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Teaching Residents Genomic Pathology: A Novel Approach for New Technology

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Abstract

Genomics-based diagnostics have become part of patient care. As pathologists have the expertise in clinical laboratory testing as well as access to patient samples, all genomic medicine is genomic pathology. This article will review the evidence that there is a critical need for pathology resident training in genomics. Several individual program curricula are described as well as the progress of the Training Residents in Genomic (TRIG) Working Group. This group has made significant advances towards developing, implementing and evaluating a national curriculum in genomics for pathology residents. The novel approach of the TRIG Working Group can be used as a model for training pathology professionals in any new technology.

Keywords

Genomics; next-generation sequencing; gene chips; direct-to-consumer genotyping; molecular pathology; medical education; residency training

In October 2010, a meeting took place at the Banbury Conference Center at Cold Spring Harbor Laboratory. Attendees included representatives from major pathology organizations, insurance consortiums, industry, the National Institutes of Health (NIH) and the military. The goal of the conference was to define the future of pathology in the era of genomic medicine. The resulting recommendations, published in 2011, listed seven projects to help ensure that pathologists play a major role in applying genomic technology to patient care.[1] One of these projects ("Blue dot" project #1) had the goal "to ensure that every Accreditation Council for Graduate Medical Education (ACGME)– approved residency in pathology in North America includes a mandatory curriculum in genomics and personalized medicine." An editorial accompanying the Banbury Conference summary stated that "although all seven projects certainly have merit and are important to pathologists … project 1 is, without doubt, a 'no-brainer'" and "the need to introduce NGS and whole-genome technologies topics into medical student and pathology resident education is mandatory."[2]

This article will review the basis for the above recommendations and why the need for genomics-related education has only increased. The current state of pathology resident training in genomics will also be discussed with particular emphasis on the progress of the Training Residents In Genomics (TRIG) Working Group. This group's unique approach can serve as a model for teaching novel technologies to pathology professionals.

Genomic Medicine is Genomic Pathology

While standard molecular pathology typically involves analysis of single gene variants or re-arrangements, genomics refers to the ability to analyze large portions of the genome with a single "test." All bases can be sequenced (genome), just the gene-coding regions (exome), or

only genes that are expressed (transcriptome). Next-generation methods, relying on massively parallel sequencing, have shortened the testing time frame from years to weeks with costs rapidly decreasing. Chip technology also allows genotyping of up to a million single nucleotide polymorphisms (SNPs) as well as measurement of copy number variation and expression profiling.

With these advances, genomic technology has found clinical applications in almost all areas of medicine. In regard to oncology, Jones et al. described a patient with an oral adenocarcinoma not responding to chemotherapy.[3] A whole genome and transcriptome sequence was obtained leading to the finding that the tumor was driven by the RET oncogene. Treatment with a tyrosine kinase inhibitor halted disease progression for four months. When the tumor began to grow again, re-sequencing revealed new mutations that bypassed RET, leading to drug resistance. In another case, a patient had apparent acute promyelocytic leukemia by histology but the typical *PML-RAR* fusion could not be identified using standard FISH or PCR assays.[4] Using NGS, the authors found a novel *PML-RAR* fusion product leading to proper treatment with all-trans retinoic acid as opposed to a bone marrow transplant.

Microbiologists have used NGS to assist in epidemiologic studies. During the 2011 *Escherichia coli* outbreak in Europe, the genomic sequence of the pathogen was obtained in less than a week using NGS technology.[5] In one study, the epidemiology of a tuberculosis outbreak could not be determined using traditional methods.[6] Whole genome sequencing of isolates from 32 patients led to an understanding of outbreak dynamics.

Genomic technology has also been used to identify the cause of rare genetic diseases. A child with inflammatory bowel disease had failed multiple treatments and had multiple surgeries.[7] Whole genome analysis revealed a variant consistent with a form of hemophagocytic lymphohistiocytosis leading to successful treatment with a bone marrow transplant. Other studies have performed genome, exome and transcriptome analysis on healthy individuals to determine if they have genetic variants leading to disease risk.[8,9] The risk analysis is based on genome-wide association studies (GWAS) which, typically using case-control design, identify SNPs associated with various conditions such as heart disease, diabetes and cancer as well as predicting response to medications.[10]

Genomic technology has also been used for pre-natal disease prediction. One company has developed an assay to screen for over 100 genetic diseases that is now available for clinical use.[11] Another commercially available assay uses NGS, with a sample of the mother's blood, to detect trisomy 21 in a fetus. The approach quantifies the amount of chromosome 21 DNA.[12]

Clearly, genomic testing is now a part of patient care and its role will only continue to increase. Regardless of the application, whether tubes of blood sent to the hematology, chemistry or microbiology laboratories or surgical specimens sent to the cutting room, pathologists have access to the patient samples. Pathologists also have the expertise to ensure accurate and precise testing and already write the reports for "classic" molecular pathology that help guide patient care. Given the current role of the pathologist in laboratory testing and the access to patient samples, all genomic medicine should be considered genomic pathology.

NGS and chip analysis represent just another testing method. While similar testing is available through direct-to-consumer (DTC) companies, without direction by or input from a pathologist, there is potential for patient harm. In one example, a laboratory mix-up at a DTC genetic testing company led to distribution of incorrect results.[13] In another, Ng et al. sent samples from five individuals to two different DTC companies.[14] Taking into account

all the disease risk predictions for the five subjects, 33 percent of the time, an individual received a report of an increased risk for a disease from one company and a decreased risk for the same disease from the other. These findings clearly demonstrate the limits of DTC genetic testing and use of GWAS to predict individual risk as well as the need for pathologists to standardize test methodology and interpretation.

Physicians who are not pathologists are generally not trained in the principles of method validation, quality assurance, and quality control. This knowledge is especially crucial for genomic testing. As an example, a 10,000 SNP panel for disease risk may have an error rate of only 0.01%; however, if the risk of the disease in the population being tested is only 1 in 100,000, 60% of the population may be misdiagnosed as having the disease.[15] Of course, pathologists are very familiar with these calculations. As an example, although diagnostic assays for HIV have high sensitivity and specificity, when used in a low risk population, many testing positive do not actually have the disease (i.e., a low positive predictive value).[16]

Pathologists have already been involved in a pilot program for NGS of tumors that has enrolled several patients with advanced or refractory cancer.[17] The work flow for the clinical laboratory included the need for sample preparation, sequencing, analysis and validation. A “multidisciplinary sequencing tumor board” including pathologists, oncologists, medical geneticists, bioethicists and experts in genomics and informatics was created to facilitate interpretation of data. The authors note “any results that affect clinical decision-making must be validated using a Clinical Laboratory Improvement Act (CLIA)-certified test” and that they “anticipate that the molecular genetics and pathology communities will move high-throughput sequencing toward CLIA certification, which will ultimately reduce costs and improve turnaround time.” In a similar vein, the authors of the aforementioned article describing NGS technology to identify a novel *PML-RAR* fusion protein wrote “to fully use this potentially transformative technology to make informed clinical decisions, standards will have to be developed that allow for CLIA-College of American Pathologists certification of whole-genome sequencing.”[4]

A Need for Education

Without significant pathologist oversight of genomic testing, there is the real risk for inaccurate results and poor patient care. As such, education in genomic pathology must become part of residency training.

There is currently limited training of most health professionals in clinical genetics, let alone genomic medicine.[18–20] As an example, a study of 112 medical schools in the USA and Canada found that only 11% of courses include “practical training” in medical genetics. [21] In another study that surveyed 214 internists, 74% described their knowledge of genetics as somewhat or very poor and 77% indicated a need for more training.[22] This lack of training becomes evident when one examines genetic test ordering practices of physicians. One CLIA-certified laboratory discovered 107 errors in orders for genetic tests. Almost 70% of these errors were related to ordering an inappropriate test.[23]

While incoming pathology residents have the same limited practical genetics knowledge as other medical school graduates, the ACGME requires that education in “molecular biology” be a component of their residency training.[24] This training, however, does not need to include genomics. The Program Information Form (PIF), completed by program directors to assist assessors on site visits, only asks whether there is specific training in FISH, PCR, DNA sequencing and microarray techniques. Even the PIF for the molecular pathology fellowship programs, as well as a recently published curriculum for molecular pathology fellows, does not refer to genomics or NGS technology.[25] While training in molecular

pathology and laboratory management are important starting points, they are not sufficient to enable pathologist oversight of genomic testing.

Genomic Pathology Training: Individual Program Approaches

Recognizing the need for genomics education, several residency programs have instituted training in genomic pathology. In 2009, the pathology department at Beth Israel Deaconess Medical Center (BIDMC) instituted a mandatory genomics curriculum for pathology residents. The faculty not only included pathologists but also, given the need for a collaborative approach in applying genomics to patient care, genetic counselors.

The curriculum was developed to cover knowledge, affective and performance-based objectives.[26] To provide an adequate knowledge base, three lectures were created. The first gave a general overview of genomics and emphasized the reasons pathologists should play a major role in overseeing genomic testing. The second lecture described genomic testing methods. The third reviewed the role genetic counselors play in patient care and how even single gene testing can lead to significant ethical concerns.

To demonstrate the ability to apply knowledge (i.e., performance-based objectives), the residents were asked to search the medical literature to find an article, related to a disease of their choice, that used genomic methods. The resident reviewed the article with an advisor and, over several meetings, prepared a 15-minute presentation for the other residents. Through this process, the residents learned to critically analyze the literature. In fact, residents found an error on a DTC genetic testing website. The website reported a SNP led to a 1.8-fold increased risk for multiple sclerosis and cited a literature reference. When the residents reviewed the reference, the actual odds ratio was 1.37.[27]

“Affective” objectives are often overlooked in pathology curricula. It is important, however, to understand the emotional effects of genetic testing on a patient. To provide a sense of the issues involved, the department offered to pay for residents to have testing from a DTC company. The company used a gene chip to identify SNPs and, using data from GWAS, make predictions for disease risk (given as a percent probability of developing the disease). The testing was completely voluntary, results were not seen by course faculty, and genetic counseling was provided by the company selected. By structuring the curriculum over several months, the residents could continue in other rotations and also hear the lectures to have adequate information before making a decision on the testing. This schedule also allowed residents to select an article for their presentation after the DTC testing results had been returned. In several cases, the results drove article selection. A sense of relevance and “need to know” are important for adult learners and the testing provided incentive to understand the material.[28] In an anonymous survey, no resident reported feeling coerced into undergoing testing and several commented on how it added to the educational experience. It should be noted that offering testing is not a new concept in clinical pathology education. At some programs, residents perform testing for other laboratory tests, such as a type and screen, on their own blood.[29]

To stimulate national interest in teaching genomics to pathology residents, the BIDMC curriculum was published in 2010 and key components, including the resident presentations, were made available online.[30–32] Given changes in the field and based on resident feedback, the curriculum is currently undergoing revision. Plans are to integrate the curriculum into an already existing month-long molecular pathology/cytogenetics rotation and include exercises related to genomic annotation and communication of results to patients.

Pathologists at Stanford University have also created a genomics training program for residents. An introductory mandatory curriculum involves 10 lectures that were made

available on YouTube in 2012.[33] The presentations integrate concepts of molecular pathology with genomics. For example the first lecture gives an overview of methods for measuring and manipulating DNA and begins with the discovery of DNA, evolves into a discussion Sanger sequencing and then ends with a review of NGS technology. There are additional talks on NGS methods and microarrays as well as lectures on specific applications of molecular pathology and genomics in hematology, histocompatibility antigen testing, pharmacogenomics, solid tumors and inherited disorders. A final lecture discusses ethical, regulatory and commercial issues related to personal genomics. An advanced elective has also been developed for residents, faculty or fellows "who expect to actively apply genomic data interpretation tools in their research and practice."[34] The elective consists of didactics related to annotation of NGS data, statistical methods and computer programming and also includes hands-on exercises.

While several pathology residency programs have instituted genomics training, to better assess the need for a national curriculum, a survey was conducted through the Pathology Residency Directors Section (PRODS) of the Association of Pathology Chairs (APC). PRODS membership consists of 185 residency program directors and 42 (23%) responded to the survey. Of the respondents, while almost all (93%) provided training in molecular pathology, only 28% had their residents interact with genetic counselors. Only 31% provided any training in genomic pathology topics such as NGS and DTC genotyping. For programs with training, the primary teaching modalities were lectures or journal clubs. For programs without training, 91% wanted to start to initiate a curriculum but lack of time in the current resident schedule (76%) and lack of faculty expertise (52%) were cited as the primary barriers. Due to these barriers, 74% of pathology residency directors did not plan on initiating training for at least a year or more. Creation of online modules was rated as the most helpful tool in implementing a new curriculum or improving an existing curriculum in genomic medicine.

The TRIG Working Group

The survey results demonstrated a clear need for materials to assist residency programs in teaching genomic pathology. Based on this need, the Training Residents in Genomics (TRIG) Working Group was formed in 2010. Under the aegis of PRODS and APC and with administrative support from the American Society for Clinical Pathology (ASCP), the working group includes experts in molecular pathology, medical education and genetic counseling, and members of major pathology organizations. The National Society for Genetic Counselors (NSGC) and the National Coalition for Health Professional Education in Genetics (NCHPEG), a group of over 50 organizations dedicated to genetics education, also appointed representatives. The TRIG Working Group includes three past presidents of the Association for Molecular Pathology (AMP), a past editor-in-chief of *The Journal of Molecular Diagnostics,* the former chief of the molecular pathology section of the National Cancer Institute and the executive director of NCHPEG.

A major goal of the working group is to develop a curriculum and learning tools to help implement genomics training for pathology residents. Members decided to begin by reviewing the BIDMC curriculum and, in a structured format, gave suggestions for improvement. By 2011, new objectives were created for a more comprehensive curriculum with plans for four lectures: an introductory lecture followed by three core lectures on genomic methods, applying genomic technology to clinical care and communicating with the patient. After presentation of the objectives at the July 2011 PRODS session at the APC Annual Meeting, lectures and lecture notes were created and were made available in 2012 on the Intersociety Council for Pathology Information (ICPI) website.[35]

A second major goal of the TRIG Working Group is to promote the importance of training pathology residents in genomics. There have been presentations at the annual meetings of the Academy of Clinical Laboratory Physicians and Scientists (ACLPS), ASCP, NCHPEG and NSGC. In 2012, at a first ever joint companion meeting of the ASCP, American Society for Investigative Pathology and AMP at the United States and Canadian Academy of Pathology annual meeting, the lectures with references were distributed in a booklet form and several slides were incorporated into speaker talks. Given its success, a second companion meeting was held at the 2012 ASCP Annual Meeting. This session featured actual presentations of two of the TRIG lectures, a demonstration of genomic data analysis and a panel discussion on the future of genomic pathology. A short course incorporating the TRIG lectures with an interactive data analysis component is also planned for the 2013 College of American Pathologists (CAP) Annual Meeting.

The TRIG group has also authored several articles on resident training in genomics. A peer-reviewed article detailing the approach of the TRIG Working Group in teaching novel technologies was recently published in *Personalized Medicine*.[36] Abstracts were accepted for platform presentations at the 2011 NSGC and NCHPEG annual meetings. An informational article has also appeared on the NCHPEG website and one is scheduled to be published in a 2013 issue of *Critical Values*.[37]

The third major goal of the TRIG Working Group is to incorporate genomics-related questions on the pathology resident in-service exam (RISE). Administered by the ASCP to almost all pathology residents in the United States, the RISE offers an opportunity to assess the national status of resident training in genomic pathology.[38] The TRIG Working Group created both knowledge and survey questions that appeared on the 2012 RISE and questions have been prepared for the 2013 exam. The survey questions will provide information on resident attitudes related to genomic pathology as well as demographic information on the extent of training. The knowledge questions will provide a direct measurement of resident ability in genomic pathology. The questions are currently ungraded but, following this pilot phase, there are plans to incorporate genomics topics as an official component of the RISE.

A Novel Approach in Medical Education

The TRIG Working Group represents a novel approach in pathology education. While many groups in pathology have developed curricula, this work is often accomplished within a single organization.[25,39] As genomic technology will affect all of medicine, curriculum development requires not only collaboration between pathology organizations but also with other specialties. A single organization or specialty approach would preclude selecting from the best possible individuals as well as limit the degree of dissemination of any educational tools. As such, while created through PRODS, the TRIG Working Group includes individuals from major pathology and genetic counseling organizations and represents one of the first collaborative efforts in pathology education.

In addition, most efforts in pathology education have focused on only developing a curriculum (i.e., creating a list of objectives).[25,39] From the beginning, the TRIG Working Group has been focused on creating actual tools to foster curriculum implementation. The freely available lectures and lecture notes represent one of the first efforts in pathology to not just suggest what needs to be taught but provide the materials to enable the teaching. Already, there have been almost 1500 visits to the TRIG Working Group page on the ICPI website.

Finally, few groups creating pathology curricula have considered mechanisms to evaluate the dissemination and efficacy of their work. The TRIG Group will utilize the RISE to determine resident attitudes and knowledge related to genomic pathology. This approach is

not only unique for pathology. Few medical education projects in any specialty have used a tool as powerful as the RISE that can target almost all residents in the United States in a particular medical field.

Moving Forward

The TRIG Working Group through its inter-organizational collaborative approach, creation of teaching tools, and use of a major national exam for evaluation represents a novel approach to pathology education. The initial work of the TRIG Working Group was used as the basis to apply for an R25 grant from the NIH. In 2012, the chair of the group was awarded this grant for approximately $1.3 million over five years. The funds will primarily be used to create, with the support of the ASCP educational design team, online modules to teach genomic pathology to residents. The modules will integrate the information from the lectures with exercises involving annotation of data and creation of genomic pathology reports. These modules will be freely available and also evaluated using a pre/post-test design at four residency sites. The degree of national implementation of residency training in genomic pathology and resident knowledge will be evaluated using the RISE.

To more fully implement training, organizations that oversee resident education need to develop genomics-related requirements. The ACGME Residency Review Committee for Pathology has taken the first step by including, in a draft document for the “new accreditation system,” that the resident should understand “concepts of personalized medicine.” It is hoped further work will define specific competencies within this general requirement. The American Board of Pathology should begin to include genomics questions on both anatomic and clinical pathology exams. Requiring genomics knowledge to become board-certified would provide significant impetus, not only for residency programs to include training but for pathology residents to learn the material.

Summary

Sequencing the first human genome took 13 years and 2.7 billion dollars.[40] Today, the price tag is less than $10,000 and treatment decisions have been based on genomic testing.[3,4,7,17] Clearly, genomic medicine is entering clinical practice and pathologists need to take a leading role. In fact, given pathologist expertise in clinical diagnostics and access to patient specimens, all genomic medicine is genomic pathology. Clearly, we need to educate pathology professionals in genomics. This conclusion was reached at the Banbury Conference Center two years ago and remains true today.[1]

Novel diagnostic modalities are always entering the pathologist’s workplace. Consideration must be given to the fact that many training programs may not have adequate resources or faculty expertise to teach these new topics. The TRIG Working Group’s inter-organizational collaborative approach, creation of actual educational tools for resource limited programs, and evaluating progress using the pathology RISE are all unique. In addition, the significant funding from the NIH will allow one of the largest studies in pathology to determine the efficacy of a curriculum. The approach of the TRIG Working Group represents a new, structured and effective model for pathology education in novel technologies.

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