

## IN THIS ISSUE

**Regulation and guidance on genomic cancer tests inconsistent**

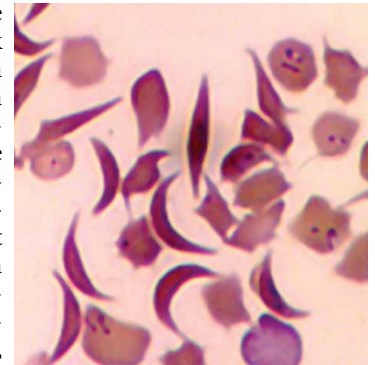
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The rapidly evolving nature of genomic testing for cancer inevitably makes any examination of its current status obsolete almost as soon as it is announced. With the considerable confusion around the proper role of the US Food and Drug Administration (FDA) in the regulation of genomic testing, professional organizations have stepped into the void, assessing and recommending tests across a spectrum from germ-line to tumor testing and from laboratory-developed tests for rare forms of cancer to broad multigene risk-assessment tests. For instance, the National Comprehensive Cancer Network (NCCN) recently chose to endorse only one genomic tumor test for use in patients with early-stage breast cancer. That test—Oncotype DX, a 21-gene assay from Genomic Health—is among 45 tests systematically reviewed by a multidisciplinary group seeking a better understanding of the tests' endorsement trajectory. Chang et al. examined how recommendations agreed or disagreed across recommendation sources and compared these recommendations with the tests' FDA-approval status. Of the tests studied, 18 had two or more groups weighing in on their appropriateness, with only 67% agreement. Yet only five had FDA approval, with an additional five receiving FDA "clearance," a category for medical devices deemed substantially equivalent to an already approved product. Given the confusing regulatory milieu, the authors found disagreements among endorsing groups problematic when clinicians are trying to make decisions about the appropriateness of ordering gene tests for patients. —Karyn Hede, News Editor

**Despite newborn screening, some infants with sickle cell disease at higher risk of death**

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Children born with sickle cell disease in New York are at higher risk for death despite recent advances in reducing mortality, according to a Centers for Disease Control and Prevention-funded long-term follow-up study. Wang et al. report that children with low birth weight and those with US-born mothers were at highest risk of premature death, based on data obtained from birth and death certificates provided by New York state authorities. In New York, 1 in 230 newborns born to non-Hispanic black mothers and 1 in 2,320 newborns born to Hispanic mothers are diagnosed with sickle cell disease, figures that are higher than the national average. Researchers followed 1,911 newborns born between 2000 and 2008 and identified 21 deaths, 12 of which were attributed to sickle cell disease. Low birth weight conferred a significantly higher (ninefold) mortality rate among children with sickle cell disease, compared to those with normal birth weight. Similarly, children with US-born mothers had a higher risk of death than children of foreign-born mothers (3.1 vs. 1.2 per 1,000 person-years;  $P = 0.05$ ). However, putting those figures into perspective, children born with sickle cell disease during the study period had a much lower risk of death than children born only 10 years earlier. The investigators attributed the low mortality rates to interventions that include earlier diagnosis, parental education, and standardized preventive measures such as penicillin prophylaxis, hydroxyurea administration, and pneumococcal immunization. —Karyn Hede, News Editor



## NEWS BRIEFS

**Genomic clinical trial recruiting takes to Facebook**

Need clinical trial study subjects? There's an app for that. Researchers at the University of Michigan are hoping that using the social media site Facebook will help them reach tens of thousands of potential new study subjects for a clinical study loosely defined as a search for gene-environment interactions. The Genes for Good Facebook app is the primary recruiting tool for the study, which asks participants to send in a sample



of saliva and periodically fill out online health forms in exchange for information about genetic heritage and ongoing access to the study's health mapping tools.

To participate, subjects must be adult US citizens who agree to answer detailed questionnaires not only about health history but also about "habits, attitudes, and relationships," according to the researchers' website (<http://genesforgood.sph.umich.edu>). The investigators offer to return information about genetic ancestry, including access to an interactive map with information about individual migration patterns of maternal and paternal ancestors. As an added enticement, they offer to tell participants whether they harbor Neanderthal DNA. In an interesting twist, they also offer participants the