Ontario Protocol Assessment Level: Clinical Trial Complexity Rating Tool for Workload Planning in Oncology Clinical Trials

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Abstract

Purpose: The Ontario Institute for Cancer Research supported the creation of a working group with the objective of developing a standard rating scale to evaluate clinical trial complexity and applying the scale to facilitate workload measurement for Ontario cancer research sites.

Methods: The lack of a mechanism to measure the workload involved in a clinical trials protocol was identified and confirmed by a literature review. To collect information on how Ontario sites were assessing workload, a survey was distributed and evaluated. As a result, the working group developed the Ontario Protocol Assessment Level (OPAL), a protocol complexity rating

scale designed to capture the workload involved in a clinical trial. After a training workshop on the application, OPAL was evaluated by 17 Ontario cancer centers to demonstrate its reliability and consistency during a 3-month pilot study.

Results: Twenty-seven protocols were reviewed by multiple sites, and the majority of the sites reported OPAL score differences between 0 and 1.5.

Conclusion: OPAL provides clinical trials departments with an objective method of quantifying clinical trials activity on the basis of study protocol complexity. With consistent application of OPAL, sites can manage staffing objectively. The working group is continuing to monitor the application of OPAL in Ontario.

Introduction

The Clinical Trials Network (CTN) is a unique partnership between the Ontario Institute for Cancer Research (OICR) and Ontario's cancer research sites. The mission of OICR's Clinical Trials Program is to lead the process of improvements necessary to promote speed, quality, and accessibility of clinical trials for patients in Ontario. The OICR recognized that it was necessary to assist the clinical trial professionals to collaborate in navigating the intricate regulatory, ethical, therapeutic, scientific, and business demands of clinical research. CTN membership is composed of cancer clinical trials professionals from 27 sites in Ontario, including clinical trials managers, clinical trial nurses, coordinators, pharmacists, data managers, research ethics board coordinators, and investigators. The CTN identified the need to measure the workload of a clinical trial protocol. OICR supported the creation of a working group to develop and evaluate a complexity rating tool for workload planning in oncology clinical trials.

Methods

OICR choose a collaborative approach for the development of a workload measurement tool. This allowed all the cancer clinical sites to be involved in the evaluation of the product. A call for members was sent out to all sites, and a working group (WG) was formed from members across Ontario.

The WG

The WG was composed of experienced clinical trials managers from cancer centers across Ontario. These included three larger

cancer centers, three smaller cancer centers, and OICR's Clinical Trials Program. The objectives of the WG were to (1) develop a standard rating scale to evaluate clinical trial complexity and (2) facilitate and educate Ontario cancer research sites to apply that scale to workload measurement.

A set of guiding principles was developed by the WG, which provided a framework for this project. According to these guidelines, the assessment instrument must (1) be simple to apply, (2) measure work specific to clinical trial professionals, (3) be useful for determining workload capacity, (4) include all phases of trials, and (5) not be intended for academic review.

Literature Review

The literature review revealed a process gap for capturing workload complexity in clinical research, confirming the issue identified by the CTN members. The published articles for measuring workload defined workload complexity as the time needed to complete a specific task.^{1,2} These studies did not address the complexity related to conducting a clinical trial, even though the increased complexity of protocols has resulted in increased workload.³

Current Practice in Ontario

A current practice survey was distributed to 27 sites to collect baseline data on current workload assessment methodology. Results indicated that 95.7% of responders were involved in some type of protocol feasibility analysis to estimate cost/impact at their respective sites; only 13% of sites had a system for

rating clinical trial workload. These systems were reviewed by the WG. The survey revealed that feasibility decisions were based on the trial manager's knowledge, the experience of staff, and the estimated times for performing tasks. This confirmed the need to develop an objective workload measurement tool to facilitate equal distribution of work in clinical trials at cancer research sites.

Tool Development

The WG established standardized nomenclature for all aspects of a clinical trial. They divided the structure of a clinical trial into three main segments: activation, active study coordination, and follow-up. The WG identified the consistent tasks or specific processes that are routinely completed within each segment of any clinical trial, regardless of complexity. These are considered to be the core tasks, which include but are not limited to protocol review, informed consent form review, and research ethics board submission during the activation segment; source documentation completion, adverse event monitoring, safety reports, and visit monitoring during the active study; and ongoing protocol administration, sponsor-related safety reporting, and query completion during follow-up.

In addition to core tasks, many protocols require incremental procedures that are unique to each trial. These incremental procedures generate increased complexity, which leads to increased workload. These procedures would include, for example, prestudy site visit, investigator meeting, and equipment needs (eg, storage or computer checks) during activation; review of pathology, biomarker studies, radiology, and patient diaries during the active study; and additional assessment of quality of life or length of follow-up during follow-up.

Ontario Protocol Assessment Level (OPAL)

The WG developed a visual model based on a pyramid diagram, adhering to the guiding principle that the model must be simple to apply. The pyramid rating scale is ranked from levels 1 through 8; each level indicates an incremental increase in trial complexity (eg, additional tasks; Figure 1). The OPAL scale begins with less complex, nontreatment trials at levels 1 and 2 and progressively advances through to complex phase I intervention trials at level 8. The scale can be used to rate all segments of trial activity as well as phases of clinical trials.

Flexibility was necessary to allow for instances in which it would be appropriate to decrease or increase the score depending on the complexity of the clinical trial. With input from all the cancer sites, optional elements at 0.5 increments were developed that may be incorporated into any level to create a maximum score of 10 (Table 1). It should be noted that with the optional elements, although it appears that a score of 10.5 may be reached, it was determined during the educational sessions that most of the optional elements were already embedded in the level 8 phase I complexity rating.

OPAL Pilot Project

After initial development of the tool, Ontario's cancer clinical trial sites remained engaged, participating in a pilot project to evaluate OPAL. The participating sites ranged in size from large

academic centers with more than 20 coordinators and data managers to small sites with just three coordinators. The aim of the pilot project was to demonstrate that OPAL was reliable and that scoring was consistent across clinical trials protocols and across sites. This was accomplished by comparing the scoring of multicenter protocols from the participating cancer clinical trial sites. A training workshop was held to educate staff at 23 sites about the development and creation of OPAL and how to apply it to assess a clinical trial protocol for workload analysis.

Sites agreed to assign an OPAL complexity rating to all new protocols reviewed at their respective sites from April to June 2009 and to submit their results electronically to the WG. The WG was able to assess OPAL's consistency as a result of each site's independent assessment and OPAL ratings of the same multicenter protocols.

Results

Summary of the Data Collected

One hundred seventy-six OPAL assessment ratings for new clinical trial protocols were received from the 17 participating cancer clinical trials sites in Ontario. Of these assessments, 27 protocols were reviewed by more than one site.

Analysis of the OPAL scores determined that a variance of up to 1.5 was acceptable, on the basis of research practice models and participation in correlative studies. Two trials were rated with a variance of 3.5. Review determined that a misinterpretation of the definition of special procedures produced the higher OPAL scores. OPAL needs to be applied consistently at the site and should be based on local practices to produce measureable site workload information.

After the pilot study, OPAL was revised to more accurately reflect activity reported by the sites. Educational updates reflecting these revisions were provided through webinars.

Application of OPAL for Workload Measurement

Protocol workload. All cancer clinical trial protocols can be rated with OPAL. The OPAL score is determined by the type of intervention being studied and the number of incremental procedures included. The assigned OPAL score represents the protocol workload for the administrative component of managing a protocol. It is described as the work required to maintain the clinical trial protocol even if there are no patients enrolled.

Case workload. The case workload represents the patient or case workload component of managing a clinical trial. To calculate case workload, the number of active cases is multiplied by the OPAL score. An active case is defined as a patient enrolled in the clinical trial and undergoing an active intervention. Active cases move to follow-up once all active intervention is completed. A staff member can have active and follow-up cases in the same study, and both are measured using the OPAL score. For patients in follow-up, the case workload is divided in half because the workload is significantly reduced during the follow-up period.

Total workload. The total workload for the clinical trial is the total case workload plus the OPAL score for protocol management. For example, if the coordinator has a trial protocol with

Figure 1. The Ontario Protocol Assessment Level (OPAL) pyramid scale. Copyright 2010 Ontario Institute for Cancer Research. Adapted with permission.

Table 1. Optional Elements That Can Be Added to the OPAL Score

Weight	Element
0.5	Protocol-mandated inpatient
0.5	On-site monitoring (≤ 3 mo) or 100% source documents submission
0.5	No. or duration of treatment/follow-up visits
0.5	Industry sponsor/CRO factor
0.5	Multiple (≥ 3) surveys/questionnaires

Abbreviations: OPAL, Ontario Protocol Assessment Level; CRO, contract research organization.

an OPAL score of 5 and enrolls four patients, then the active case workload will be 20 for the subjects and 5 for the protocol, resulting in a total trial workload score of 25 (Table 2, trial D). The process is repeated for each study protocol that the coordinator is responsible for, and this provides the manager with an objective measurement of the coordinator's workload.

Department workload. The above process is repeated for each staff member within the department. Each staff member manages a variety of trial protocols, with study and patient activity scattered

Table 2. Using the OPAL Score to Determine Workload

Staff and Trial	OPAL Level	Active Cases	Follow-Up Cases	Workload
1				
A	4	5	1	26
B	5	12	0	65
C	7	3	1	31.5
D	5	4	0	25
Total	—	24	2	147.5
2				
E	6	3	1	27
F	7	2	0	21
G	2	14	0	30
H	6	5	1	39
Total	—	24	2	117

Abbreviation: OPAL, Ontario Protocol Assessment Level.

across the segments of a clinical trial: activation, active study coordination, and follow-up. The total workload of each staff member provides a snapshot of the department's activity that can be used to determine the individual's or the department's workload capacity.

As shown in Table 2, both staffs have the same number of active and follow-up cases and manage the same number of trials. The application of OPAL demonstrates the difference in actual workload on the basis of trial complexity, thus providing data to support requirements to increase staffing, reassign trials, or reallocate staff. For example, adding a new trial protocol with an OPAL score of 8 required the expertise of a senior coordinator for staff 1. The new trial had an estimated patient recruitment of four and therefore an estimated total workload of 40. The manager reviewed the department workload, and it showed that staff 1 had the higher workload with a score of 147.5, and that taking on additional protocols might strain the coordinator. Appropriate trial workload could then be reallocated from staff 1 to staff 2 to create available capacity for staff 1 to add the new protocol to their workload and as a result, evenly distribute the work.

As demonstrated in the pilot project, OPAL is a consistent protocol complexity rating tool. It allows for flexibility within each site to determine workload application on the basis of their staffing model. At some institutions, the tasks are delegated to more than one person; for example, the coordinator screens patients, obtains consents, and attends clinic visits, and the data manager completes the case report form documentation. The site needs to determine the percentage of the workload that each person is responsible for and allocate the OPAL case workload score accordingly (eg, a coordinator and a data manager are sharing the case workload for a trial). The OPAL protocol workload score is allocated only to the coordinator responsible for the administration of the protocol. If coordinators split the workload evenly, each would be allocated 50% of the case workload.

An Ontario Cancer Center's Experience

One of the Ontario cancer centers has been applying the OPAL workload measurement tool for the past year. This is a large cancer center that supports more than 24 full-time equivalent staff involved directly in cancer clinical trials. It enrolls more than 600 patients onto all types of cancer clinical trials annually. This center has a hybrid model for clinical trials, delegating tasks to more than one person.

The clinical trial feasibility process begins with each new protocol being reviewed by the clinical trials screening committee. This committee is composed of three clinical trials research staff and three investigator physicians. Each member independently assigns an OPAL score for each new protocol. If there is variability between the scores, the committee reviews the ratings of each reviewer and the reasons for their scores to achieve consensus on the rating. Once the committee agrees on a final score, it is assigned to the protocol. Using this score and the expected number of patients to be enrolled, the manager can estimate the workload that will be involved and assign the study on the basis of the trial requirements and the available workload capacity. All the staff are directly involved in workload measurement using OPAL, and status reports are updated to include new trials, assign closed status to a trial, add new cases, or change cases from active to follow-up status.

There is variability in staff efficiencies in completing work because of differences in experience levels or adopted processes. Process inefficiencies were recognized as one of the barriers to clinical trials, as outlined by Dilts and Sandler.⁴ This can be reduced by reviewing the OPAL total workload scores of each staff member in the clinical trials department. If a staff member appears overwhelmed by his or her workload, the OPAL score for the assigned trials may be re-evaluated and changed if necessary to reflect any protocol changes. If the OPAL score is determined to be correct, then a review of the processes should be conducted to look for improved efficiency.

Summary

The consistent application of OPAL allows sites to manage human resource needs with regard to clinical trial workload. It provides clinical trials departments an objective method of quantifying clinical trials activity on the basis of factors that contribute to increased workload. The total workload of staff varies, and workload needs to be reviewed quarterly to reflect the fluctuation in cases.

OPAL scores can be used to provide (1) the number of cases managed per staff member, (2) the number of trials per staff member, (3) the total workload per staff member, (4) the ability to equalize or capture distribution of workload, and (5) objective data to assess the need for additional or reallocated resources.

Conducting clinical trials involves a combination of frequency and complexity of tasks. OPAL has been created in an attempt to capture this activity in a simple, objective manner. The WG is currently collecting additional data from Ontario, and the results are being disseminated in the biannual clinical trials operations meeting at the OICR. The WG will continue to monitor the application, and OPAL will be modified if necessary to reflect the needs of the clinical trial sites in Ontario.

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ASCO
American Society of Clinical Oncology

Appendix

Table A1. Core Tasks for Each Trial Segment

Trial Segment	Tasks	
	Protocol Related	Participant Related
Activation	Protocol review	
	Research ethics board informed consent form	
	Cost/impact	
	Sponsor-regulated documents	
	Site start-up tools	
	Training:	
	Case report forms	
Active study coordination	Procedure	
	Source documentation	Recruitment
	Safety reports, serious adverse events (local)	Prescreening
	Ongoing protocol administration:	Consent
	Safety reports	Screening
	Amendments	Consent process
	Annual renewal	Baseline work-up
	Maintaining study documents	Registration and randomization
	Health Canada	Completion of case report forms, e-data
	Monitoring:	Queries
	Central/local	Study visit:
	On site	Special procedures
	Audits/inspections	Intervention:
Follow-up		Chemotherapy
		Oral medication
		Radiation therapy
	Ongoing protocol administration	Visits
	Sponsor-related safety reporting	Special tests
	Close-out	Case report forms
		Source documents
		Adverse events
		Reconsent
		Queries

Table A2. Examples of Specific Tasks Added to Core Trial Activity

Trial Segment	Tasks	
	Protocol Related	Participant Related
Activation	Budget/contracts	
	Site visit	
	Investigator meeting	
	Initiation meeting	
	Interdepartment coordination:	
	Pharmacy procedures	
	Chemotherapy procedures	
	Radiation therapy physics	
	Radiology	
	Pathology/laboratory	
	Contract research organization	
	Special equipment:	
	Storage	
	Computer checks	
	Centrifuges, electrocardiographs	
Active study	Radiology	Quality of life
	Compact discs	Diaries
	Pathology	Drug compliance
	Lab kit	
	Internal quality assurance	
Follow-up		Quality of life