUMMARY FEEDBACK

The table below provides a brief summary of the key themes that arose from the Expert Panel feedback and how the Committee responded to this feedback.

Respondent Feedback	Committee's Response
Many respondents expressed concern that the targets did not reflect differences in urgency by disease site and tumour biology. Some proposed alternative wait times by specific indications.	The report was revised to clarify that these targets are system tools and are not intended to guide decisions about the urgency of the need for surgery for an individual patient. Those decisions require careful consideration of individual clinical presentation and patient values and preferences and will continue to be made at the discretion of the surgeon in consultation with the patient.
Many respondents pointed out that the urgency for cancer surgery depends on many factors such as the stage of the disease, the tumour site, the patient's perceived anxiety, impending complications, pain and suffering, and psychological effects that should be taken into consideration in the urgency score.	Again, the report was clarified to emphasize that these targets are system management targets. The factors contributing to urgency in individual patients would be reflected in the surgeon's assessment of the patient's situation.
The assignment of specific cancers to category 1 (e.g., ovarian) and category 3 (e.g., prostate) were challenged by many respondents.	The Committee agreed that a more generic categorization of urgency (i.e., without stating specific cancers) provided more flexibility. References to ovarian and prostate cancer were removed.
Some types of surgery (e.g., immediately life-threatening cases, benign tumours with major/urgent health concerns, diagnostic surgeries, postponed surgeries within a watchful waiting strategy) were mentioned that did not fit into any of the proposed urgency categories.	The report was clarified stating that these surgeries were outside of the Committee's scope of work.
Some respondents felt that a total of three categories was too few.	The Committee considered this input and decided that by decreasing the proportion of surgeries that should be completed within one month from the proposed 95% to 80% would help to address this concern.
The target wait time of 28 days for most cancers was challenged.	Again, the Committee felt that the decrease to 80% would allow more room for longer wait times. As well, the report was revised to ensure that the target wait time was not interpreted as the "ideal" wait time.
Many excellent comments were contributed by the respondents. As well, many expressed skepticism that these targets could be achieved.	A new section was added to the report showing current performance against the proposed standards (with some data limitations). The Committee added a short section on implementation challenges.

APPENDIX E: Wait Time Definitions

Wait Time Event	Definition	Comment
Specialist Referral Date	Date on which a request for consultation with a specialist is received in the specialist office. If the specialist does not accept the referral at this time (e.g., referral form incomplete, workup not complete), this date does not change.	Patients/disease may have multiple specialist referral dates. One per specialist type.
Specialist Consult Date	First date on which a patient sees the specialist for consultation regarding this specific problem.	Mandatory for treated patients. One per patient/disease per specialist type. Should be linked to a referral date.
Decision to Treat (DTT) Date	Date on which sufficient pre-treatment testing is complete, the physician can reasonably assume that the patient will be treated, and the patient has agreed to the treatment. If the patient is not proceeding straight to that modality of treatment but has a planned delay (other cancer treatment first, patient choice or physician choice) then a "Ready to Treat" date needs to be specified.	Mandatory for treated patients. One per patient/disease/modality/ treatment intent combination. If there is no planned delay, the DTT date is the same as the RTT date.
Ready to Treat (RTT) Date	Date on which any planned delay is over, and the patient is ready to begin treatment from both a social/personal and medical perspective.	Mandatory for treated patients. One per patient/disease/modality/ treatment intent combination If there is no planned delay (other cancer treatment first, patient choice or physician choice), the RTT date is the same as the DTT date.
Start of Treatment Date	Date of treatment. This includes the date of any therapeutic service or procedure (e.g., surgery, operation, endoscopy, first treatment with radiation treatment or systemic therapy).	Mandatory for treated patients. One per patient/disease/modality/ treatment intent combination.