Editorial

SUSAN LECLAIR

After more than a year of study, the Presidential Commission for the Study of Bioethical Issues reports that the rapid growth in unanticipated findings from advanced medical tests, especially in genomics, has outpaced the ability of physicians to handle them ethically. Help to precisely identify what genomic or other medical-test data can produce meaningful benefits, is needed. The report, *Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts* also include the need to determine what data patients want to see and to have explained.

For the past decade or so, increasing numbers of voices have been raised to support the idea that the amount of raw data, as opposed to interpretative findings, are overwhelming the health care delivery system. In as early as 2004, Michael Laposata et al. published a ground-breaking article in the Archives of Pathology and Laboratory Medicine concerning the creation of interpretative reports and the positive response of physicians to these reports. ASCLS has also voiced its opinion on this topic.

What seems to be missing in the public record are the ideas, investigations, and reports of how hospitals and clinics of every size and description are attempting to address this problem. In many circumstances, perhaps the issue is one of how to design a traditional quantitative research project or an innovative qualitative one. In others, it might be a lack of confidence in writing for publication. In yet another, it might be an all-too-common apathy for either the work or the writing.

However, this work is critically important at this time and place. The national desire for higher quality at a lower price will have profound effects on the clinical laboratory. Only a few years ago, one attempt to lower the number of bureaucratically determined "unnecessary" tests tried to reduce most tests to one a day. This process also attempted to separate into single tests the quantification of each of the immunoglobulin subtypes. Thanks to a concerted effort of providers and patients alike, this process was truncated but the thought that lessening the number of laboratory tests would lessen the cost that is currently in the billion dollar realm is never that far away.

Whether we look at laboratory testing from the point of view of Patient Safety (and ASCLS has had a highly productive committee investigating and creating materials) or from the point of view of quality assurance (and ASCLS has been highly active in this field as well), it is the responsibility of each of us to make sure that our patients get the best care from laboratory professionals. As more laboratories offer testing for molecular diseases or markers, it is important to include in the procedures opportunities for medical laboratory scientists to be involved in the interpretation and correlation of these results. But, this issue is not limited to the new or fancy testing. How many complete metabolic panels are ordered unnecessarily? My personal favorite is the order of a sickle cell screening on a previously diagnosed patient "to see if anything had changed".

Financial, efficiency or evidence-based studies all assume that there are no pre-analytical influences in laboratory testing. Many groups investigating the utility of the clinical laboratory do not include laboratory professionals. Indeed, in some situations, they are consciously omitted as not relevant. The laboratory is in danger of becoming just that - a room with equipment that apparently functions without people or with any outside influences. For example, how sure are you that all of your lipid studies are being performed on specimens drawn from patients who have fasted for 10 hours? Many people want to know when "their time" has come. This is it. We prove our worth as professionals or there may not be another chance. So, speak out, write up and define your professional space.