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ACMG Lobbying State Legislatures on Genetic Counselors' Scope of Practice Draws Criticism

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This article has been updated to note Marc Williams' current role at Geisinger.

NEW YORK – The American College of Medical Genetics and Genomics is lobbying state legislatures to add language to genetic counseling licensure bills that would restrict genetic counselors from independently ordering certain types of genetic tests and conveying the clinical implications of the results to patients.

Genetic counselors are already upset with ACMG leadership after they took a similar stance last year on H.R.3235, a federal bill that would allow genetic counselors to receive Medicare payment for genetic counseling and incident services. The ACMG's latest actions with lawmakers on the state level have further deteriorated its relationship with genetic counselors and garnered criticism from the broader medical genetics community.

The college represents approximately 2,400 medical geneticists, including those with MD and PhD degrees working in clinical care and labs, and master's degree-trained genetic counselors. The widening fissure over the activities that genetic counselors should and should not do, or their scope of practice, may be the fault line of a changing genomics workforce in which genetic counselors as a group are growing faster than MD geneticists. Some doctors may also feel that genetic counselors are stepping on their turf, especially when it comes to test ordering.

"There is a huge need for genetic services in this country and beyond. And to be honest, the medical genetics community has not risen to the challenge of training enough [MD] professionals to meet that need, whereas genetic counselors have," said Omar Abdul-Rahman, an MD geneticist and director of genetic medicine at the University of Nebraska's Munroe-Meyer Institute.

He recently ended his ACMG membership due to the college's stance on genetic counselors' ability to order tests. "In the future of genetic services, there will be a complete paradigm shift from what we've seen in the past," Abdul-Rahman said.

The disagreement over genetic counselors' scope of practice is ultimately about a difference of vision about the future of genetic services, and how to increase patient access to necessary genetic tests and expertise while limiting harms. The ACMG believes the best way to achieve this is if genetic counselors and doctors work together, especially when it comes to ordering genetic tests that diagnose disease or guide treatment.

"What we know works, because it has worked for nearly 30 years, is that when genetic counselors work within a collaborative team, patients are very well served," said ACMG President Anthony Gregg.

The National Society of Genetic Counselors, the broader genetic counseling community, and many MD and PhD medical geneticists have publicly opposed ACMG's stance and said that genetic counselors should be allowed to order genetic tests independently. They have countered with data that show that when genetic counselors double-check genetic tests ordered by healthcare providers, it reduces clinically inappropriate testing and saves healthcare dollars. On this side of the debate are also mounting examples of doctors misdiagnosing patients or recommending unnecessary, invasive interventions after misinterpreting results of genetic tests they've ordered, and patients narrowly avoiding harm because they saw a genetic counselor who caught the error in time (*see examples in Genetic Testing Challenges in Oncology series*).

NSGC President Sara Riordan said genetic counselors know their scope of practice and aren't trying to diagnose or treat patients but stood firm when it came to test ordering. "Where we do have expertise is in ordering genetic tests because we have specialized training and because we work, day in and day out, facilitating genetic testing and counseling about the results," Riordan said. "Particularly in areas like cardiology and oncology and neurology, where physicians don't necessarily have genetics training, they really rely on the genetic counselor to provide that expertise."

The brewing disagreement between the ACMG and genetic counselors resurfaced this year as lawmakers in Oregon, Montana, and Maryland took up bills to establish criteria that genetic counselors would have to meet to be licensed in the state. The bills also include language outlining genetic counselors' scope of practice. In January, the ACMG wrote to lawmakers sponsoring these bills (*see here, here, here, and here*) and urged them to adopt language restricting genetic counselors from practicing medicine, which the college defines as diagnosing, managing, examining, and treating a patient, and ordering medical tests, including genetic tests.

In Oregon, H.B.2619 states that genetic counselors can "identify and coordinate" genetic tests and other diagnostic studies but stops them from "diagnosing, testing for, or treating" a genetic condition or disease. In Montana, H.B.217 would allow genetic counselors to "identify, order, and coordinate" genetic tests and explain test results but would restrict them from ordering other diagnostic tests. In Maryland, S.B.34 in the Senate and its companion H.B.299 in the House of Delegates would similarly allow genetic counselors to order genetic tests and explain the results.

All these pending licensing bills direct genetic counselors to refer patients to doctors for diagnosis or treatment, but the ACMG believes that these bills as written would still allow genetic counselors to practice medicine. In its letters to state lawmakers, the college has proposed amendment language to the Montana and Maryland bills that would have genetic counselors and doctors ink a formal "collaborative relationship" and establish the rules under which genetic counselors can order genetic tests and communicate results to patients. The ACMG would like these bills to specifically require physician sign-off on genetic counselor-initiated orders for tests that provide diagnostic information or guide treatment.

The ACMG's letters to state legislators come a year after the college wrote to sponsors of H.R.3235, the federal Medicare payment bill for genetic counselors that was introduced in the House of Representatives in the 116th congressional session. In January 2020, the college wrote to the sponsors of the bill that if H.R.3235 passed as written, it would allow genetic counselors to receive Medicare payment for activities that only doctors are trained to do, such as ordering medical tests. The ACMG told legislators that while it supports genetic counselors' ability to receive Medicare payment for counseling services, it cannot support any policies that would allow them to practice medicine.

Genetic counselors, meanwhile, have licensure in 29 states. Most of these laws say genetic counselors can "coordinate" or "identify" testing, while 10 states explicitly allow genetic counselors to order tests independently. In the states that allow genetic counselors to "coordinate" and "identify" testing, institutions can still require a doctor's signature on test orders, but according to John Richardson, NSGC's director of policy and government relations, more states are considering going back and adding the word "order" to their existing licensure laws.

However, since genetic counselors' scope of practice is established through the sates, he is uncertain why the ACMG raised scope of practice issues with H.R.3235. If the bill is reintroduced in the current Congress, and the college recommends language on collaborative agreements be added, Richardson said genetic counselors would still be able to independently order tests in the states that allow it. "Medicare would allow whatever is allowed at the state level," he said. However, such language would mean that genetic counselors would have to establish a formal agreement with every doctor that referred a Medicare patient. But because such a relationship wouldn't be needed for non-Medicare patients, this would set up a two-tier system for access, Richardson said.

Deepening divisions

The college's position on H.R.3235 has angered genetic counselors, as well as their MD and PhD colleagues. More than 200 MD/PhD medical genetics have signed a letter attesting to genetic counselors' ability to "synthesize medical information, in conjunction with the physician’s evaluation and diagnosis," and "ensure that the most appropriate genetic test is provided." They have urged the ACMG to reconsider its position on the bill.

Among the signees is David Ledbetter, a PhD medical geneticist who until last year was the founding CSO and executive VP at Geisinger Health System in Pennsylvania. While he agrees that ordering tests is technically the practice of medicine, he believes it isn't in the best interest of patients for the ACMG to hold so strictly to the definition. "Following the letter of the law or rule around MD geneticists' scope of practice guarantees many, many patients will not get appropriate care, will not get testing, will not get seen in clinic," said Ledbetter, who recently became chief clinical officer at Dascena, a company using machine learning to build predictive algorithms that improve patient care.

Ledbetter is ultimately guided in this debate by what will broaden access to appropriate care for most patients, "and that trumps everything else," he said.

According to one estimate from 2018, there were more than 74,000 genetic tests on the market and 14 new tests launched daily. Medicare spending on genetic testing in 2018 doubled to around $1 billion. The government is particularly concerned that a significant portion of this growth is from unnecessary testing and is closely tracking fraudulent billing practices. Many commercial insurers have hired genetic counselors to ensure that billed tests meet their coverage criteria.

Growing test utilization has also increased demand for genetics expertise, and the genetic counseling community has tried to meet that demand. According to NSGC's latest professional status survey, there were nearly 5,200 certified genetic counselors as of January 2020, and by 2030 the workforce is on track to double. MD geneticists by comparison are not a growing group, Ledbetter observed. "It's the MDs who are rightfully concerned about their future viability," he observed. "But becoming increasingly territorial is not the right strategy."

Abdul-Rahman at the Munroe-Meyer Institute in Nebraska has worked closely with his genetic counseling colleagues on the federal Medicare payment bill and to expand state licensure. Hoping to help ACMG and NSGC arrive at common ground on the scope of practice issue, he suggested the college poll members to gauge how they stand on it and publish a point-counterpoint piece in *Genetics in Medicine*, the monthly peer-reviewed journal of the ACMG. Abdul-Rahman was disappointed that ACMG so far has only held a series of educational webinars on H.R.3235, but when the college began lobbying state legislators on the licensing bills, that was "the last straw," and he ended his membership.

"I realized that [the college was] now seeking to undermine years and years of advocacy work that we, ACMG and NSGC members, have done together," Abdul-Rahman said. In states that don't have licensing requirements for genetic counselors, patients are at risk for harm because they can receive inappropriate guidance from individuals who don't have a master's degree in the discipline.

Genetics can also be a politically fraught topic. Abdul-Rahman recalled the extensive education that was needed to enact licensure laws in some conservative states and convince legislators that genetic counselors weren't going to tell women to have abortions. He worried that ACMG's contrary position on these state licensing bills can send the wrong message and move the entire field of genetics backwards.

Moving in the right direction?

ACMG's Gregg told GenomeWeb that there is a lot of misinformation about its position on genetic counselors' scope of practice, and so, the college decided to host educational webinars on H.R.3235. "There is this perception that we are opposing licensure, which we are not. There is a perception out there that we don't want to have counselors reimbursed. That's a misperception," he said. "There is a perception out there that that we want counselors supervised."

The ACMG supports the ability of genetic counselors to independently counsel patients, Gregg stressed, and when it comes to ordering tests, it wants to see genetic counselors work with doctors, not under them. "We don't want to use the term supervised for genetic counselors," he said. "We want to replace that term with ... collaboration."

As Gregg sees it, the integration of genomic information into medicine is complex and the collaborative agreements requirement that ACMG has proposed for inclusion in state licensing bills would lower the risk of a misdiagnosis or inappropriate treatment by setting up rules for when genetic counselors can order tests independently and when a doctor needs to be involved. In its letters to state legislators, the ACMG acknowledges that genetic tests that assess disease risk or guide family planning can be "safely" ordered by certified genetic counselors.

But letting genetic counselors order tests that diagnose a patient's condition or inform their treatment on their own would increase the risk of harm from a misdiagnosis or incorrect interpretation of results, Gregg believes. He declined to provide specific examples, however. "I don't want to impugn a discipline. … I don't think it's that far off for people to appreciate that in medicine there will always be potential harms that are out there," he said.

Meanwhile, across the country, often at the request of doctors, genetic counselors are the ones identifying the tests to order for patients, even though the test orders carry the MD's signature in states that don't allow genetic counselors to independently order tests. At Brigham and Women's Hospital in Boston, Robert Green, an MD geneticist and associate physician, said genetic counselors and doctors certainly collaborate on the best course of action for patients, but he also described genetic counselors as "instigators and implementers" of genetic testing, who extend physicians' time. A genetic counselor may identify the test for a patient, but "the legality of it is it's my name on that test order, not theirs," he said.

Other MD geneticists acknowledged this same practice and wondered the extent to which their signatures are protecting patients from the harm. For example, at the Munroe-Meyer Institute, Abdul-Rahman regularly signs off on genetic tests that genetic counselors order for patients at the University of Nebraska's Buffett Cancer Center. "Do I think I'm an expert in cancer genetics? Absolutely not," he said. "Technically, we have what ACMG is arguing provides good care, a collaboration where I'm the ordering provider. But I can tell you there is no added safety because my name is on that order."

If the ACMG is afraid that once genetic counselors can independently order tests they will set up shop and start practicing medicine and diagnosing patients, then "there is no evidence to support [that] fear," Abdul-

Rahman said, observing that genetics blurs the lines in terms of what constitutes a diagnosis. A breast cancer patient with a germline BRCA1 mutation has a diagnosis of hereditary breast cancer, and in his view, a genetic counselor is perfectly capable of explaining the implications of that inherited mutation without a doctor.

Moreover, he and others noted that patients often come to genetic counselors with a physicians' referral, after they've been diagnosed with a condition or because counseling and testing may help a doctor arrive at a diagnosis. Even if patients were to seek out genetic counseling on their own and receive testing ordered by a genetic counselor, they'd have to see a doctor to act on the results.

For Dinesh Lulla, a pediatric neurologist at Boys Town National Research Hospital in Nebraska, it is really important to first examine the patient and develop a course of action for genetic testing in collaboration with the genetic counselor. "I don't just decide on my own what test to order," he said. "I sit down and discuss the case with the genetic counselor, and we come to a combined decision. As long as we come to a combined decision, I'm okay with genetic counselors ordering the test."

Working in collaboration, genetic counselors have helped him order appropriate testing for his patients. In one particularly challenge case, involving a patient with developmental delay, seizures, and vision issues, Lulla was initially considering exome sequencing for the child and his parents to try to pinpoint the genetic cause, but a genetic counselor after taking a detailed family history, suggested exome sequencing the child's brother who had a similar presentation. "It saved a lot of time, because we did the genetic test for the brother long before I actually saw him in my clinic," he said.

The need for collaboration may be practice dependent, he said, acknowledging that some general practitioners may not be that knowledgeable about genetics, and it may also depend on the experience of the genetic counselor. A recent graduate may not immediately know a specialty like neurology well enough to be ordering tests on their own, Lulla said.

Paldeep Atwal, an MD geneticist who runs his own concierge telegenetics clinic and who was previously medical director of Mayo Clinic's Individualized Medicine Clinic, has worked closely with genetic counselors throughout his career and noted that he is a strong supporter of licensure, reimbursement, and the independent practice of genetic counseling. He also sympathized with the ACMG's position on collaboration, recognizing that patients receive optimal care when different specialists work in a collaborative environment. "We're moving towards that nationally," he said.

Atwal is also medical director of genetics services at PWNHealth, a network of clinicians that facilitate diagnostics via telehealth. Although Atwal said he didn't have permission to speak on PWNHealth's specific test ordering protocols, the third-party physician network-enabled testing model has become particularly popular among CLIA-certified testing labs as a way of offering consumer-facing diagnostics services and expanding test access to those who lack it.

Green noted that people can now get genetic testing a number of different ways that don't involve any doctor, in the case of direct-to-consumer firms like 23andMe, or at least, not their own doctor, in the case of labs that utilize third-party physician networks. These new models have raised concerns about patient harm, said Green, who co-founded the genomics services company Genome Medical in 2016 to address the growing need for genomic counseling and medical consultations amid increasing test utilization.

While allowing genetic counselors the ability to independently order tests might make the work of Genome Medical even easier, he doesn't share the ACMG's concern that this would increase patients' risk for harm, since consumer-facing delivery models are already in place. "ACMG's resistance to this, may be with the best of intentions, but it is not moving in the correct direction when we think about the need for genomics expertise," he said.

Collaboration or oversight?

Atwal, on the other hand, does see the ACMG's point about the risks. Some of the cases Atwal helps diagnose, involving inborn errors of metabolism or multisystem mitochondrial genetics, are often too complex for the average clinical geneticist and requires the involvement of subspecialists. In these difficult cases, genetic counselors and doctors working together can still order the wrong tests and mak incorrect management decisions. In these situations, the error may not be the fault of the genetic counselors, but in his mind, they are more reasons for collaboration.

"I don't think it's oversight," he said, noting that in certain areas of testing, such as genetic testing to assess hereditary cancer risk, Ob/Gyn, oncologists, and breast surgeons are not under any illusion that they're supervising genetic counselors on which test to pick for a patient. "The genetic counselor is clearly in charge of that," he said, but maintained that which steps to take next based on the results is best decided in a collaborative way. "That's where the college is coming from."

The NSGC argues, however, that a legal requirement for genetic counselors to ink "collaborative agreements" with referring physicians would delay patient care. Genetic counselors receive referrals from large regional systems involving many physicians, particularly because they lack genetics expertise and rely on the genetic counselor to identify which test to perform, the NSGC's Riordan said. A requirement to have a collaborative agreement with every referring physician would be impractical, add expense, and require physicians to take on partial liability, in her view. "In practice, while collaboration happens naturally, we see collaborative agreements actually being a barrier" to seeing patients quickly, she said.

As part of the NSGC's 2020 professional status survey, the society collected data on how quickly genetic counselors were able to see patients on their own and with a physician and found that for emergent cases, where genetic services may be needed sooner rather than later, genetic counselors on their own can see two-thirds of cases within one to three days. But when genetic counselors are working with a doctor, only around 30 percent of emergent cases are seen in that one-to-three-day window.

Some MDs similarly wondered if the ACMG's collaborative agreements requirement would truly result in collaboration. What the college is calling collaboration sounds to Green like "physician privilege," and the idea that the ACMG would try to define the scope of practice for genetic counselors doesn't sit well with Abdul-Rahman. Just as he knows he can't perform neurosurgery, Abdul-Rahman said it's important to recognize that genetic counselors also understand their scope of practice, what they can do and what their limitations are. "For some reason, the ACMG sees themselves as sort of big brother, as the responsible oversight group for another profession," he said. "I don't understand where they get that authority."

Regardless of where medical geneticists stand on genetic counselors' scope of practice, they're generally surprised that the NSGC and the ACMG are still at loggerheads on this issue, and if anything the disagreement has only intensified over the past year. Some are hoping that the organizations will try to come together after Marc Williams, former director of the Genomics Medicine Institute at Geisinger and current professor, takes over as ACMG president in mid-April. Williams could not comment for this article because he cannot speak on behalf of the ACMG until his presidency begins, but his former Geisinger colleague, Ledbetter, is optimistic for "a potential fresh start and new opportunity with the new presidency,"

Meanwhile, the genetic counseling licensure bills in Montana and Maryland have moved ahead without the ACMG's collaborative agreements language. The Senate version of the Maryland bill (SB34) has unanimously passed a Senate floor vote and is expected to advance through the House. "The language recommended by ACMG is not necessary and it is inconsistent with genetic counseling laws in most other states," a representative from the office of Senator Clarence Lam, a democrat representing Baltimore and Howard County in Maryland and the sponsor of SB34, said in a statement. The spokesperson noted that the bill was written in consultation with doctors in the state and it appropriately reflects the relationship between physicians and genetic counselors, since it requires genetic counselors refer patients to doctors for diagnosis and treatment.

A similar bill unanimously passed in the Senate last year but ran out of time in the House because the Maryland General Assembly adjourned early due to the pandemic. Lam's office expects the bill will be passed by the assembly this year.

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