'Bedside-to-bench' research: precision medicine in the making

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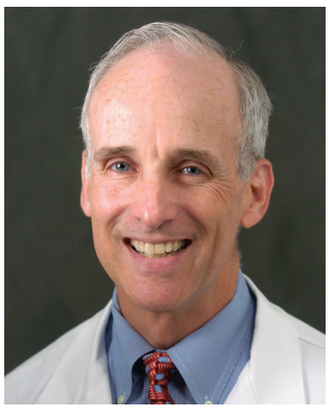
President Obama's State of the Union address in January included an interesting announcement of relevance to all practicing oncologists, their patients, and cancer researchers: the establishment of the Precision Medicine Initiative, which has been underwritten by a US $215 million allocation in the 2016 Budget. The president noted at a subsequent event at which he unveiled the details of the initiative that most medical treatments use the "one-size-fits-all approach," which as we know, in the reality of our day-to-day practice often translates into a handful of patients enjoying many benefits from a particular therapy, while many patients might see no or very few benefits from the same therapy. Through the Precision Medicine Initiative, the hope is that researchers will be able to draw on an extensive patient data set complied from pooled electronic health records and in some cases, from existing NIH-funded studies, to develop new ways of detecting, measuring, and analyzing biomedical information. By examining the individual's characteristics and genetic make-up and the genomic drivers of his or her cancer tumor, more precise diagnoses should be possible, therapies should be more targeted – that is, specific to the patient's individual make-up and health history – so that personalized medical care becomes a reality.



Of course, as with any new advance, there are risks. It is crucial that the privacy of the patients and study volunteers who agree to have their health information pooled into the national research cohort is absolutely secure as is the exchange of data across systems. In addition, there is always the chance that the advances will be used by some for commercial advantage. I have seen many an advertisement this past year enticing vulnerable cancer patients to undergo testing or to have their tumors tested for genetic mutations and suggesting that doing so will open up a world of readily available and curative therapies. We must guard against such commercialization and direct-to-consumer promotion of these advances in precision medicine. It is a relatively new field, and we need more research and a deeper, evidence-based understanding of the workings of these assays before they become routine.

I also hope there will be ways in which large sets of data can be tested and analyzed in the private and public sectors to establish how drugs, devices, and/or therapies in general perform outside of the laboratory or carefully structured trial setting, in the real-world setting oncologists and their patients occupy. These databases are available and should be analyzable. Dovetailing with the ideas of sharing and testing is the overarching role of the electronic medical record. So many of us are buckling under the pressures of having to use this complicated and time-consuming electronic system, whose key value at this early stage seems to be solely that of "documenting" what we are doing. But the full, true value of doing so is still to be realized.

In a way, what we are doing by contributing patient data to the national research cohort is reversing the bench-to-bedside process: we're submitting real- world "bedside" data for "bench" analysis and verification. And once that data is channeled back to us for use in our evidence-based daily practice, we can be reassured it will be more inclusive of the populations we treat but who are often excluded from many clinical trials – children and the elderly, people with comorbidities such as cardiovascular disease or diabetes, those who have been exposed to harmful environmental, socioeconomic, or lifestyle conditions. We need access to that kind of data if we are going to achieve the goals of the president's initiative. In his own words, the initiative could "not only help us find new cures, but also help us create a genuine health care system as opposed to just a disease care system." In such a system, prevention will be as important as diagnosis, treatment, management, and cure; and quality of life and care and cost-effectiveness will be the substrate for all of our decisions across the health care spectrum.

This new order of delivering health care that includes broader access to medical information sourced from the real-world setting will hopefully generate crucial collaboration and interconnectivity between oncologists, nurses and midlevel providers, patients, and researchers

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as they work toward achieving better outcomes, clinically and cost- and quality-wise. The articles in this month's issue reflect some of these new approaches as they hone in on patient quality of life, provider-patient communication, cost of therapy, and the use of targeted EMR interventions. On page 87, Greven et al examined the effects of the nutritional supplement, ArginMax, on sexual functioning and quality of life among women who survived cancer. The investigators reported no significant impact on sexual functioning among the women who received ArginMax, but a significant improvement in quality of life at 12 weeks among those who received the supplement compared with those who received placebo. Belkora and colleagues (p. 104) also looked at female survivors, this time those who'd survived breast cancer, and examined the need for decision and communication support when deciding on treatments. The investigators note that many qualitative studies have identified the barriers to communication and informed decision making at that time, but they sought to quantify the need for decision support. Key among the findings were that participants had made their decisions about therapy during their first visit with a specialist and although they generally were happy with those decisions, in hindsight they would have preferred to have more information before the first visit.

Data from electronic records form the basis for 2 other articles this month. The first, a retrospective study by Nickman et al (p. 95), drew on data from EHRs to examine the cost of palliative external bean radiotherapy for bone metastases in men with prostate cancer; and in the second, Bernens and colleagues assessed the impact of targeted EMR intervention on the use of growth factors in cancer patients.

Also this month, we bring you a revamped Community Translations column on page 84. It includes the original write-up of a study upon which a particular US Food and Drug Administration approval has been based, as well as the "What's new, what's important" sidebar by the section editor, Jame Abraham, and occasionally an accompanying Commentary and sidebar on treatment of the topic tumor. New to the package is a write-up and accompanying visual of the drug's mechanism of action. Jane de Lartigue, who writes the bimonthly features on New Therapies, is the author of the new Community Translations. Turn to page 84 to read her report on palbociclib and letrozole, which was recently approved for treating women with ER-positive, HER2-negative advanced breast cancer.