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Review

Alzheimer's disease research in the context of the national plan to address Alzheimer's disease

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ABSTRACT

In 2012, the first National Plan to Address Alzheimer's Disease in the United States (U.S.) was released, a component of the National Alzheimer's Project Act legislation. Since that time, there have been incremental increases in U.S. federal funding for Alzheimer's disease and related dementia research, particularly in the areas of biomarker discovery, genetic link and related biological underpinnings, and prevention studies for Alzheimer's. A central theme in each of these areas has been the emphasis of cross-sector collaboration and private–public partnerships between government, non-profit organizations and for-profit organizations. This paper will highlight multiple private–public partnerships supporting the advancement of Alzheimer's research in the context of the National Plan to Address Alzheimer's.

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1. Introduction

1.1. Background

More than 5 million Americans (Alzheimer's Association, 2014) and 35 million people worldwide are estimated to be living with Alzheimer's disease (AD) today, with the

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prevalence expected to quadruple by 2050 as the world's population ages (Alzheimer's Disease International, 2009). The potentially devastating impact of the disease on public health, the global economy, and society in general has been recognized by governments worldwide (Rosow et al., 2011). Global organizations such as the World Health Organization (WHO) (World Health Organization and Alzheimer's Disease International, 2012) and Organization of Economic Co-operative Development (OECD) (OECD, 2013a, 2013b) are beginning to take action to address this crisis. In December 2013, leaders from G8 countries convened a Dementia Summit in London to craft an international response to the dementia crisis, resulting in a declaration calling for increased support for research and improved care for both individuals and caregivers (G8 Health Ministers, 2013). In addition, the G8 leaders established a goal, commensurate with the US National Plan to Address Alzheimer's (will be described later) to effectively treat or prevent dementia by 2025. With this goal in mind, the country leaders have convened four subsequent legacy events and multiple ancillary events to discuss actionable items for governments to achieve to address this crisis.

Mounting an effective response to the Alzheimer's epidemic will require international research collaboration and innovative approaches to the sharing, integration and analysis of diverse types of data from multiple sources (Carrillo, 2013). The growing number of private–public partnerships is catalogued in an annual compendium, compiled by the Alzheimer's Association, and highlight both the diversity and collaborative nature of this space (Snyder et al., 2014). In addition, new multidisciplinary research from areas such as clinical, imaging, biomarker, genomic and other omics studies, combined with efforts in electronic health records, payer claims, and new technologies that track real-time data should inform a better understanding of the earliest neuropathological and behavioral events that herald the oncoming disease.

1.2. National plan to address Alzheimer's disease

To address the growing Alzheimer's epidemic, the Alzheimer's Study Group, a non-partisan independent panel formed under the auspices of the Congressional Task Force on Alzheimer's Disease in the U.S., released a set of recommendations in March 2009 (Alzheimer's Study Group, 2009). Key among their proposed actions was a call for the development of a strategic plan to focus national efforts in Alzheimer's research, care and support. Building on these recommendations, the U.S. Congress unanimously passed the National Alzheimer's Project Act (NAPA) in December 2010. Signed into law in January 2011, NAPA required the U.S. Department of Health and Human Services (DHHS) to develop and annually update a comprehensive national Alzheimer's strategy; coordinate Alzheimer's disease efforts across federal agencies; and establish an Advisory Council on Alzheimer's Research, Care, and Support.

The National Plan to Address Alzheimer's Disease ("National Plan"), released in 2012 and developed with input from a broad constituency of experts in aging and dementia, as well as individuals and families affected by AD (U.S. Department of Health and Human Services, 2013), sets as its first goal to "prevent and effectively treat AD by 2025." It also called for greater public awareness of AD, improved health care provider education and outreach, and increased support for Alzheimer's caregivers.

To support the National Plan's research goal, the National Institutes of Health (NIH) hosted the *Alzheimer's Disease Research Summit 2012: Path to Treatment and Prevention*, which resulted in the beginning of an integrated, multidisciplinary research agenda on AD. Since that time, leading AD researchers, convened by the Alzheimer's Association, have provided additional input on the scale and scope of resources (Alzheimer's Association Expert Advisory Group on NAPA, 2012) with scientific milestones (Alzheimer's Association National Plan Milestone Workgroup et al., 2014) necessary to achieve the 2025 goal. In February of 2015, the NIH hosted *Alzheimer's Disease Research Summit 2015: Path to Treatment and Prevention* to revisit the milestones set in 2012, evaluate progress to date and, if needed, to revise the existing milestones to be commiserate with the research goal of the National Plan.

In addition to the research agenda established by NIH, the National Plan has helped to foster other important accomplishments. For example, to support the National Plan's strategy to facilitate translation of promising research, the Food and Drug Administration (FDA) established draft guidance on the expedited approval process of drugs for early-stage AD (Food and Drug Administration, 2013). To support the National Plan's strategy to expand research aimed at preventing and treating AD, the National Institute on Aging (NIA) has led the effort to develop new tools to enhance participation in AD clinical studies (National Institute on Aging, 2014). Consistent with the National Plan's strategy to foster international collaboration, the NIA, in partnership with the Alzheimer's Association, launched the International Alzheimer's Disease Research Portfolio (IADRP), a comprehensive, online database of global AD research by participating organizations (Liggins et al., 2014).

The creation of the National Plan has fostered an environment resulting in increased federal funding for AD research in recent years. In fiscal year 2012, the federal government provided an additional $80 million for AD research, and in fiscal year 2013, NIH Director Dr. Francis Collins dedicated $45 million from his own discretionary budget to AD research. In fiscal years 2014 and 2015, the federal government provided an additional $100 million and $25 million, respectively, for AD research. Future accomplishments, most notably achieving the 2025 goal, will depend on further investments in AD research (Egge, 2014).

2. Alzheimer's research in the context of the National Plan

The US National Plan outlines a number of science areas of emphasis key to advancing knowledge of AD and related dementias. One of these key strategies is the need to focus partnerships and collaborations across sectors, including government, for-profit and non-governmental organizations, to expand existing and create new private–public partnerships. The landscape of collaborative efforts is highlighted each year in a compendium published in *Alzheimer's & Dementia* (Snyder et al., 2014). Such efforts both leverage

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