GENETICS

The Illusive Gold Standard in Genetic Ancestry Testing

New regulations on disclosure, authority, and responsibility would shape how genetic ancestry tests are used.

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Genetic ancestry testing is being applied in areas as diverse as forensics, genealogical research, immigration control, and biomedical research (*1*–*3*). Use of ancestry as a potential risk factor for disease is entrenched in clinical decision-making (*4*), so it is not surprising that techniques to determine genetic ancestry are increasingly deployed to identify genetic variants associated with disease and drug response (*5*). Recently, direct-to-consumer (DTC) personal genomics companies have used ancestry information to calculate individual risk profiles for a range of diseases and traits.

Despite the proliferation of companies providing genetic ancestry information, DTC genetic ancestry tests fall into an unregulated no-man's land, with little oversight and few industry guidelines to ensure the quality, validity, and interpretation of information sold. Scholars and scientists have therefore urged the genetics community to take a leadership role in offering guidance to the DTC genetic ancestry market (*6*, *7*).

In November 2008, the American Society of Human Genetics (ASHG) issued recommendations on ancestry testing that emphasized the need for greater responsibility, research, explanatory clarity, collaboration, and accountability by DTC companies, academia, and potential consumers (*8*). While highlighting the clinical implications of ancestry testing, the statement also discussed limitations to the scientific approaches used to infer genetic ancestry, including the incomplete representation of human genetic diversity in existing databases, the false assumption that contemporary groups are reliable substitutes for ancestral populations, and the lack of transparency regarding the statistical methods that companies use to determine test results.

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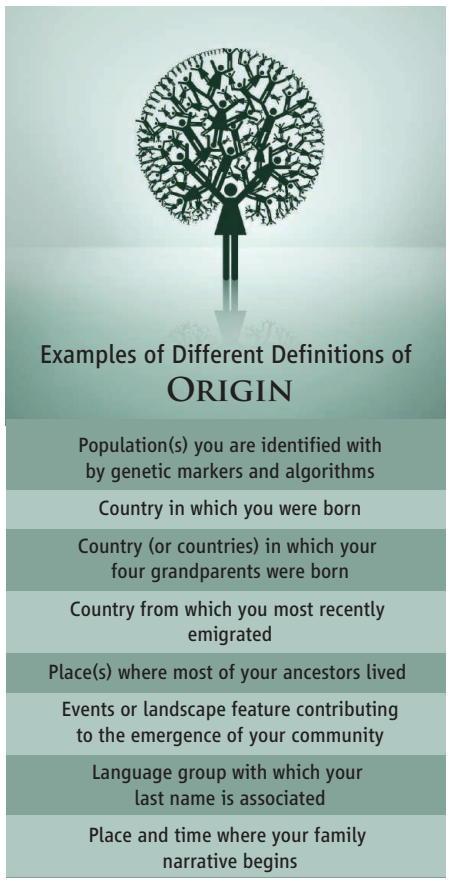
The ASHG statement identifies key issues surrounding the science of ancestry estimation and represents an important first step. However, an effective public policy for the growing market of genetic ancestry tests must build on the ASHG's recommendations and must generate specific mechanisms and approaches. Questions that remain include these: (i) In practice, what do responsibility and accountability mean for academia, industry, and consumers? (ii) How can diverse stakeholders reach a common understanding of the limitations of genetic ancestry tests and their broader implications for human identity? (iii) What role should governmental agencies play in creating infrastructure that effectively addresses the most challenging issues related to DTC genetic ancestry tests?

Mutual Responsibility and Accountability

The ASHG sees academia, industry, and potential consumers as sharing responsibility for conveying and understanding the limitations of genetic ancestry testing. But what do responsibility and accountability mean in human population genetics? This question is critical because the limitations of ancestry testing are entrenched in a broader set of issues that emerge well before these tests reach market. In particular, ethical questions about the collection and use of DNA samples must be resolved before researchers are permitted to sample many of the populations needed to approximate the full range of human genetic diversity. Historically, relations between researchers and study populations have ranged from open negotiations to opportunism, misunderstandings, and even duplicity (*9*).

The importance of this issue is illustrated by the recent decision of the Arizona Court of Appeals to reinstate the 2004 lawsuit of the Havasupai Tribe against the Arizona Board of Regents (*10*). The Havasupai originally consented to have Arizona State University researchers collect DNA samples for diabetes research, but the samples were used without permission to study schizophrenia, inbreeding, and prehistoric human migration from Asia (*11*). One Havasupai allegation is that ASU's ethics oversight was negligent. However, in many instances, research can be compliant with existing human subjects protections yet fail to recognize long-standing differences in access to institutional and legal power, as well as questions about who holds authority to determine future uses of samples (*12*). The Havasupai case is not the only instance of Native American samples collected with consent only for health research, but then used to pursue other areas of inquiry that were not originally identified. Samples taken and traded under less stringent ethical regimes still remain in scientists' collections and may be used for purposes beyond the original research questions (*13*, *14*). It is a scientific imperative that we enact enforceable policies that determine what constitutes responsible and accountable collection and secondary use of DNA samples.

Current guidelines issued by the Office for Human Research Protections (OHRP),



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U.S. Department of Health anhd Human Services (DHHS), do not classify research involving previously collected samples that have been delinked from individually identifiable private information as "human subjects research" and, thus, do not specify requirements for informed consent in such research (*15*). With application of ancestry informative markers (AIMs), though, population-specific labels may be ascribed to anonymized DNA samples. Such samples, now identifiable to a politically and socially salient group, may be used to answer questions that were never approved when the group initially donated samples. Such practices fall outside current ethical oversight. The National Bioethics Advisory Commission has urged consideration of whether research on stored tissue would examine traits with political, economic, or cultural significance and could affect subjects' communities, but this recommendation has not been taken up by the OHRP (*16*). ASHG and other governing bodies should formulate policies to guide ethical collection, use, and repatriation (where appropriate) of biological samples.

Finding Common Language

The high stakes of genetic ancestry research require innovative approaches to dialogue, collaboration, and power-sharing between academia, industry, consumers, and community groups (especially those that have been disenfranchised from the research process) (*9*, *17*, *18*). A first step may be joint creation of a vernacular that characterizes key concepts like probability, association, origin, and ancestry to help minimize variability that exists in how such concepts are understood across fields, communities, and governmental and commercial entities with different vantage points.

For example, the term "origin" is not transparently or consistently defined. To a geneticist, origin might refer to ancestral populations inferred for an individual on the basis of specific genetic markers, specific algorithms for assessing genetic similarity, and specific reference populations. To a casual consumer, origin might mean "the country where I was born," "the country (or countries) where my grandparents were born," "the place or language group where my last name originated," or "the place and/or time where my family narrative begins" (see table, page 38). To a Native American, origin might also signify the landscape feature or event where his or her people emerged or acquired their identity.

Even accepting a genetic or genealogical conception of origin, should each identifiable ancestor or genealogical line be considered an origin? Population origins are rarely defined with that kind of multiplicity in mind. Given that each person may have many ancestors from the same place, does one have more ancestors than origins? Which biogeographical point in the genealogical line of an individual or population do we pinpoint as the origin? What is the rationale for naming ancient genetic lineages according to more recent and shifting ethnic, national, racial, or tribal categories? What are the implications of considering one contemporary population to be the ancestral origin of another?

There are no clear answers to these questions. However, recognizing that key terms can have disparate meanings for different groups will be a critical step toward effective dialogue. Refining a genetic vernacular requires educating both scientists and nonscientists and will depend on incorporating the multiple spheres of expert knowledge of human relatedness. Efforts by genetic researchers and other scholars, community groups, regulators, and industry partners to share their varied understandings may help stem miscommunication and increase rigor.

A Role for Leadership

Human genetic variation research is a continuously shifting landscape. This dynamic marketplace puts in stark relief the limitations of categorical thinking about how genetic information is produced and applied. Genetic ancestry information can rarely be compartmentalized as either clinically relevant or merely historical. Nor is there a bright line between academia and industry because genetic researchers in universities increasingly collaborate with and move into industry. Even notions of the greater "public" are blurred as consumers of genetic products start their own companies (*19*).

Given the very different interests of the various stakeholders, resolution of differences will not be an easy, much less voluntary, process. For instance, the ASHG statement calls for greater transparency, but private sector providers of ancestry testing have proprietary reasons for keeping secret their own particular combinations of key technology, software, and population sampling procedures, and many are unwilling to disclose the size and composition of their reference populations. Without mechanisms to enforce transparency, it is difficult to assess the scientific basis for specific assertions of biogeographical ancestry.

Federal agencies such as the Federal Trade Commission, the Food and Drug Administration, and the Centers for Disease Control and Prevention could play pivotal roles in setting industry standards for what constitutes responsible and accountable practices. These agencies can promote the dialogue and research necessary to discover common language and to identify best practices for presenting the limitations of current genomic technologies and the risks associated with over-extrapolating or misinterpreting genetic ancestry results. New regulations on such matters will help shape how practitioners are able to communicate genetic ancestry testing results to consumers. How these regulations will be put in place is going to be a struggle between various parties that have shown little indication that there will be a compromise that will be acceptable to all. Political will and leadership toward addressing fundamental differences in perspectives may ultimately determine whether a gold standard for genetic ancestry testing can be achieved.

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LETTERS

edited by Jennifer Sills

Less-Toxic Cigarette Use May Backfire

IN THE NEWS OF THE WEEK STORY BY J. COUZIN-FRANKEL AND R. KOENIG ("EXPANDED U.S. DRUG agency to control tobacco," 19 June, p. 1497), Gregory Connolly points out that promoting less-toxic cigarettes has not been shown to reduce tobacco-related death and disease. In fact, promoting the use of cigarettes containing lower levels of nicotine may even increase tobacco-related death and disease.

Of the excess deaths caused by smoking, about 29% have been caused by heart disease and stroke, about 16% by lung cancer, and the rest mostly by assorted other kinds of cancer (*1*). Many people think of lung cancer as the chief culprit because lung cancer is a relatively rare disease in the absence of smoking, whereas heart disease is quite common. Nonsmokers get lung cancer at about 1/40th the rate of smokers (*2*), whereas heart disease and stroke are major causes of death in both smokers and nonsmokers (*1*).

Studies have shown that nicotine addicts smoke until they have absorbed enough nicotine to satisfy their craving (*3*). This means that they will smoke more cigarettes if the cigarettes contain lower concentrations of nicotine. This, in turn, means that they will be subjected to more of the "tars" (the cancer-causing ingredients of the smoke) in their attempts to get their usual dosage of nicotine (the ingredient responsible for heart disease and stroke). In the end, smokers of low-nicotine cigarettes will remain at the same risk for heart disease and stroke but increase their chances of developing cancer.

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NIH Needs a Makeover

NIH GRANTS ARE COVETED AND LAUDED POSsessions among scientists. They are considered a mark of accomplishment or promise, offered for scientific merit and devoid of politics. Unfortunately, the system that bestows the grants has become tangled and inefficient.

The lack of quality reviewers is a major issue. The guidelines for reviewer selection on the NIH Web site are vague at best (*1*). We need individuals who are experts in their fields, but there are no specific guidelines as to what defines "expert." These flimsy criteria made it easy to increase the number of reviewers to an astonishing 30,000 (*2*) in the wake of the stimulus grant deluge, but do not ensure that the reviewers are of high quality. The Center for Scientific Review is desperate to recruit reviewers and is drafting individuals who have poor records of NIH grant awards or weak publishing histories. How can those individuals be trusted to review grants?

Even without the unprecedented number of grants resulting from the stimulus, it is difficult to recruit and retain adequate numbers of qualified reviewers. (Three to four reviewers are solicited to critique each grant.) Study section reviews are still conducted largely on-site, requiring considerable time investments from reviewing scientists. The NIH should make better use of modern telecommunications technology; the grant discussions could easily be conducted via video/teleconference, freeing up not only time but copious amounts of money spent on travel and lodging.

The newly introduced guidelines for reviewing grant applications also pose a challenge to NIH. Assigned reviewers now summarize the strengths and weaknesses on a grant in "bullet forms," which allow for numerical scores but not detailed comments. A grant is scored in five categories (significance, investigators, innovation, approach, and environment), but a final score on overall merit determines the percentile score for funding determination. It is not yet clear whether individual scores have any bearing on the overall score. Moreover, without detailed comments from the reviewers, an applicant does not have much feedback on how to revise a grant for resubmission. The new system is intended to improve the review process, but requires close monitoring to determine whether it is serving the purpose.

It is time to appoint a strong leader at NIH who has the understanding of a lifetime researcher and the authority to revolutionize the institution. It is imperative that the infrastructure be strengthened immediately to advance biomedical research pursuits. **S. K. DEY**

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Keeping Infection at Arm's Length

IN THEIR REPORT "TOPOGRAPHICAL AND TEMporal diversity of the human skin microbiome" (29 May, p. 1190), E. A. Grice *et al.* found that the richest area (in ecological terms) appeared to be the volar forearm, and the antecubital fossa topped the diversity list. This is the exact site physicians use to perform venepuncture, and the results should inform future disinfectant protocol.

Disinfection is often inefficient. When a swabbed venepuncture site is punctured before the antiseptic agent dries (*1*), the bactericidal effect is compromised. In some cases, official guidelines go so far as to consider cleansing the skin optional (*2*).

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Ineffective disinfection has substantial consequences. Blood culture contamination after venepuncture is relatively common and may lead to false positive cultures and unnecessary antibiotic use and hospital stays (*3*). Furthermore, bacteria can be introduced in the bloodstream, causing local or systemic infection. Among the bacteria detected in this body region by Grice *et al.* were the *Staphylococcus aureus* species and phyla hosting pathogens that are responsible for the most common causes of bloodstream infection and sepsis (*4*).

The findings in this report provide grounds for more meticulous disinfection, at least until trials offer us more definitive evidence.

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Make Way for Robot Scientists

IN THEIR 19 JUNE LETTER ("MACHINES FALL short of revolutionary science," p. 1515), P. W. Anderson and E. Abrahams, commenting on our work on the automation of science, state that we are "seriously mistaken about the nature of the scientific enterprise." Their argument seems to be based on two premises: (i) There are two types of science, normal and revolutionary, and normal science "does not contribute very much to the advancement of knowledge." This view dismisses as unimportant the vast bulk of science, and must surely be wrong. (ii) Whereas normal science may be automated, revolutionary science never will be, as there is no possible "mechanism." It is certainly true that revolutionary science cannot currently be automated, and in our Report ("The automation of science," 3 April, p. 85) we described the automatically generated science as "modest…but not trivial." Nevertheless, the inability of some critics to imagine a mechanism does not eliminate the possibility that one exists.

Indeed, the mechanism we propose is the one that has been successfully applied to chess: There is a continuum in player skill, and computers slowly improved with advances in computer hardware and software until they now play at world championship level. We argue that there is a similar continuum in the ability to do science, from what robot scientists can do today, through what most human scientists can achieve, up to the level of a Darwin or Newton.

The Physics Nobel Laureate Frank Wilczek has said that the best chess player in the world is "non-human" and that this may well be true for the best physicist in 100 years time (*1*). Finally, Anderson and Abrahams ignore the possibility of machines and humans working together to do revolutionary science that neither could do alone.

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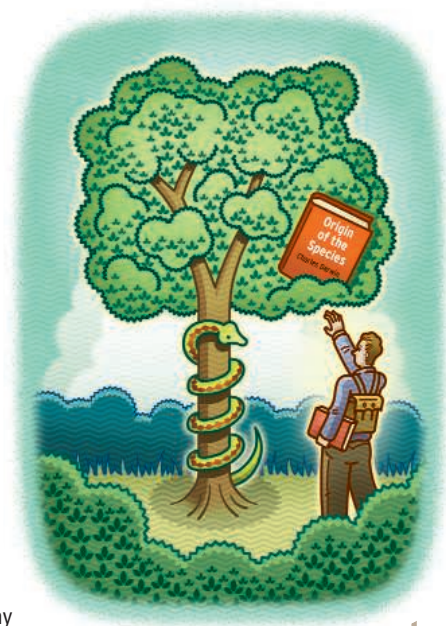
LIFE IN SCIENCE

Creationists Made Me Do It



I was always a mediocre student, especially in high school. I never really knew what I wanted to do, and nothing seemed to excite me. This changed in my senior year, when a creationist visited my biology class.

On that fateful day, all the science students were herded into the school auditorium, where we listened to a long and richly illustrated lecture describing literal creationism. We were informed that in an effort to "balance" our education, we would soon hear an equally long lecture on evolution. This, like many things I heard that day, turned out to be false. The evolution lecture never materialized. Remarkably, I graduated from senior biology having learned only about creationism.

School had finally gotten my full attention. I wanted to know what we were missing, and why. For the first time in my life, I willingly (eagerly even) picked up my textbook and studiously read it. With growing interest, I realized that evolution made an awful lot of sense, and that I was being hoodwinked by my biology class.

It's hard to overestimate the appeal of rebelling against the system to a teenaged boy, and that day marked the beginning of my path to a career in evolutionary biology. We learned other things in science class that year, too—for example, that all actions have an opposite reaction. For at least one sulky teenager in the small town of Owen Sound, Ontario, it took a creationist to make him into an evolutionary biologist.

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EDITOR'S NOTE

This is an occasional feature highlighting some of the day-to-day humorous realities that face our readers. Can you top this? Submit your best stories at www.submit2science.org.

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Looking to Bacteria for Clues

IN HIS NEWS FOCUS STORY "ON THE ORIGIN of sexual reproduction" (5 June, p. 1254), C. Zimmer highlights the importance of the phylogenetic perspective championed by John Logsdon, but by considering only eukaryotes he overlooks an important bacterial clue to the evolution-of-sex puzzle.

Until recently, bacteria were thought to be sexual; they have well-characterized processes that cause recombination of chromosomal alleles, and these parasexual processes were assumed to have evolved for recombination in the same way as meiotic sex in eukaryotes. However, a more critical analysis of the genes responsible for the parasexual processes suggests that they did not evolve for sex after all. Instead, the chromosomal recombination they cause appears to arise as unselected effects of related processes, the evolutionary functions of which are well established (*1*).

The fact that bacteria lack genes evolved for recombination indicates that meiotic sex must have evolved in eukaryotes to solve a problem that bacteria don't have. Bacteria apparently get whatever recombination they need by accident—why do eukaryotes need so much more?

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CORRECTIONS AND CLARIFICATIONS

Letters: "Organics: Evidence of health benefits is lacking" by K. Clancy *et al*. (7 August, p. 676). The title should have been "Organics: Evidence of nutritional superiority is weak."

Policy Forum: "The illusive gold standard in genetic ancestry testing" by S. S.-J. Lee *et al*. (3 July, p. 38). When data were extracted for indexing, the first author's name was incorrectly parsed; her surname is Lee.

News Focus: "The brain collector" by G. Miller (26 June, p. 1634). Henry Molaison died on 2 December, not 8 December, 2008. Also, the credit for the photo of Jacopo Annese should be "Kevin Donley."

Reports: "IL-21 is required to control chronic viral infection" by H. Elsaesser *et al*. (19 June, p. 1569; published online 7 May). The date of receipt was 22 October 2008, not the later date in the original *Science* Express publication. The date has been corrected both online and in print.

News Focus: "Obama moves to revitalize Chesapeake Bay restoration" by E. Stokstad (29 May, p. 1138). The credit for the image on page 1139 should be "Adapted from ECO-CHECK.ORG" (not ECO-CHECK.COM). The link has been corrected online.

Reports: "Del-1, an endogenous leukocyte-endothelial adhesion inhibitor, limits inflammatory cell recruitment" by E. Y. Choi *et al*. (14 November 2008, p. 1101). The following sentence should be added to the acknowledgments in reference 26: H.F.L. was supported by the German Academy of Sciences (Leopoldina).

Letters to the Editor

Letters (~300 words) discuss material published in *Science* in the previous 3 months or issues of general interest. They can be submitted through the Web (www.submit2science.org) or by regular mail (1200 New York Ave., NW, Washington, DC 20005, USA). Letters are not acknowledged upon receipt, nor are authors generally consulted before publication. Whether published in full or in part, letters are subject to editing for clarity and space.

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