MAYO CLINIC

From Hypothesis to Bedside

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Medical research can be a challenging process, slowed by the complicated nature of translating research into treatment, but Mayo Clinic's Nathan Staff, M.D., Ph.D., Assistant Professor of Neurology, has a plan to surmount these obstacles and streamline the research process. He and his colleagues detailed this plan in an issue of the journal Science Translational Medicine.

Take Alzheimer's research for example. Even if the next major breakthrough in treating the condition is discovered, it may take up to "16 to 17 years" for that treatment to reach patients, according to Dr. Staff's article. A study performed by the U.S. National Cancer Institute identified several "bottlenecks" causing this slowdown, some of which included: the hand-off from academia to industry, the transfer of manufacturing from research lab to good manufacturing practices (GMP), and difficulties in clinical trial regulation.

Another study, by Anthony Windebank, M.D., and colleagues (Biomaterials 2000), found that a large percentage of successful studies using animal subjects were never advanced to human testing, essentially leaving the study findings in limbo. They found the causes of this were: the hand-off from academia to industry, early trial design not focused on GMP, and academic scientists not prepared for the regulatory approval process. One noted finding of this study was that several researchers expressed their ultimate goal as publishing study findings rather than developing those findings into a therapy, leaving that step to the industry.

Dr. Staff recognizes several of these hurdles in his discussion and proposes two main remedies. The first is to redirect funding towards studies aimed at producing clinical treatments. This means government funding agencies, nonprofits, and private investors must focus on approving studies that have a clear plan to translate their research for use in the field.

The second remedy is to educate researchers on the process involved in taking a therapy through the regulatory process. To facilitate this, he says, communication must be bolstered between the parties involved, the clinician-investigator and the regulating agency. Mayo Clinic provided an example of this cooperation in a recent study focused on Amyotrophic Lateral Sclerosis (ALS), often referred to as Lou Gehrig's disease. At Mayo Clinic, the department of Neurology and the Center for Regenerative Medicine established a strong, two-way communication channel with the FDA Center for Biologics Evaluation and Research. By participating in this cooperative communication, Mayo Clinic was able to establish two studies using stem cell therapy to treat ALS in 2009 and 2011.

Dr. Staff points out that medical research is designed to bring new therapies to the community and by strengthening education and communication, those therapies can reach the community much faster.

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