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Looking at the way diseases manifest and progress might reveal that the solutions around the management of diseases need to be tailored differently

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Antonella Santuccione Chadha, Head of Stakeholder Engagement for Alzheimer’s disease at Biogen and co-founder and CEO of the Women’s Brain Project, dives into the non-profit organization’s role in rethinking the way we look at sex and gender as a gateway to precision medicine. She explains how artificial intelligence (AI) is helping researchers better understand biases in data sets, the practical applications of being aware of sex and gender differences, and their efforts to aid policymakers, academia and the pharma industry.*

Let’s start at the beginning. What motivated you to start looking at brain diseases and the way they affect women in particular?

Through my clinical experience, as well as my scientific career, I learned that there are differences in the way diseases affect men and women from a prevalence and incidence perspective, but not many studies were going beyond that. Years ago, a team of scientists that I was working with raised a simple yet important question: what if the differences go beyond prevalence? We started our scientific work, which was based on an analysis of available evidence, and learned that it is not only about the incidence of disease but rather how they manifest in female bodies compared to

male bodies, as well as the way diseases are diagnosed, how they progress over time and are treated. Some drugs affect men and women differently.

It was a scientific question that drove my personal interest in learning about the subject.

We realized that we were on to something and it became a new way of looking at things.

Where has the discussion now moved and how is the knowledge you have acquired being used?

Today, there is an ongoing and profound discussion on how sex and gender can be considered as the gateway to precision medicine. With such analysis of sex and gender differences, one can acquire knowledge that goes beyond to include race, ethnicity, and other diversities. Precision medicine is about bringing the right molecule, at the right time, at the right moment. This approach is helping create a more sustainable healthcare system.

Precision medicine is based on big data analysis. It is genomics, metabolomics, and proteomics, combined with sex and gender differences. We have learned that even wealth and the economic status of patients can have an impact on the way we fight diseases. All of this is possible thanks to AI, it can only be done with new technologies that can interpret a big data set and start to tailor medical solutions in a precise fashion.

How did the decision to formalize the Women Brain Project come about?

WBP is a non-profit founded not too long ago, in 2016. It consists of a group of experts hailing from various disciplines, including medicine, neuroscience, psychology, pharmacy, and communication, who work together with caregivers, patients and their relatives and other stakeholders.

WBP experienced exponential growth because the whole scientific community, together with health providers, began to support its work. WBP has strong academic partners like Harvard University, Brigham and Women’s Hospital, and the University of Melbourne, among many others. WBP also works with pharma companies and policymakers. In 2020, WBP held the first roundtable with regulatory bodies from all over the world that joined collectively to discuss sex and gender as the gateway to precision medicine. During this event, the FDA shared with other regulatory bodies the work of their Office of Women’s Health, its value, and why its work is important. It was revealing because there is no women’s office at the EMA or Swissmedic.

WBP also works together with the OECD and WHO. The organization is mainly supported by pro bono work at the moment, with volunteers and scientists from all over the world pushing the discussion and trying to become bigger and more sustainable.

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The differences you speak about are understood from a scientific perspective but not as much from a societal perspective. How can you close that gap?

For me, it is not about who can better drive a car but rather why certain diseases manifest in a certain way in women versus men and how we can optimize related treatments. We need to understand the progression patterns of diseases in both genders and then explain them. Looking at the way diseases manifest and progress might reveal that the solutions around the management of diseases need to be tailored differently.

There are diseases like Parkinson’s that are much more prevalent in the male population and others such as Alzheimer’s, depression, and anxiety, which are more represented in women.

For cardiovascular disease, for example, there was a huge campaign to educate the male population about certain types of lifestyle behaviours that could prevent them like smoking, physical activity, reducing weight, etc. But women were not included in that campaign. By not including the female population, the number of cardiovascular events in that population did not change. Only later on were female-specific campaigns generated.

If you look at recent data from the OECD, you will find that the number of women affected by dementia is much higher than men. We have strong evidence that shows that certain female phases such as menopause might imply an abundant remodelling of the hormonal setting that has a strong impact on brain and body functioning.

We have to take a closer look at these facts. We need better research and better algorithms. I am not saying that all biases can be fully removed, our nature is different from a genetic perspective, but you can be aware of the biases in the systems you use to design better solutions. I think that we are learning about many biases because of AI, it is an opportunity because they show that biases are intrinsic to our data sets. AI solutions are making us aware so we can fix the problems.

Have you faced reluctance from the research community in wanting to see more data?

As long as you stay factual and science-based, there isn't much reluctance from other sides to believe what you have to say. Data cannot be denied in the scientific community. As a paradox, the pandemic helped us make our point because mental health and sex and gender differences were highlighted.

We now know that even in a coronavirus pandemic, sex and gender differences play a role. More men are dying because of infection and they get more complications related to the disease, even though women represent the majority of the workforce at the front line for managing patients with COVID-19. Out of a tragedy, we have had the opportunity to leverage the evidence to showcase to the world that sex and gender differences are fundamental to understand the pathogenesis of disease but also to tailor solutions around them.

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What practical advice and knowledge are you looking to share and how could it impact the way the industry develops therapies?

Considering the differences between men and women, and other diversities has a direct impact not only on the efficacy of studies and the drugs developed but also economically and financially for stakeholders.

At the moment, the RAND Corporation is working on a report that will showcase the importance from a business perspective of including women in clinical trial development and related solutions.

For example, the side effects of some COVID-19 vaccines such as allergic reactions or anaphylactic shocks are observed more in the female than in the male population. This is not yet very well analysed or understood. There is overwhelming evidence that shows that if you invest more in early planning, developers and the healthcare system will see better returns.

What is your final intention with the project, is it an advocacy group?

We are going beyond advocacy; we are generating valuable data. We are putting patients at the centre, working with policymakers, pharma companies and technology companies. We have collaborations with start-ups in the field of digital biomarkers, for example. We want to drive the transformation from within.

There has been a similar approach in oncology products, tailoring them for smaller patient groups, but as a result, the therapies have become more expensive. Are you worried about that happening in this case?

We are already losing resources because drugs are being prescribed to the wrong patients. It affects adherence because if you do not have a beneficial effect, people will not stick to the therapy. It is a vicious cycle. I do not believe that it will be more expensive because the solutions will be more tailored, there will be more adherence to treatments and a better response.

However, there is a long road ahead. Diagnoses related to the brain are not easy because we do not possess tools that allow us to have certainty. We need to better understand what is happening with medical conditions such as schizophrenia, depression, anxiety, dementia, and so on.

You have mentioned before that you are looking forward to building an institute. Will it focus on fundamental clinical research on the area, or will you work more with data sets?

The idea is quite simple: to repurpose the data we already have and make sense of it based on diversity. Starting from sex and gender and looking at other possible learning we can generate related to other determinants like ethnicity, race, socio-economic status and, whenever possible, genomics, proteomics, and metabolomics.

We are at a mature phase; we have had conversations with the University of Basel, the health department from the city of Basel and multiple stakeholders who might want to join the effort. We will also be a service provider because drug developers and novel technology designers will be able to use the data. This learning will allow for better-tailored solutions; one-size-fits-all is obsolete in any field.

* ***Disclosure: The views and opinions expressed herein are those of the author and do not necessarily reflect the views of the organizations she is affiliated with or its employees.***

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