Latest News & Updates from the Personalized Medicine Coalition

Letter from the President

In 2005, the Royal Society (London, UK) issued a report on the prognosis for personalized medicine contending that it would be at least 20 years before patients would be prescribed treatments based on their genetic make-up. According to the Society, the promise of personalized medicine offered more 'hype' than hope, which translated into the opinion that there was no need to invest in the new paradigm.

Since then, a steady drumbeat of new diagnostic and therapeutic products, not to mention an increasing demand on the part of providers and patients for new drugs with fewer side effects and adverse events, combined with a push from pharmacy benefit managers in the USA for a reduction in the cost of healthcare without decreasing quality, has led to widespread recognition that science and technology pointed inexorably towards a promising new frontier in medicine. Just last month, the *New England Journal of Medicine* reported that a simple blood test, at a fraction of the cost of a biopsy, worked just as well as taking a little piece of a patient's heart to predict the risk of rejection of a transplanted organ. While there is much disagreement about the rate of progress, and even more about how fast regulatory, reimbursement and educational systems should seek to accelerate personalized medicine, most observers envision a new era based on its principles, one which is very much worth investing in.

Nevertheless, the belief that advocates of personalized medicine rest their case more on hype than reality continues to find expression. Sharon Begley (science editor of *Newsweek*, NY, USA), for example, in a *Newsweek* column from 18 May 2010 entitled: "DNA as crystal ball: buyer beware", argues that, despite what she calls enormous investment in research, personalized medicine represents 'much ado about nothing', or in the words of a geneticist whom she quotes, "The mountain has labored and brought forth a mouse" [101].

To be sure, as Ms Begley points out, biology is complex. There are few straight lines that can explain or predict Alzheimer's and other multivariant illnesses. Nevertheless, in her desire to throw cold water on the hype of personalized medicine, she overstates the opposition to it. She argues that new research that shows how different patients respond to therapies, which has led to the relabeling of multiple drugs to recommend genetic testing before they are prescribed, is built on more of a chimera than reality.

To argue her case, she says, for example, that the US Centers for Medicare and Medicaid Services (MD, USA) declined to pay for genetic tests that would allow physicians to more accurately determine the dose of the widely prescribed, but difficult-to-dose anticoagulant, warfarin.

The facts are otherwise, however. After the US FDA relabeled warfarin in 2007, and again this year, to encourage doctors to perform a routine genetic test to determine how patients metabolize the drug in an effort to slow down the second most common cause of drug-related visits to the emergency room, Centers for Medicare and Medicaid Services decided to pay for the test in ongoing clinical trials. The agency, as well as private payers, wisely wanted to see the results of those trials to determine if the tests were clinically useful, as well as cost effective, before saying that they would pay for them.

The results of one of those trials have now been published. Medco (NJ, USA), in cooperation with the Mayo Clinic (MN, USA), determined that they could reduce hospital admissions by 30% by administering a simple saliva-based test before prescribing warfarin – clear evidence that we have seen the future and personalized medicine works.

By linking therapies to molecular diagnostic tests, including, but not exclusively, genetic ones, personalized medicine envisions improving healthcare while also lowering

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overall costs. If we know anything from following the healthcare debate in the USA, it is that we must get the cost of healthcare under control without sacrificing quality. ‘One-size-fits-all’ trial-and-error medicine should give way to a new era of targeted therapeutics, in which the right patient receives the right drug at the right time.

Over 2000 years ago, Hippocrates wrote, “It’s far more important to know what person the disease has than what disease the person has”. As the increasing number of marketed drugs that are indeed personalized aptly demonstrates, his ancient insight is fast becoming the new reality.

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Reference

- 101 Begley S: DNA as crystal ball: buyer beware. *Newsweek* 18 May 2010
www.newsweek.com/2010/05/18/dna-as-crystal-ball-buyer-beware.html