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Letter to Editor

Need for New Treatments in the Prevention of Degenerative Intellectual & Developmental Disabilities (DIDD)

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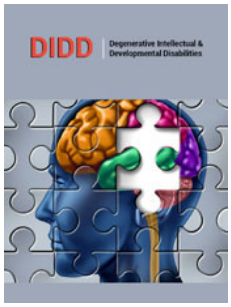

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Submission: September 18, 2019

Published: March 06, 2020

Volume 2 - Issue 1

How to cite this article: Isaac MB, Isaac EL, Isaac MT. Need for New Treatments in the Prevention of Degenerative Intellectual & Developmental Disabilities (DIDD). Degenerative Intellect Dev Disabil. 2(1). NPMS.000526.2020.

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Letter to the Editor

More than one billion people in the world live with some form of disability, of whom nearly 200 million experience considerable difficulties in functioning as reported by the WHO [1]. In the next years this will growth due to ageing populations and the higher risk of disability in people living with chronic health conditions such as diabetes, cardiovascular disease, cancer, infectious diseases and mental health disorders.

As example, an estimated 43.8 million people globally live with dementia (2016 figures). Nichols et al. [2] highlighted potentially preventable associated links with global disease burden, such as high BMI, high fasting plasma glucose, smoking, and a high intake of sugar-sweetened beverages. We continue to be confronted with unwelcome negative findings of new medical treatments of the Alzheimer's disease (AD) with trials based only on the clinical pharmacology of amyloid pathology. In 2019, Knopman et al. [3] reported the failure of BACE inhibitors and monoclonal antibodies in the treatment of mild cognitive impairment (MCI), mild and moderate AD, where the cognitive decline of a patient can be discerned at as early as 13 weeks of taking the trial drug. The results using MRI biomarkers suggested a decrease in cortical thickness due to diminution of inflammatory modulation following administration of drugs that target amyloid levels.

For example, vector-spread infectious diseases, diet, climate change and environmental contamination are well defined epidemiological factors, of which there is a need of fine-grained measurement. Current vaccines and advances genetic therapies in Spinal Muscular Atrophy [4], cancer and dementia developed have not included any of these new technologies or methodologies to develop a better understanding of prevention, or what is the best time to use them in the natural history of the disease. The primary interests of scientific regulators are public health and providing patients with access to the right drugs, at the right time and with the right dose. There is also great focus on facilitating patient access to medical treatments for people suffering of neurodegenerative disorders and intellectual disability which are in growing global need, among other medications for a variety of illnesses and disorders. In an ever-evolving process, the European Medicines Agency (EMA) and the Food and Drug Administration (FDA), have made positive progress and have updated their respective guidelines on the qualification of novel methodologies for biomarkers and clinical outcomes [5-8] and new regulatory indications to reflect an improved methodological approach and ensure better regulatory clinical trials of neuropsychiatric disabilities in mental health.

Of course, regulators are members of the public, and share a common interest in the incorporation of new research ideas to facilitate global clinical trials. There is significant interest in the facilitation of discussion between global research funding agencies to increase transparency of the evaluation process, as well as to stimulate collaborative research in order to decrease the regulatory burden on researchers [9]. In the case of degenerative disorders , both the EMA and FDA have harmonized the proposed use of biomarkers, MRI , digital technologies and to describe people medical needs and collaborate with IMI-AUIMS and IMI-PRISM to improve the digital tools to measure behaviors in neuropsychiatric disorders [10].

However, current brain degenerative disorders models are predicated on the presence of pathology in the brain and we have no other information about what other environmental factors, healthy lifestyle habits, climate changes impact in degenerative disorders. It is apparent that novel approaches are required to resolve this impasse, with trans-disciplinary, non-silo, thinking, involving are age of disciplines - geographers, statisticians, physicians, and regulators? We suggest that a conceptual parallel can be found in existing modelling of infectious disease distribution and development of vaccines. This is an important response to climate change, where focused models of disease vector distribution as a function of increasing global temperatures, environmental factors can be measure by digital data and can inform policies of vaccination targeting [11].

The biological rationale of diagnosis is a good starting point to tackle the early diagnosis of degenerative disorders, and clearly identifies strategic priorities for the study of these disorders. There is much at stake. Not only are degenerative intellectual and development disabilities of critical importance in our society, but an accurate evaluation of the personal risk of developing these illnesses also reflects the mounting demand for individualized healthcare. It is vital that no stone is left unturned in the investigation and search for robust treatments, especially for and in the earlier stages of this devastating condition; and the sooner this is done, the better. Regulators and clinicians can play their part and are doing so in facilitating robust investigation using updated and evolving guidelines and fora for stakeholders.

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