From the President’s Desk—CAP Center: If we couldn’t do it, who could?

R. Bruce Williams, MD

May 2019—The CAP Center for Pathology and Laboratory Quality for Evidence-Based Guidelines has partnered or collaborated with more than 20 societies to produce 15 published laboratory practice guidelines—with 10 more underway. The Center is one of the best things we do and one of the things we do best.

One thing about the CAP: We make no small plans. It was that way when we decided to inspect and then accredit laboratories. It was that way when we decided to hold an independent annual meeting. And it was that way when the CAP Center had its first official guidelines published in *Archives of Pathology & Laboratory Medicine*.

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First, some history. Daniel Hayes, MD, who was responsible for American Society of Clinical Oncology breast cancer initiatives, in 2005 asked M. Elizabeth Hammond, MD, who then chaired our Council on Education, if she thought the CAP might consider a joint project to write guidelines for the use of HER2 testing in breast cancer. She did, and we learned a lot from ASCO when creating those guidelines and those for ER/PR testing that soon followed. This got some of us thinking about the need for more evidence-based guidelines and our place in developing them. In 2008, Dr. Hammond was asked to take the lead in exploring what would become the Center.

The idea was to build a home within the CAP where we could collaborate with other specialists to research the best evidence available about emerging medical science and write clear, concrete practice guidelines. Through the Center, we would invite and examine comment from pathologists and other specialists and write iterative drafts. The outcome would be readily accessible guidelines offering evidence-based content on topics tied to cutting-edge medical science that would be useful to patient care. As I said, no small plans.

There were a lot of concerns. Some members thought the whole idea was outside our wheelhouse. This is something new and different that we’ve never done before, they said. It will take too much time. It will cost too much money. How can we know that it will be worthwhile, that we have the expertise within the CAP, that we can

count on help from the other medical groups?

So we did what we do when we see an opportunity to support our patients and the best interests of pathology at once. We circled back to the question: If we don't do it, who will? And we realized we could indeed find the time, money, and expertise to do it right.

The CAP Center took off with Dr. Hammond as chair, and its first guidelines were published in 2012. It's been seven years now and our collaborations with ASCO and more than 20 other specialty groups have had substantial benefits. We've gained insights into clinical practice, the specialty groups have seen the value of analytic practices in the laboratory, and we're all still learning.

The bigger challenges relate to the pace of emerging science—particularly precision medicine, which has its own lexicon. Raouf Nakhleh, MD, who chairs the Council on Scientific Affairs, says that the need for the best available evidence accessible to nonpathologists without an interpreter exploded when personalized medicine began to find its footing. That may have been the single best reason to create the Center, Dr. Nakhleh says, because when a lot is happening at once, the real problem is figuring out what is most relevant.

The Center is designed to distill what needs to happen first and provide a place to talk that through. To that end, we have had the benefit of a thoughtful document developed in 2011 by the then Institute of Medicine of the National Academies titled "Clinical Practice Guidelines We Can Trust," which looks at approaches to managing conflict of interest, establishing transparency, and forming a balanced, qualified multidisciplinary team. More recently, the Center has added another resource, known as GRADE (Grading of Recommendations Assessment, Development and Evaluation), an internationally recognized tool to weigh the strength of evidence and create guidelines that are transparent, clear, and consistent. GRADE will foster communication across disciplines and enable us to show our value to all facets of medical care. An editorial in *Laboratory Medicine* explains how it works (Schmidt RL, et al. 2019;50[1]:5–7).

One early concern was that our initial projects were focused on anatomic and breast pathology. Elizabeth Wagar, MD, who succeeded Dr. Hammond, brought more guideline projects into the realm of clinical pathology, encouraging a deeper dive into other biomarkers and immunotherapies. That was a big step, but as Dr. Wagar likes to say, the CAP has chosen to look outward for new ways to help our patients and to grow awareness of how pathology contributes to patient care. Patrick Fitzgibbons, MD, who now chairs the Center, also sees our potential through a wide-angle lens. He has noticed, for example, that our guidelines are being applied to develop metrics for the CAP Pathologists Quality Registry. What goes around comes around.

After guidelines are complete, they are shared across the CAP. The Council on Accreditation, for example, reviews final guidelines to identify items for referral to responsible councils and the Checklists Committee. Because the CAP has deeming authority to represent the Centers for Medicare and Medicaid Services, we are tasked with making sure that our accredited laboratories comply with CLIA requirements. It takes time to write the checklist requirements that implement a new guideline, and that cannot begin until the guideline is approved. So it is important to understand that release of a practice guideline does not trigger its use in laboratory inspection. Laboratory inspectors work with the checklists.

I'd like to recognize our wonderful staff led by Lisa Fatheree at the CAP. Center teams review and revise; we may receive thousands of comments on a given guideline and *every single one* is carefully weighed. It never ends. Fortunately, our staff is energetic, diligent, and bright, with wide expertise. The Center could not function without them.

As the science presses forward, Center guidelines will grow along with it, giving our colleagues new tools to inform and refine patient care and opening new avenues of inquiry for translational research. And we will provide a space within which to continue the pursuit.

Dr. Williams welcomes communication from CAP members. Write to him at president@cap.org.