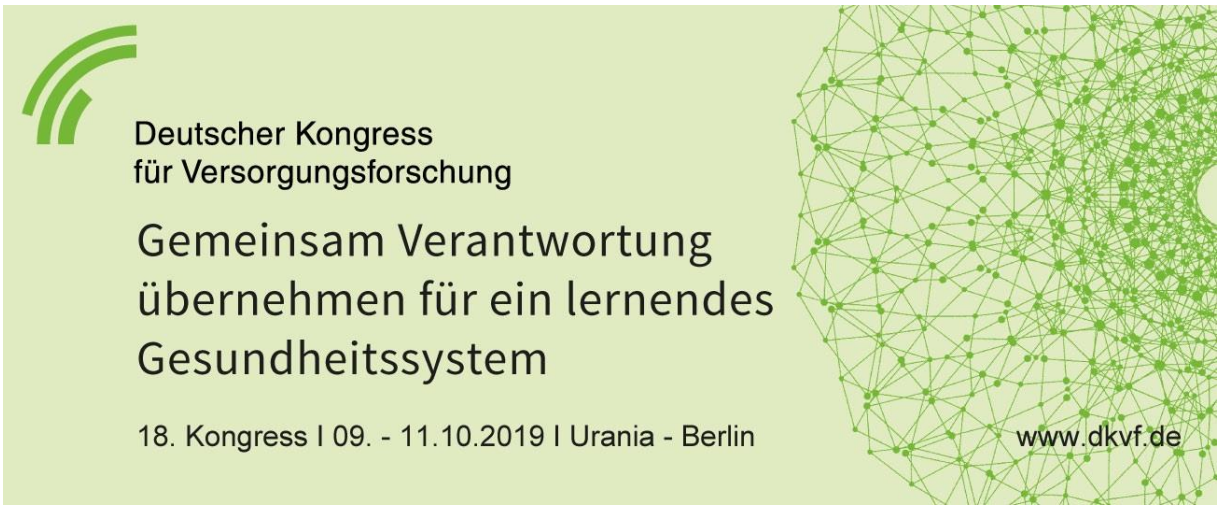


How to tackle research waste?

Prof. Dr. Hywel Williams
(Bildnachweis: privat)

The keynote lecture at the opening of the German Congress for Health Services Research will be given by Hywel Williams, Professor of Dermato-Epidemiology at the University of Nottingham. He has led and advised on several clinical trials on various skin diseases and is a strong advocate of evidence-based medicine. In 2015, he was appointed as the new Director of the National Institute of Health Research Health (NIHR) Technology Assessment Programme which manages most (350+) of the national publicly funded clinical trials in the UK. In this interview, he explains his views on the quality of clinical research and ways to improve it.

Professor Williams, the title of your keynote lecture is "Tackling research waste"? How big is the problem?

Williams: It's very big; not a week goes by without me spotting research that is either unnecessary or poorly done, or poorly reported. I think this applies to at least 50 percent of the research in my field. The need to increase value in research was first addressed by Iain Chalmers and Paul Glasziou in *The Lancet* in 2009. They estimated that the percentage of research waste is even higher, at about 85 percent.

Usually, scientific publications include a discussion part, where the authors address bias problems and the relevance of their results is compared with previous findings. This is obviously not enough.

Williams: No, definitely not. And often, comments in scientific discussions are very nonspecific. You must have seen this phrase a hundred times: "More research is needed to prove the hypothesis." In many cases, we don't need additional studies; a meta-analysis of individual participant data from the studies already available to identify the factors that result in better treatment response would be much more helpful. Less research but better research is needed. And if additional studies are necessary, it would be important to define outcomes which are relevant to patients and which have also been used in other studies, so that the results can be combined with existing data. That is the principle of core outcome measures.

What are the main causes of research waste?

Williams: I think the first cause is a lack of training amongst clinicians, researchers, and particularly research users. In the UK, it was only very recently that critical appraisal of clinical trials was

integrated into the curricula of medical schools. Secondly, it is very important to identify research gaps, for example from Cochrane systematic reviews or from public engagement exercises, then to prioritize those gaps and then to commission research on those topics. Commissioning research on prioritised research gaps is one of the unique features of the HTA programme in the UK, and it has also allowed us to encourage scientists to start working on scientifically "unpopular" research topics such as leg ulcers and falls in the elderly. Thirdly, researchers are under pressure to publish. But perhaps the biggest problem is what is known as the butterfly behaviour of researchers: They work on a study for a few years but when the results don't seem so good, they flutter off to the next flower (research grant), which smells sweeter. As a result, it may take them years to write down their old research results, if they do at all. It still disturbs me that around 50% of clinical trials are never published for various reasons, all of which are unacceptable.

But it would be hard to change this system.

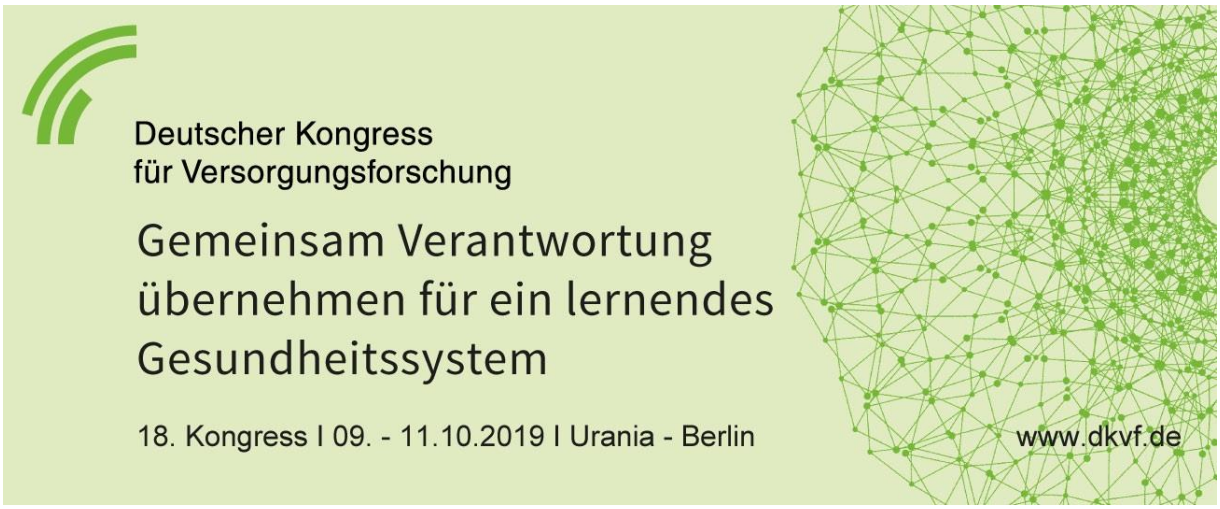
Williams: Not necessarily. Policy makers and higher education institutes could encourage team science rather than glorifying the individual, and one could reward research projects that are valuable for society rather than placing the focus on the number of high-impact publications in journals. The system can change.

What are your recommendations to improve the quality of clinical research?

Williams: We must involve patients and the public in prioritizing research questions and in conducting research itself. In the UK, we have a process called "priority-setting partnerships", or PSP, and it is overseen by the James Lind Alliance which is supported by the NIHR. That organisation has developed a methodology for identifying research gaps by bringing patients and healthcare professionals together to identify shared research priorities. This process not only applies to doctors but to all stakeholders involved in delivering and using health care such as nurses, midwives or physiotherapists. Methodologists are also involved to help guide what questions are possible to address and how they might be addressed – I see this PSP process as a critical first step towards curtailing research waste.

If patients want to participate, do they have to be familiar with healthcare research or the principles of clinical studies?

Williams: A certain amount energy needs to be put into educating patients and the public on how they can best contribute to research prioritisation and designing better research. But you have to be careful not to train them to become amateur scientists; you want to make them feel empowered to give a genuine patient or public view. That requires effort and funding. In the UK we have patients



involved in NIHR HTA prioritizing committees and in funding committees. They help us decide how to spend the public money we are using.

Clinical studies to achieve approval of a new drug or procedure are usually designed by the pharmaceutical industry. And of course, industry is guided by economic considerations when addressing a certain medical need. How can we deal with this potential conflict of interest?

Williams: In my own field of dermatology, I work at the very last stage of translational research. We do not work with industry as we want to address the really important questions that industry would never tackle, such as behavioural interventions or cheap drugs in common usage that have never been tested adequately. Whilst industry does a very good job at developing new drugs, there is still a need for countries to fund their own health technology assessment programme that is completely independent in order to give public assurance that there is no vested interest driving the research.

Many results of study that were initiated by the pharmaceutical industry have never been published.

Williams: I agree, publication bias still exists. But as I mentioned earlier, this problem occurs with academic-led studies too. Very often, however, industry-sponsored studies suffer from the wrong choice of the comparative therapy. New drugs, for example, are tested against placebo, not against the available gold standard. On the basis of these data, the product is approved, although nobody knows how it compares with existing treatment options. The key, again, is educating research users to demand more active comparator studies. Educating research users might take a long time to show results. In the UK HTA Programme, we make funding of clinical research contractually dependent on registration of a clinical trial before recruitment and we insist on 100% publishing the results. If investigators don't follow these rules, we can stop their study. And we can stop them from applying for future public funding. Appropriate funding can have an immediate impact on reducing such research waste.

The interview was conducted by Dr. Katrin Mugele, press contact DKVF 2019, dkvf-presse@dnvf.de.