Interview with
Professor Matthias Rose
on developing patient-reported outcomes and the PROMIS initiative

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Abstract
Professor Matthias Rose is Medical Director of the Psychosomatic Department at the Charité University Hospital in Berlin, Germany. In this interview, I discuss with him patient-reported outcomes and the Patient-Reported Outcomes Measurement Information System (PROMIS®) initiative, which, according to the PROMIS website (http://www.healthmeasures.net/explore-measurement-systems/promis) is "a set of person-centered measures that evaluates and monitors physical, mental, and social health in adults and children" that "can be used with the general population and with individuals living with chronic conditions".

Professor Matthias Rose

MEW: Thank you for agreeing to this interview, Professor Rose. What is the most common mistake you see in the development of patient-reported outcomes (PROs)?

Prof. Rose: I think the most problematic thing is that people jump straight into it without thinking about what is the construct they really want to measure. Frequently, we are approached by different parties who say they want to measure "quality of life" without really understanding what is meant by that. In my view, people try to

PROMIS®
In 2004, the US National Institutes of Health initiated the development of a comprehensive Patient-Reported Outcome Measurement Information System (PROMIS®). The aim of this initiative is to improve substantially the standards for the assessment of the self-reported health status. Over 300 measures of physical, mental, and social health are available for use with the general population (adults and children) and individuals with chronic conditions. The PROMIS measures have been tested and validated in large reference populations making them suitable for research on different conditions.

The programme has generated a reliable and oftentimes more sensitive system, customised to the patient, which poses fewer questions than traditional paper-based PROMs do.

Find out more at http://www.common-metrics.org/ or www.healthmeasures.net/promis where you can also take an online computer adaptive test demonstration.

bypass the first steps in developing the conceptional measurement model much too often. They pick out some established instrument from the literature without questioning its appropriateness for their particular research question.

MEW: Given this, how important is the development of guidelines like the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) steps in identifying and evaluating an existing PRO measure?

Prof. Rose: Very important. I think that the longer you are in the field, the more clearly you see the need for the basics to be correct. Initiatives like the ISPOR guidelines[1] are very useful in ensuring that the basic elements needed in a PRO are present.

MEW: Patient-reported outcome measures (PROMs) are the instruments used to measure a patient's health status or health-related quality of life at a single point in time. However, are there too many PROMs?

Prof. Rose: There are probably over 4,000 different PROMs out there, and most of them are carefully developed and validated. Although this is an impressive amount of work, I believe that this plethora of instruments actually hinders their acceptance. For PROMs to enjoy the same level of acceptance like biomarkers, we need much greater standardisation and less confusion.

MEW: Which is what the Patient-Reported Outcome Measurement Information System (PROMIS®) is trying to achieve, right?

Prof. Rose: Yes. Think of it like this. Today, most PROMs are like thermometers using different scales, which makes it highly complicated to compare measurement results among them, even if they measure the same construct. PROMIS provides a common metric to allow this (Figure 1). Thus, if you score your instrument on the PROMIS metric, scores resulting from different assessment tools can be instantly compared in a meaningful way. Just like using different thermometers to measure temperature.

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Thus, PROMIS also addresses another old dispute in the field, which is if you favour generic or disease-specific tools. Disease-specific tools are typically more responsive to demonstrate treatment effects, whereas generic tools allow comparisons between different clinical populations. When you look into the construction principle of disease-specific tools, essentially they are a compilation of health domains combined in one composite score.

PROMIS domains are generic, but they can at the same time act as building bricks providing a disease-specific score. Thus, the compilation of health domains is specific, not the assessment itself.

Let me give you a more concrete example. PROMIS identifies the elements such as physical function, pain, anxiety, and so on, which are relevant to everyone. You can then pick and choose the different domains which are relevant for different diseases. For example, some of the PROMIS domains are relevant for both heart disease and musculoskeletal disease (e.g. physical function), but others are only relevant for heart disease (e.g. dyspnoea).

This is the core of the idea behind PROMIS. The combination you choose is disease-specific but not the constructs! We have liberated the different domains from being tied to specific instruments – and diseases.

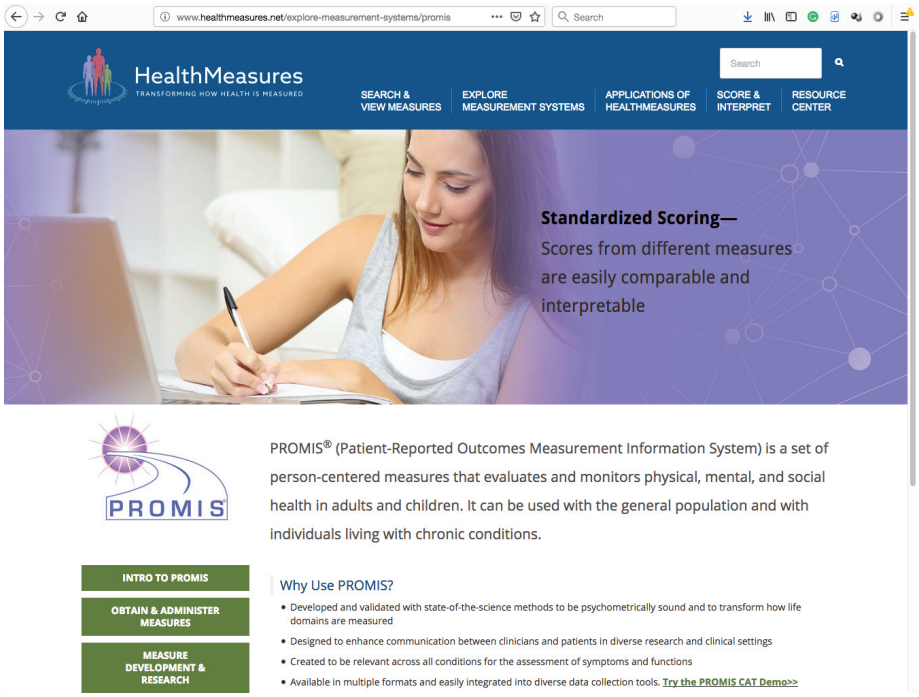

Figure 1. Home page of the PROMIS website, which is part of HealthMeasures.
HealthMeasures consists of four precise, flexible, and comprehensive measurement systems that assess physical, mental, and social health, symptoms, well-being and life satisfaction; along with sensory, motor, and cognitive function.

MEW: You have been involved in PROMIS since it began and are the Chair of PROMIS Germany. You have seen a lot of progress, but what is the next quantum leap for PROMIS in your opinion?

Prof. Rose: PROMIS started because we had new methods like computer-adaptive tests (CATs), which could be employed for more precise measurements. In addition, the initiative has such political clout with the necessary funding behind it to make it happen. But the bigger achievement of PROMIS is that it creates a framework of health. It has the potential to set scales independent from the tools, indispensable for standardisation. Consider it this way, for the first time, in the world of patient-reported outcomes, we would have definitions and scales that are as easy to understand as, for example, the Celsius scale is for temperature.

There will never be complete agreement on which instrument to use, that's human nature. After all, people never want to have just one type of car, but the advancement in PROs that

PROMIS will bring means we are moving closer to achieving the status of biomarkers that I previously mentioned.

MEW: Given that you are talking to EMWA, what country in Europe is furthest in developing and adopting PROMs?

Prof. Rose: In my opinion, it is the Netherlands. The Dutch mindset has always been innovative and open to adoption. If you look at different research consortiums for European Union funding etc., the Dutch are always well represented. So, if I had to pick any one country in Europe, I would choose the Netherlands.

> I have always been a missionary for patient-reported outcomes.

MEW: What should medical writers keep in mind when they write about PROs?

Prof. Rose: They should be careful with the terms they use. Don't confuse outcomes with predictions or determinants. The term patient-reported *outcomes* is used but people are often not thinking of outcomes when they write this, but are rather thinking of *predictions*. An outcome is something you expect to change or vary based on other factors. You should be clear in what it is that you are reporting.

When writing, make sure that you distinguish between the proximal outcomes (i.e., symptoms and function) and the distal outcomes (e.g. quality of life). For example, with heart failure, shortness of breath and physical function are proximal outcomes, which are likely to change due to medical interventions. However, a distal outcome like quality of life might not be affected by the intervention, as aspects also relevant for this construct, like level of job satisfaction or environmental factors, are not targeted by the intervention.

A conceptual model well known within the German healthcare system is the one developed by Wilson and Cleary[2] a couple of decades ago. It is a basic model, but one which is very effective at classifying different measures of health outcome. It might be useful for medical writers who are new to the subject of patient-reported outcomes to learn more about this model.

MEW: Any last comments?

Prof. Rose: I have always been a missionary for patient-reported outcomes. It is great that a journal like *Medical Writing* is concentrating on the subject and helping to get the message about PROs out there.

Conflicts of interest

The author is employed by Smith & Nephew.

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Diarmuid De Faoite is the guest editor of this issue of *Medical Writing* and a member of the EMWA Executive Committee. His daily work involves patient-reported outcomes in orthopaedics.