

## SUNQUEST EXCLUSIVE INTERVIEW

### “The Dark Report’s” Robert Michel on Predictive Medicine

Sunquest is pleased to feature the third in a three-part exclusive interview series with Robert L. Michel, Editor-in-Chief of the Dark Report and President of The Dark Intelligence Group, Inc. Robert is an industry-renowned commentator, consultant, author, editor, speaker and entrepreneur. He is also a leading expert on the management of clinical laboratories and anatomic pathology group practices.

The topic for this interview is how hospital laboratories are preparing to lead healthcare into the era of molecular diagnostics and predictive medicine.

#### *What do you see as the impact in the next five years of predictive medicine and technologies on the overall healthcare industry and specifically for hospitals, laboratories, pathologists and physicians?*

Let's start with laboratory medicine as a consultative resource because that's a critical factor in implementing predictive medicine—particularly from the lab's perspective. It's not news to laboratory professionals that pathologists, lab PhDs and other skilled laboratory professionals understand when it is timely in a patient's life to order particular lab tests and how to best develop a care plan to follow, as indicated by the test results.

Unfortunately, many clinicians do not engage pathologists and other lab professionals as consultative partners in developing patient care plans, determining the right lab testing protocol and—as those lab results and other diagnostic information are received—evaluating that information to make diagnostic decisions and select appropriate therapies.

Progressive hospitals and health systems should seek to create active programs that bring this laboratory consultative expertise to clinicians at appropriate points in the care continuum. This will position their institutions to be seen as leaders in implementing predictive medicine. It will also help these hospitals and health systems improve patient outcomes in ways that are acknowledged by payers, particularly in the form of higher pay-for-performance reimbursement.

A good example is selection of the right coagulation tests for cardiologists, neurologists and OBGYNs as they see patients with conditions the lab recognizes as likely arising from coagulation anomalies that affect the individual patient's ability for normal blood clotting or thinning. In a tragic example of what can happen when appropriate expertise is not brought to bear, there are documented cases where men faced legal action after being reported as abusive parents, the result of a mistaken diagnosis of “shaken baby syndrome”. Infants were brought to an ER with bruises and internal bleeding resulting from normal play that at first appeared to be symptoms of abuse, but turned out to be the result of a coagulation defect in the child. A traumatic family experience on many levels, some of which would have been avoided with proper laboratory expertise.

#### *Word is just starting to get out on this issue.*

It's a particularly compelling example of the consultative role that pathologists can play. In this case, being experts on coag pathology can very much help a clinician who's treating patient conditions rooted in coagulation disorders and not other clinical problems.

#### *How do you see this playing out for predictive medicine?*

As new technologies and science associated with predictive medicine—which we might also characterize as genetic and molecular-based diagnostics—enter the clinical marketplace during the next five years, it will transform clinical practices for one disease-state pathway after another.

The model for this exists in testing for leukemia, lymphoma, breast cancer, HIV and several other infectious diseases. This is where a new level of sophisticated diagnostic tests comes into play to (A), diagnose the disease, (B), determine appropriate therapies for the disease, and (C), monitor the patient's progress against those therapies.

The example of HIV viral-load and mutation testing offers a good demonstration of this model, as the viral load guides the physician over time as to the effectiveness of the drug cocktail prescribed for the patient. And if the viral load begins to increase, then the HIV mutation testing done at the genetic level informs the doctor as to how the HIV virus has mutated against which specific prescription drugs. Armed with that knowledge the physician can change the drug protocol with the goal to observe viral load dropping as a measure of the new drug regimen's effectiveness.

At the end of the next five years we may very well look back and see hundreds of disease states affected by this sequential introduction of useful new molecular diagnostics.

The early evidence of this trend is already visible. Look at the test menu for different genetic tests. The list of genetic tests probably tops two thousand unique assays—many of which were not available just four years ago. Whole-gene sequencing is another molecular technology area transforming swiftly. Another example is a company in the Washington, DC, area that only develops assays looking for multiple genes and defects that are collective markers for specific diseases. This company, in the last five years, has expanded its clinical test menu from three to five useful assays to as many as 100. Keep in mind that this example represents just one slice of the diagnostic continuum.

***Bringing the consultative expertise to care providers is going to be key to healthcare organizations moving into that predictive medicine and personalized medicine model, because of the complexities of the laboratory tests. How many different combinations of genetic testing are there going to be?***

In lymphoma leukemia you see the hematopathologists working closely to consult with the hemato-oncologists as a regular member of the diagnostic and therapeutic team. The opposite model might be prostate-cancer pathologists and urologists, who essentially read the tissue and send a diagnostic report to the referring urologists, period. If the urologist has questions the pathologist is happy to chat on the phone, but under this conventional model the pathologist is not typically inclined to proactively consult with the urologist.

It is for these reasons that progressive hospitals and health systems are already working to close that gap in the knowledge flow from laboratory medicine to the clinical setting. Only in this way will the full potential of proactive medicine—informed by genetic and molecular testing—play an important role in transforming the practice of healthcare.

*For more information on The Dark Intelligence Group, its newsletters, events, and free daily news briefings, visit: <http://www.darkdaily.com/> or call: 512-264-7103.*