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Interview: US Personalized Medicine Coalition – Exploring Pathways Towards Patient-Centred Healthcare

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Adaptive pathways are among the possibilities being examined for incentivising medicine and future innovation in the United States, says Amy M. Miller, Ph.D., Executive Vice President of the Washington DC-based Personalized Medicine Coalition. But some key hurdles remain, not only from a scientific view, but also from a policy perspective. Dialogue and an exchange of ideas between the US and the EU can help spur progress.

"I started as your typical research post-doc and I decided that research itself wasn't as interesting as using research to improve science policy," Amy Miller says of her motivation to get involved in the policy side of healthcare. For the past eight years, she has been working with the Personalized Medicine Coalition towards this end, helping to further PMC's mission of promoting the understanding and adoption of personalised medicine concepts, services and products to benefit patients and the health system.

"Pathways are new here in the United States and they can be designed to incentivise personalised medicine and future innovation," says Miller. "Right now we are looking at pathways – as well as other alternative payment models – from the perspective of how they can support innovation, how they can support personalised medicine, and how they can support a system that is focused on improving the quality of patient care."

Pathways and payment - the US case

In the US, there are two ways to understand pathways – and they have very different meanings, says Miller. First, there is the regulatory path for companion drug diagnostic combinations, a track that, according to Miller, sometimes works very smoothly. "For example, the FDA [US Food and Drug Administration] has a great track record of getting personalised targeted oncology drugs through the FDA process, along with their companion diagnostic technologies," says Miller. However, she explains that non-oncology products seem to be more difficult to get through: "That track is less well articulated and the path can be cumbersome."

Then there is a very different pathway, which is also a major point of interest in the US as it tries to move its healthcare system "from a fee-for-service payment system to one that pays for value," notes Miller. One example of this is "pathways per treatment." Most popular in cancer treatments, pathways per treatment are a notable issue in private healthcare plans in the US, says Miller, explaining: "Some of the private health plans here in the US will, for a certain type of cancer for example, refer to an outline of what therapies a doctor may use and what therapies the doctor should

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not use. If they stick to that outline and stick to the cookbook, they get a financial incentive; if they do not follow the cookbook, they don't get the financial incentive."

White House Precision Medicine Initiative

From Miller's point of view, two regulatory fixes are needed for precision medicine to advance successfully in the US:

- The articulation of how the FDA will regulate gene sequencing tests;
- The question of how to make electronic medical records interoperable.

In hopes of helping to pave the way for precision medicines in the US, the Obama Administration this year launched the White House Precision Medicine Initiative, a $215 million investment that aims to "pioneer a new model of patient-powered research that promises to accelerate biomedical discoveries and provide clinicians with new tools, knowledge, and therapies to select which treatments will work best for which patients."

The PMI is a large, multi-cohort study that will follow a group of people longitudinally. The cohort of "one million Americans" is a focal point: This is a normal cohort meant to broadly map the US population by following average Americans longitudinally and is designed to have all of their electronic medical information available through one electronic health record, which can be accessed on the go, and by the patient participant himself.

This, says Miller, is what she finds so exciting about the initiative: "This kind of patient empowerment can drastically change how Americans experience healthcare. Imagine that a person taking part in the trial has his/her information entered into the EHR – if that person were to be diagnosed with a serious health condition at 35, he/she could then obtain the right information from the EHR and give it directly to the physician," she explains. The programme's ability to put information in the hands of the patient is, to Miller, what makes it so fundamentally groundbreaking – and an exciting project to watch.

Benefits of trans-Atlantic dialogue

As the US continues to evolve from a system of pay-for-service to pay-for-value, Miller acknowledges the benefits of dialogue with the European side, where healthcare has evolved very differently. Projects such as the European

Medicines Agency's Adaptive Pathways Pilot Project, as well as the drug evaluation programme of NICE (National Institute of Health and Care Excellence) are both worth watching from the US side, she says.

Despite different regulatory and payment systems, some conversations appear universal. The discussion around data privacy, for example, is prevalent in the US and EU alike. When it comes to personalised medicines in the US, Miller sees the discussion taking place but notes that it is the people who are sick who, in her experience, seem to be "far less concerned about their data and the security of their data than others."

The bottom line across the board is the desire for improved treatment – and nobody knows this desire better than patients themselves. As healthcare stakeholders in both the EU and US explore new ways to deliver better medicine to patients, be it via adaptive pathways development or precision medicines, greater involvement from the patient side is a common thread.

Speaking of the "one million Americans" cohort, Miller reiterates this point: "To me, that is one of the most exciting parts of this programme: It is changing *who* controls healthcare."

More about the Personalized Medicine Coalition: http://www.personalizedmedicinecoalition.org

More about the White House Precision Medicine Initiative: https://www.whitehouse.gov/precision-medicine

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