Critical Practice Gaps in Oncology:

Implications for Development of Effective CME to Meet Accelerating Educational Needs

A CCO White Paper

September 2015 - Clinical Care Options' (CCO) recently published outcomes and needs assessment data demonstrated a dramatic negative "awareness shift" of key treatment information among both hematologists and oncologists. Practice-changing data are now emerging so quickly, and in such great volume, that treating oncologists do not learn about new agents and integrate the latest data until much later in the drug development process and, in many cases, not until *well after* agents have been approved for use.

In this White Paper, we highlight the key findings that dramatically illustrate acute gaps in practicing oncologists' knowledge and competence by drawing on educational outcomes assessments from multiple programs, as well as member surveys conducted in 2013 through 2015. In addition, we suggest innovative changes to CME offerings that recognize this deficit and that can help mitigate these gaps and improve patient care.

In particular, CCO has been evaluating and employing new strategies for delivering current practice-changing information in a "just-in-time" manner that takes into account both the information overload and rapid changes that characterize oncology practice today. These strategies are being employed in multiple areas, including our local live meetings, patient education-focused activities, and our innovative *in*Practice® point-of-care platform. Although this analysis is specific to our hematology/oncology data, we believe the same lessons apply in areas such as rheumatology/immunology, virology, and other therapeutic areas where the pace of change is increasing as well.

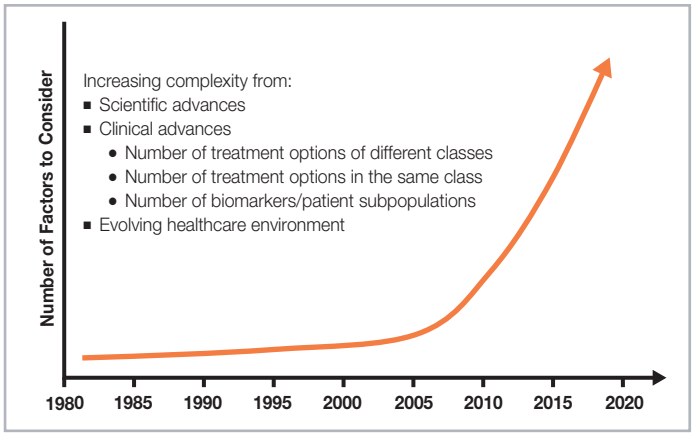
The Looming Crisis in Oncology Knowledge

Looking at recent outcomes and needs assessment data, we have been struck by the realization that there is a growing crisis in oncology-related knowledge and competence. The chasm between what clinicians should be doing and what they are actually doing seems to have reached an unprecedented dimension. In short, the pace of clinical development in oncology has accelerated to such a point that it appears to be outpacing clinicians' ability to absorb and process new information and to actually use that information to develop therapeutic strategies that could improve patient health and potentially save lives.

To understand why this is happening, it is helpful to consider the situation just 10-15 years ago, when novel therapies and targeted agents such as trastuzumab were much fewer and further between. The phase I/II data on trastuzumab[1] were so transformative in relation to traditional cytotoxic chemotherapy that clinicians were quite excited about these early-phase data and generally had an extensive understanding and knowledge of the new agent long before it received approval, thus hastening the clinical adoption of HER2 testing and use of trastuzumab.

Since then, the oncology field has witnessed an explosion of factors that influence how a treatment is selected (Figure 1). The numbers of new drug classes are expanding along with multiple new agents within each class. Tumor types are also being divided and subdivided; for example, treatment options for chronic myeloid leukemia are now nuanced enough that clinicians must know a bevy of mutational subtypes that might affect the efficacy of specific agents.[2] Likewise, it is no longer enough to understand triple-negative breast cancer as a distinct group but rather as a heterogeneous subgroup with at least 6 subtypes, each with unique biological characteristics and clinical behaviors that each may require tailored or personalized treatments.[3]

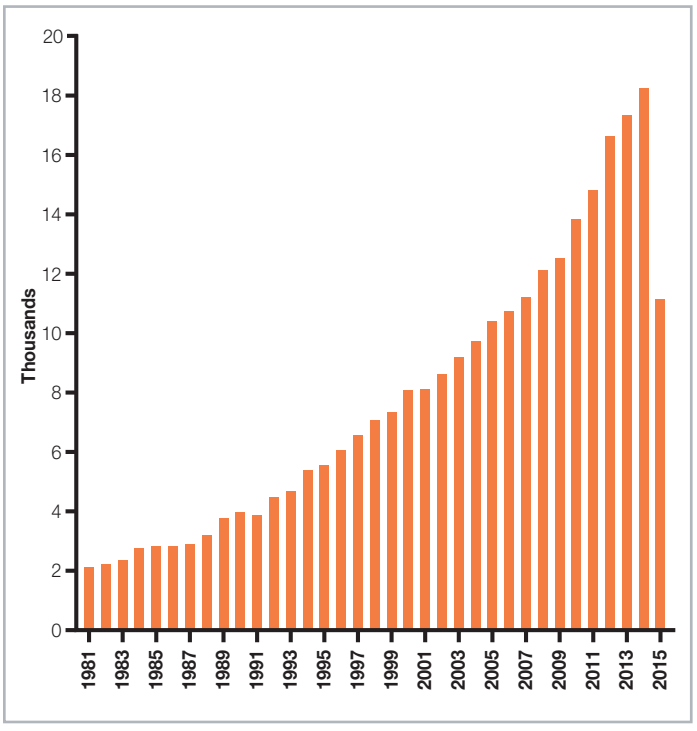
Figure 1. Explosion of factors in selecting treatment.



Fast forward to today when the pace of FDA approvals occurs at breakneck speed; there were at least 19 new approvals for oncology/hematologic malignancies in 2014 and 9 new approvals in just the first 7 months of 2015—almost all were targeted agents.[4] This subdivides the attention span of the practicing hematologist/oncologist like never before; in some cases, we now note that clinicians seem to disregard even pivotal phase III data for agents that are near approval or have already been approved, as discussed below. Thus, when a new therapeutic option becomes available, adding to the already existing complexity of making treatment decisions, any sense of urgency with regard to the need for its quick adoption in the clinic may be overwhelmed by a substantial lag time during which a lack of knowledge hampers this important adoption of new and effective therapies.

We believe the single largest contributor to this phenomenon is the sheer amount of data available that clinicians must process. Case in point is breast cancer: Thirty years ago, the number of peer-reviewed journal publications covering this therapeutic area was a manageable 2000-3000 per year; in 2015, we expect the number of publications to easily exceed 18,000 (Figure 2). In a recent CCO survey, 48% of practicing physicians agreed or strongly agreed with the statement: "It is impossible for the practicing clinician to stay abreast of the high volume of relevant medical information/data currently available."[5] The overload is exacerbated by the proliferation of media sources covering oncology developments in assiduous detail and is further compounded by the ascendance of personal mobile technology that brings a real-time stream of information, right into every clinician's hand, at any moment of the day or night.

Figure 2. Publications on breast cancer per year.

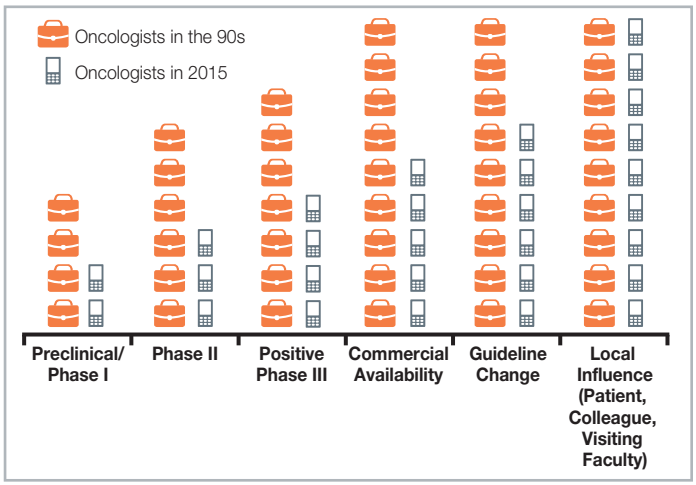


The result is akin to what psychologists refer to as *habituation*, or a state in which repeated stimulation produces a sometimes very rapid decrement in response.[6] For example, a background sound in the workplace such as a telephone ringing at an empty desk may be initially distracting, but with repeated exposures, the sound may quickly fade into the background. In the same way, repeated exposures to breaking news updates, notifications, and clinical bulletins may dull the impact of a transformative item because it must compete for the reader's attention against other equally transformative data.

Another major factor is the unprecedentedly rapid approval of many oncology agents. Case in point is blinatumomab, one of 6 cancer drugs entering clinical practice via FDA's breakthrough therapy designation in the space of just 12 months (June 2014-2015).[7] The approval of blinatumomab after a review timeline of just 75 days was recently characterized by one outpatient oncology program director as "fantastic, but that means that not many centers and not many people have had hands-on experience."[8]

We have increasingly come to the realization that CME interventions must be designed to address the realities of this new clinical environment. In particular, the most intriguing observation we have had is that uptake of new practice-changing data in today's clinical practice is frequently mediated by a **critical local influence or event.** This is illustrated in Figure 3, where the orange bar represents clinician awareness in the "old days," when even preclinical data could attract significant mind share. The gray bar represents clinician awareness today, when even commercial availability may not be enough to convince physicians to stop and learn. By contrast, we believe the interventions that still remain effective are guideline changes, and *local influence,* where patients, colleagues, and visiting faculty are the key stimulators of knowledge uptake.

Figure 3. Physician awareness of key features of new agents over time.



Increasingly, local events seem to be the inflection point where many clinicians might start to pay closer attention to practice-changing data, whether it is a tumor board; a live, expert-moderated local lecture; or even a motivated patient who does his or her homework and presents with information culled—ideally—from reputable sources.

Mechanisms of Inaction: Lack of Awareness is Pervasive in Metastatic Breast Cancer Treatment

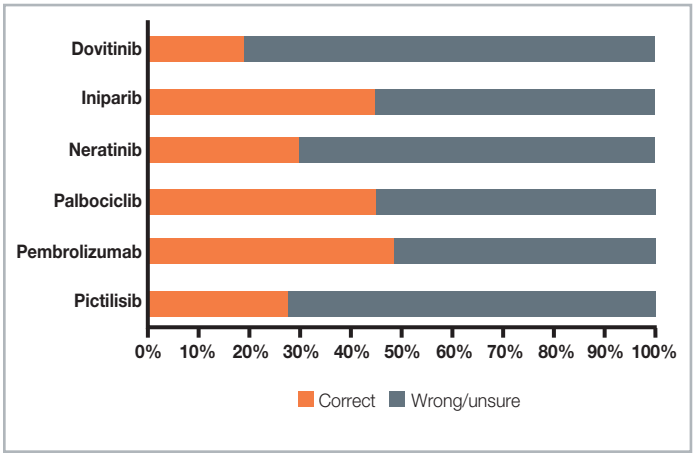
Alarmingly, our recent surveys and pre-education outcomes questions on the treatment of breast cancer routinely show that some 40% to 50% of medical oncologists and other clinicians are unable to correctly identify the target of a novel therapy, even for agents that are FDA approved.

Perhaps the clearest illustration of this crisis can be seen in findings from a comprehensive national educational needs assessment in metastatic breast cancer (MBC). CCO and its partners undertook this analysis to measure professional practice gaps among US-based medical oncologists and to identify barriers to optimal care.[9] In-depth information on this MBC needs assessment is available on the CCO Web site (clinicaloptions.com).

Conducted between October 2014 and February 2015, the MBC needs assessment included a mixed-methods approach featuring online surveys and telephone interviews. The study revealed extensive clinical practice and performance gaps, highlighting a widespread need for education on treatment options among a wide variety of providers, regardless of years of experience, patient volume, or treatment setting (academic vs community).

One key finding of this MBC needs assessment was a surprising dearth of knowledge regarding the mechanisms of action (MOA) of multiple promising investigational agents (Figure 4). For any given agent, ***less than one half*** of the survey respondents were able to correctly identify the target. This ranged from less than 20% for dovitinib to approximately 49% for pembrolizumab. Likewise, the target for palbociclib (which would go on to receive approval for MBC in February 2015; ie, near the end of the survey period) was identified correctly by only approximately 45% of respondents. These data suggest that many US oncologists were not prepared to use this promising agent when it became available.

Figure 4. Knowledge of MOA of new therapies for MBC.



This is just the latest of many such findings over the past few years. We have completed multiple "match agent to target" investigations that suggest the rapid increase in new classes of agents with novel targets challenges oncologists to stay current:

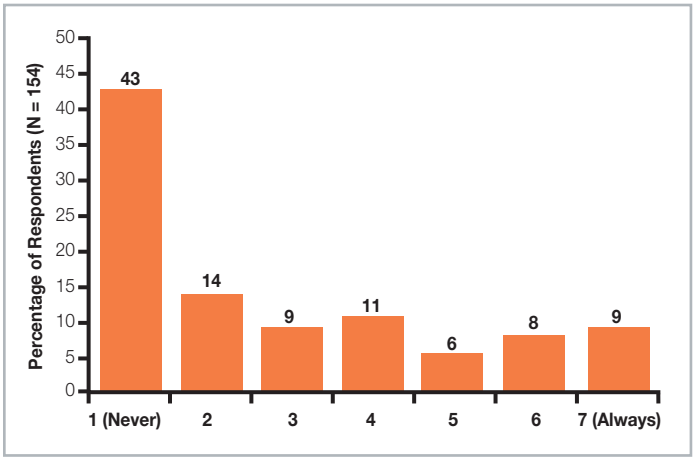
- In a February 2013 CCO survey of 148 US-based physicians treating hematologic malignancies, only approximately 62% knew the target of aflibercept and a similarly low percentage knew the target of brentuximab vedotin, despite the fact that both agents were FDA approved at the time of the survey. The correct target of ibrutinib was identified by 60% of respondents, whereas approximately 20% of physicians could correctly identify targets of obinutuzumab and idelalisib.[10]
- In a November 2014 CCO survey of 94 hematologist/oncologists focused on new agents for myeloma, approximately 60% of respondents knew the target for ixazomib and a similar number knew that for panobinostat; only approximately 55% of clinicians knew the target for daratumumab, whereas only 30% could identify the correct target for elotuzumab.[11]
- Findings of a February 2015 survey of 228 treating hematologist/oncologists revealed that awareness of alemtuzumab was relatively high, with approximately 85% of respondents correctly matching its target. Selection of the correct target for most other agents, however, plummeted, with 50% or fewer of physicians correctly identifying the targets for blinatumomab, inotuzumab, and vosaroxin. Knowledge of the target for investigational agent AG-221 was identified by less than one third of physicians completing the survey.[12]

The Smoking Gun: What Clinicians WON'T Do Today in Lung Cancer

These data establish that there are salient knowledge gaps among oncologists in clinical practice with regard to understanding how new and effective therapies work; further analysis also reveals how these knowledge gaps acutely affect competency and clinical practice.

Some of the most revealing data to date come from a recent CCO survey, conducted in May 2015, among physicians (N = 157) who manage advanced lung cancer.[13] One key question we asked was: **"How likely are you to use a promising new agent in your practice without understanding its mechanism of action?"** (Figure 5). The result was somewhat chilling: 43% indicated they would "never" act without knowledge of MOA (as indicated by a "1" on a scale of 1 to 7; average score: 2.85).

Figure 5. Responses to survey question, "How likely are you to use a promising new agent in your practice without understanding its mechanism of action?"



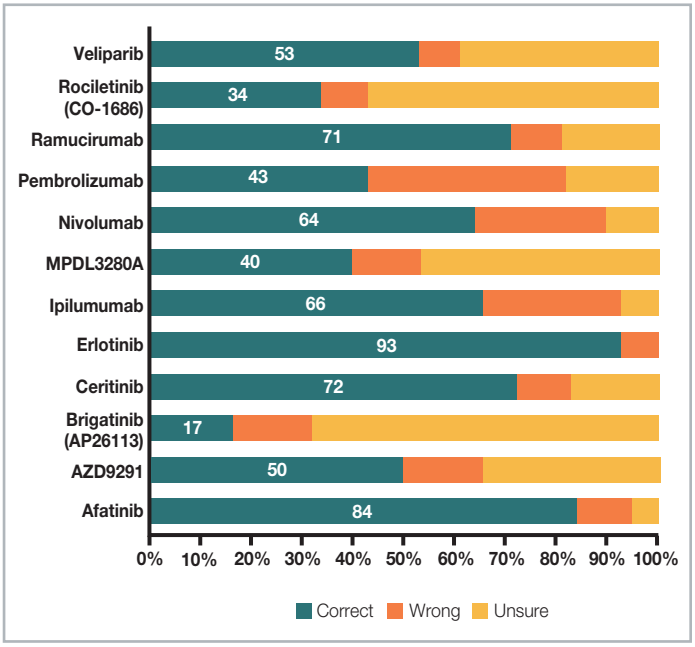
The implications of this are 2-fold: First, this clearly suggests that clinicians may pass over potentially effective or even life-saving therapies due to a lack of knowledge. Second, we saw that community practitioners were somewhat *more* likely to prescribe an agent without knowing MOA (average score: 3.18 for community physicians vs 2.68 for academic physicians). Although that is still very low, it does raise the possibility that community practitioners might be more likely to prescribe an agent *despite* a lack of MOA knowledge, even despite potentially negative consequences.

The realization that most clinicians will not prescribe drugs without knowing the MOA takes on more weight when further results of this survey are considered. In particular, there exists a great deal of confusion and lack of knowledge regarding the MOA of some very high-profile agents employed in the management of lung cancer—perhaps most notably, immunotherapeutic agents that are set to transform the practice of oncology (Figure 6). Only 64% of respondents were able to correctly match nivolumab to its target, only approximately 43% knew the target of pembrolizumab, and likewise, only 40% knew the target of MPDL3280A. The percentages were also low for ipilimumab, with only 66% of respondents correctly matching this immunotherapeutic agent to its target.

Taken together, these findings suggest that:

- A clinician who lacks a fundamental understanding of an agent may be reluctant to prescribe it despite the fact that the intervention could save lives or extend survival.
- The lack of knowledge may prevent community oncologists from referring patients to clinical trials where such potentially life-saving or life-extending treatments may be available.
- The integration of new agents into practice is delayed substantially because of a lack of fundamental knowledge about the agent.

Figure 6. Current knowledge of new agents for non-small-cell lung cancer.



Meeting the Crisis Head On: How Innovation in CME Can Make a Bigger Difference

Despite these grim findings, we believe CME providers are among the best positioned entities to help address these growing gaps in awareness and knowledge. However, we also think that many of today's standard CME models are poorly suited to tackle this challenge because they lack the agility to keep up with the rapid pace of change in oncology. Thus, we have spent a considerable amount of time developing new models, updating old ones, and thinking about how to bundle them and present integrated serial learnings in order to address the rapid pace of development in oncology and the seeming inability of physicians and other healthcare providers to keep up with a deluge of information.

Our recommendations here are as follows:

1. **Show clinicians that a gap exists.** Presenting data to learners themselves will help generate an awareness that there are serious deficits that need to be bridged. Once these pervasive practice gaps are acknowledged and understood, oncology specialists may be more likely to check and improve their knowledge more frequently.
2. **Adopt "just-in-time" learning as a key component of optimal care.** Many of the models listed below in the next section contain "just-in-time" elements that decrease the lapse between a practice-changing development and an educational exposure within the target audience.
3. **Adapt to current learning environments, online and off.** Whereas the desktop computer is still widely used to access

education, personal mobile technology is taking off, particularly among younger physicians.[14] At the same time, meetings in local venues (such as an oncologist's own practice) represent an opportunity to use CME to generate a high level of awareness of transformative data and create positive improvements in physician competence.

4. **Incorporate the patient as a decision maker.** We believe that the patient is not only a partner in care but also an increasingly important influencer of care. This is driven by larger trends in healthcare and a greater information-driven sophistication among patients and their caregivers. In this environment, we believe that the role of CME increasingly will be to help clinicians adapt to these patient-centric needs and adopt behaviors that support integrating patient partnership into daily clinical practice.
5. **Expand the learning audience.** It is important not to lose sight of the nurses, pharmacists, and other healthcare professionals who also interact closely with the patient. Increasing the number of team members with knowledge will increase the likelihood of the knowledge being brought to bear when it applies to an individual patient.
6. **Go for reach, not specificity.** Quality Improvement and Performance Improvement programs can provide interesting academic insights on small groups of clinicians; however, these programs often have very limited reach and a high cost-per-learner that may be prohibitive. Thus, we believe that for the most urgent, high-priority practice gaps, the best use of limited educational resources is to focus on programs that are designed to reach broad audiences and make the biggest real-world impact.
7. **Fewer "one-off" programs, more "all-in" curricula.** It is well documented that multiple learning moments and experiences are needed to ensure that a clinician will truly understand and apply concepts that have the potential to improve care. It is time to start thinking in big-picture terms about multiple interventions with unique educational models that reinforce knowledge, instill confidence, and build enduring competence that makes a difference to patients.

Models That Address the Need

Live, Local, CME-Certified Meetings

Local meetings (eg, an audience response system–enabled lecture held in an oncology practice during lunch hour) may serve as a turning point in the adoption of a new therapy, especially if the event is led by a recognized expert in the field who is available to answer questions and discuss treatment choices. We believe that in an era of information overload, a local encounter with an expert can be a powerful stimulus that may have a strong impact on a clinician's willingness and ability to adopt a new practice-changing therapy.

Moreover, clinicians who attend these meetings tend to be very open to asking questions that they may not be willing or able to share in larger venues with more attendees. For several meeting series, we have been able to document questions posed by local attendees in a variety of geographic regions, providing a more precise detail on the immediate educational needs of individual clinicians participating in the activity. An analysis of attendee questions can be a useful resource for a broader needs assessment process undertaken to develop programs in this topic area in the future.

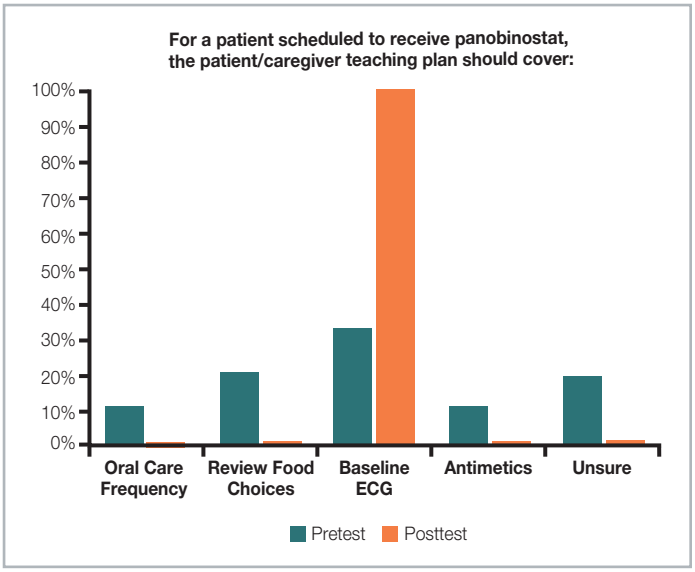
Patient-Centric Activities: Shared Decision Making

Today, competence is not only defined simply by how well clinicians can diagnose or treat a disease, but also by the extent to which they are able to engage the patient and make them a partner in the decision-making process. Effectively sharing the decision-making process with patients starts with standard patient–provider discussions (eg, informing patients of the risks and benefits of a treatment) but goes a step beyond to ensure that patients' values and preferences are incorporated into treatment decisions.

The challenge is to help clinicians understand how new patient-centric behaviors can be modeled and incorporated into practice. Toward that end, we have planned and executed activities designed to help clinicians become more comfortable partnering with motivated, information-enabled patients who do want to take an active role in their own treatment.

For example, we designed a first-of-its-kind symposium, held during Oncology Nursing Society Congress 2015, that focused on both latest advances in multiple myeloma care and the role of the oncology nurse in shared decision making, using multiple simulated patient encounters to help acclimate attendees to the process. The intervention was effective: We were able to document improvements in both clinical competency and shared decision making (Figure 7).[15]

Figure 7. Outcomes question addressing shared decision making and clinical competency.



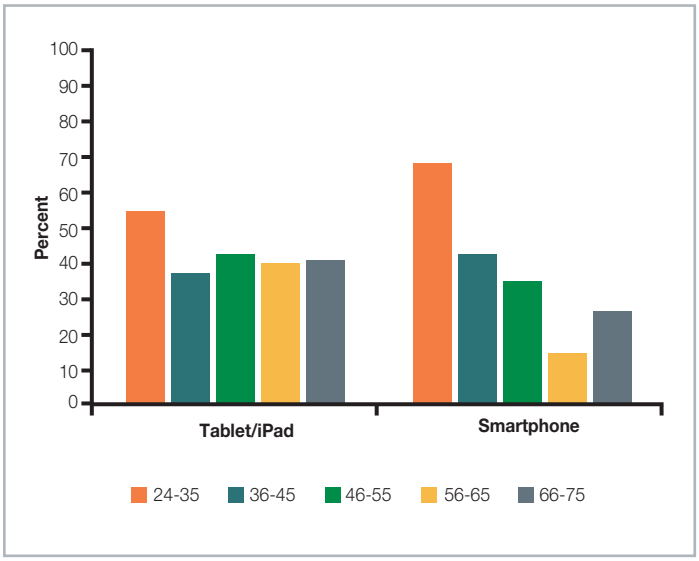
Point-of-Care Resources

Resources such as CCO's innovative *in*Practice® (inPractice.com) are adapted to the current learning environment where physicians and other oncology healthcare team members are increasingly accustomed to accessing education and information they need at the point of care to make a diagnosis or treatment decision in real time.

Our own survey data suggest that online point-of-care resources are already among the most highly rated of all activity types.[14] On a scale of 1-7, point of care rated 5.43 on average—higher than any other live or online format. Moreover, survey participants were asked about the sources of information they use to guide their patient care; 50% identified Internet-based searching/learning such as point-of-care sites among their primary sources—again, more than any other format.

This trend will continue to accelerate as younger physicians migrate in larger numbers toward personal mobile technology (ie, phones and tablets) to access that information. Through assessing generation-specific preferences of our physician membership,[14] we were able to illustrate markedly higher usage of tablets and smartphones among physicians in the so-called Millennial generation (Figure 8). The importance of this finding becomes even more clear when we consider that in less than a decade, Millennials will make up the majority of the healthcare workforce.[16]

Figure 8. How do CCO members currently access CME activities? Tablet and smartphone use, by age.



Note: For further insights into how the age of our members is influencing technology adoption and their choice of CME activity, please see our previous CCO White Paper, "Generational Shift in the Physician Workforce: What Are the Implications for CME?" (available at clinicaloptions.com/generational)

"Just-in-Time" Education: A Proliferation of Effective Models is Needed

CME funding cycles can be a barrier to rapidly assessing and addressing acute educational needs in oncology. In many cases, 1 year or more could elapse between the time an acute educational need arises and deployment of activities to address the need. Accordingly, new models are needed that take into account this traditional funding cycle and the time sensitivity of educational needs in this fast-moving field:

- Point-of-care resources should be specifically designed to accommodate urgent, time-sensitive updates, announce them, and make them immediately available. For example, in CCO's *in*Practice platform, we constantly monitor the field to identify educational needs that may be nascent or undetectable at the time the program cycle is funded. Once an urgent need is identified—for example, an approval of a new agent—an urgent update featuring expert guidance on the application of that agent to clinical practice can be rapidly deployed and integrated into the content. Moreover, point-of-care resources must be searchable to a high degree of granularity to ensure that clinicians can rapidly get very specific data they need to understand the options and make an informed treatment choice.
- Social learning platforms are increasingly an effective way to reach clinicians with rapidly developing data. However, content featured within the network must be flexible enough to address new or more specific educational needs that emerge during the course of the program's life cycle. Toward that end, CCO's social platform, *ClinicalThought*, is populated with expert commentaries made possible through multiple grants that fund the broad framework of the educational program. Effectively, this allows for development of commentaries that address emerging educational needs but remain in alignment with the originally identified gaps.
- Online decision support tools are increasingly recognized as an effective means for addressing practice gaps related to diagnosis, treatment, and ongoing management of specific diseases. In the past, it was anticipated that such tools would be useful without the need for a major update during the course of a year. Now, in many therapeutic areas, the pace of change is so rapid that a mid-year update to the tool is warranted to ensure that the expert recommendations reflect the most current available agents and strategies.
- Webinars are well suited to deploying topical, relevant educational interventions quickly after a defining event takes place. One example is CCO's *Clinical Alert* Webinar model; once a triggering event is identified, such as an approval, guideline change, or release of practice-changing data, a Webinar can be released within days compared with the longer timelines required for more traditionally planned CME activities.

What the Future Brings: Breaking the Mold

CME providers must adapt to current learning environments if they hope to stay relevant to clinicians' needs in an environment where information overload has inundated and overwhelmed oncology specialists' ability to keep up with new drug approvals, indications, and developments that affect practice. Toward that end, "just-in-time" learning will be a key component of optimal care that can be deployed through existing models or novel formats built with rapid dissemination of information in mind.

In this milieu, it is not just the hematology/oncology expert but also patients and their caregivers who represent the future of medical education. We cannot lose sight of the fact that these nonphysician members of the clinical care team may be as informed—or better informed—than physicians themselves on the latest developments; thus, they will increasingly be "local leaders" in changing the competence of the healthcare team that provides them and/or their loved ones with care.

Regardless of how the education is delivered or who delivers it, it is important to remember that the stakes are high: In hematology and oncology, each day without optimal treatment could mean patients are deprived of therapy that could ameliorate symptoms, improve comfort, or in some cases, even extend life.

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About Clinical Care Options

Clinical Care Options is a global leader in the development of innovative educational technology platform that integrates all levels of medical education and information with personalization of the clinician's experience and the integration of moderated social media. CCO has been a pioneer in the creation of continuing education and decision support resources for healthcare professionals. For more information, visit clinicaloptions.com.

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