

# Physician

The Independent Medical Business Newspaper



## Prior authorization

### *Why legislation is needed*

By Sen. Melisa Franzen, MPP, JD

I first heard about the challenges with prior authorization (PA) at the home of some of my physician constituents. They, and soon many others, told me that the prior authorization process was time-consuming, frustrating, and costly. Although a necessary process in some cases, prior authorization is too often a roadblock and headache for delivering effective care for those who need it the most; patients. The current prior authorization system is unclear and difficult to understand.

Doctors are often left scratching their heads when they prescribe medications that are covered by insurance plans, but require the additional step of prior authorization. They must then scramble to find medication the health plan will cover, or start the process to convince the plan that this is the best drug for the patient. For patients, they are caught in the middle and unable to get the medications they need. In some cases, patients have their current

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## International medical graduates

### *Minnesota's untapped physician workforce*

By Edwin Bogonko, MD, and Edward Ehlinger, MD, MSPH

What if Minnesota had a resource that could simultaneously reduce health disparities, health inequities, and health care costs? And what if that resource could also help the state catch up with huge demographic shifts, replenishing and diversifying the health workforce with clinicians capable of providing primary care where it is needed most?

We have such a resource. It's the state's numerous international medical graduates who come to the U.S. as refugees, asylees, or other immigrants and find they cannot practice in their new home. Even the most highly qualified—those fluent in multiple languages, and with years of experience delivering care in a variety of settings and with a passion for serving those in need—run into impenetrable roadblocks that no amount of expertise, effort, or drive can surmount. We have a ready asset base we ought to tap into.

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As the aging population grows, physicians are seeing more and more patients with brain disorders such as Alzheimer's disease, Parkinson's disease, depression, and post-traumatic stress disorder. Alzheimer's disease alone affects one in eight older Americans and is the sixth-leading cause of death in the U.S. The impact on patients and their families is devastating.

Yet, despite the prevalence of brain-related disorders among the growing elderly population, we still don't have effective treatments for Alzheimer's and other neurological diseases. This is unacceptable. We simply must find ways to accelerate research that will lead to effective therapies. If we don't, the terrible toll on patients and their families will continue.

In the case of Alzheimer's, we know that the major risk factor for the disease is age:

the older you get, the greater the risk. Genetics also plays a very important role; the second major risk factor is family history. For people whose parents or grandparents had dementia to Alzheimer's disease, their risk for developing Alzheimer's increases three- to fourfold. Some of this risk is due to the gene APOE4, but other genes also seem to be involved. There are still a lot of questions left to be answered.

There is great work going on in this area in Minnesota. The physicians and scientists in the Alzheimer's Disease Research Center at Mayo Clinic are at the

## The Brain Health Registry

*Accelerating the path to cures*

By Michael Weiner, MD

forefront. Ronald Petersen, MD, PhD, is world famous for his recognition that mild cognitive impairment is a clinical stage on the continuum between normal aging and development of dementia due to Alzheimer's disease. Many other scientists at Mayo Clinic have also made significant contributions to the field. At the University of Minnesota, the Center for Magnetic Resonance Research led by Kamil Ugurbil, PhD, has also been a world leader in developing the most advanced, state-of-the-art MRI imaging techniques. Furthermore, "functional MRI" was first performed at this center, leading to the development of an entire field that is impacting research and diagnosis of Alzheimer's disease. Therefore, investigators from Minnesota have produced and continue to come forth with some of the most outstanding research advances in the field.

### The research challenge

Despite progress, there is an urgent need to speed research into neurological diseases. But one of the biggest impediments is the difficulty of finding people willing to enroll in studies and clinical trials. Recruiting study participants is both expensive and time-consuming, with recruitment accounting for about a third of the total cost of running a clinical trial.

It is particularly difficult to recruit patients for studies of neurological diseases. Among the major challenges are identifying at-risk cohorts of sufficient size. The problems in recruitment are several fold. First, large numbers of subjects need to be recruited, because many subjects who volunteer

will fail to meet the criteria of the specific study and will be screened out. Second, each clinical trial or neuroscience study currently recruits subjects separately. Third, when subjects are recruited and screened, the only data that is available is the data obtained at the time of recruitment. There is no longitudinal data available that might help determine eligibility. In summary, the needs are to recruit large numbers of subjects at low cost, to obtain screening information, and to obtain longitudinal information prior to entry into a treatment trial.

Given the significant hurdles in recruiting study participants, my colleagues and I thought long and hard about potential solutions, and we came up with a website called the Brain Health Registry ([www.brainhealthregistry.org](http://www.brainhealthregistry.org)). The primary goal for this web-based effort is to recruit as many as 100,000 people into studies of neurological diseases by the end of 2017.

Our goal is to recruit, assess, and longitudinally monitor subjects and refer them into clinical trials including treatment studies. If we can do that, we can speed up research on brain diseases and thereby accelerate the development of effective therapies.

### How it works

The Brain Health Registry is designed to find potential study participants more quickly and at less cost, thus reducing the time and costs associated with clinical trials for brain disorders such as Alzheimer's disease. Simply put, the website gathers cognitive testing data online from registered members who complete questionnaires and tests on the site.

Anyone 18 and older can register to participate in the Brain Health Registry, whether or not they have a family history of brain disease or neurological risk factors. The registry is designed to detect changes over time in a person's cognitive brain health, which is why it



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is important for people of all ages to participate. But we are particularly hoping for sign-ups from the over-50 population.

The project was launched in 2014 and is overseen by UCSF Medical Center. Every aspect of the project is reviewed and approved by the UCSF Institutional Review Board (IRB). Ensuring that safeguards are in place to protect participants' privacy is a high priority.

Those who sign up to participate on the site are first asked to sign a consent form. Next, they complete a series of questionnaires about their personal and family medical history and about their diet, sleep, exercise, and lifestyle. Once the questionnaires are completed, participants are asked to take some neurological tests in an online game format. Given the important role of genetics in brain diseases, we also have plans to collect DNA from willing participants.

Participants are asked to revisit the site every three to six months to engage in these online cognition games. Participation takes an estimated one and a half hours per visit or about three hours each year. Data from the online assessments is collected over time and analyzed to identify potential candidates for clinical trials and other studies on brain-related diseases.

My colleagues and I think the Brain Health Registry will become an important tool to speed outreach to candidates for clinical trial recruitment and for other research purposes that involve data collection and analysis. Similar to the Stand Up 2 Cancer model, which was created to accelerate innovative cancer research, the Brain Health Registry is partnering with researchers across the country to collaborate in finding treatments and cures for brain diseases.

Based on the needs of the research community, the Brain Health Registry may use infor-

mation collected on the website to identify potential participants for clinical trials to test diagnostic tools and potential therapies for brain disorders. Participants will only be con-

partnerships with Cogstate and Lumos Labs (both of which provide online cognitive tests) and Johnson & Johnson, which is funding a validation study.

We're off to an exciting start.

### *Anyone 18 and older can register to participate in the Brain Health Registry.*

tacted about participating in clinical trials already approved by UCSF's IRB. Once given the opportunity to participate in a clinical trial, the choice to participate or not will always be up to the patient.

Another advantage of the Brain Health Registry is that it will reduce the need for individual recruitment efforts. We are very interested in helping genetics studies recruit, assess, and monitor subjects longitudinally.

The more members who join the Brain Health Registry and who continue their participation over time, the more data can be collected to help find viable candidates for clinical trials. This normally is a process that can take years to accomplish. We think the Brain Health Registry can help streamline that process and help recruit more diverse, but underrepresented populations including ethnic and socio-economic segments.

#### **Progress so far**

During the past year, more than 12,000 people have enrolled in the Brain Health Registry. About half of those who have signed up have returned for a six-month follow-up visit. The initial data is very exciting and is of high quality. We have found significant effects of age, gender, sleep, depression, and memory complaints on cognitive functioning. We have reported the findings at international meetings, and papers are being prepared for submission to scientific journals. We have

But more needs to be done to make this a success. We need to continue to grow the number of members and to encourage them to continue revisiting the site. We are building partnerships with organizations such as the Alzheimer's Association and Alzheimer's Prevention Initiative. We are starting to seek enrollees outside of the San Francisco Bay Area, including the Minneapolis/St. Paul area and surrounding counties.

#### **How you can help**

We hope you will join the Brain Health Registry and also encourage your patients to join. It only takes about an hour a few times a year. It's a practical way, without cost, to help advance scientific research leading to effective treatments for brain disorders, including Alzheimer's disease. The website gives people a chance to participate in meaningful research aimed at developing effective therapies for devastating brain disorders. Also, their participation may lead to access to clinical trials they may want to participate in.

We believe the Brain Health Registry will lead to faster cures for brain disorders. We ask you to join our effort. ☑

**Michael Weiner, MD**, is founder and principal investigator of the Brain Health Registry and professor of radiology and biomedical engineering at the University of California at San Francisco.

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