How do you know Natural Health Products can work – The Question of Evidence?

What is evidence?

The Oxford English Dictionary defines evidence as "information indicating whether something is true or valid". It gets more complicated when you look at the different ways evidence can be obtained and the many forms in which it comes.

Efficacy vs. Effectiveness

Talking about definitions, two terms that are often wrongly used interchangeably are efficacy and effectiveness. Efficacy is how useful something is found to be under ideal conditions such as a randomised clinical trial. Effectiveness is how something performs in a real-world situation. This often means that an intervention (a drug or a procedure) in an efficacy or an ideal controlled study performs somewhat better than in when used in everyday care. We all experience something like this when we look at the mileage posted for a new car. The posted number is the best possible outcome under ideal conditions. In our real life driving with all the extra variables we usually don't achieve the same mileage number. However, the standardized numbers (under ideal conditions) enable us to compare the performance of one car with another.

What is a Randomised Controlled Trial or RCT?

Put simply, in an RCT the participants are randomly assigned to different groups. One of the groups receives the product you are researching and one, the control group, does not. In research for medicines, participants in the control group typically receive the standard treatment for the illness you are researching or a substance which has no therapeutic effect called a placebo.

Regardless of whether you are investigating the efficacy of a drug or Natural Health Product (NHP) or any therapeutic intervention for a specific clinical condition, the RCT is the best tool to utilize for these investigations and as such is referred to as the "gold standard".

Isn't a RCT the same as Evidence Based Medicine?

No, this is not the case. Evidence Based Medicine or EBM is a term used to describe the method of arriving at the best form of treatment. In its simplest form it is based on the integration of three key elements – clinical judgement of the practitioner, the best and most relevant external evidence (in published medical studies for example), and the individual patient's values and preferences. Though it may not appear in the definition of EBM, data gathered from a RCT is the best form or external evidence for most therapeutic products notably pharmaceutical drugs.

I have heard that NHPs cannot be researched using RCTs?

No, this is not the case. Though there are important steps that needed to be taken for NHPs that are typically not needed for drugs, such as identification of plant materials when investigating an herbal medicine, numerous RCTs have been conducted, and are currently underway, investigating NHPs. In fact, RCTs have been successfully used in the research of many types of complementary and integrative health care such as yoga and acupuncture. Yes, there are challenges that must be overcome but the RCT is a very adaptable tool.

Why doesn't Health Canada use the same approach for NHPs as for pharmaceutical drugs?

Health Canada did not utilize the same approach regarding evidence for NHPs as was used for pharmaceutical drugs based on the input Canadian consumers gave Health Canada when the regulations for NHPs were developed. Unlike pharmaceutical drugs, NHPs are a diverse group of products including both traditional health products with a long history of use as well as new and innovative products wishing to make a new health claim. Canadians demanded a regulatory approach which reflected and respected the full range of evidence including that from traditional forms of health and healing such as traditional Chinese medicine and herbalism as well as evidence from more typical medical research tools such as RCTs.

How is evidence for traditional medicines assessed in support of a Product Claim?

Though traditional medicines may have been used for many years, their use for self care without the supervision of a healer or practitioner is relatively new. This makes linking traditional evidence to a claim made on an NHP a very complex question. Health Canada has developed criteria about what sort of evidence can be used to support a claim such as:

- how long the product has been used in history?
- is it from single system of traditional healing?
- if it is a traditional formula and, if so, has it been modified?

These criteria and guidelines make full use of the traditional medicine resources, such as reference books and pharmacopeia, and list approved resources which can be used making a product application to Health Canada. In addition, many of the Health Canada NHP monographs make use of traditional evidence and list the resources that were used in their development. More information about how Health Canada looks at traditional evidence and traditional medicines can be found at https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/pathway-licensing-traditional-medicines.html#a2.5

What evidence is required by Canada's NHP regulations?

As with every other aspect of the NHP regulations, when considering evidence the aim is to respect the health care choices of Canadians and support them in making informed choices about their health care options. To do this, the claim on a NHP must be clearly linked to the type of evidence used. A consumer should be in no doubt that a NHP that has a health claim that is based on traditional evidence is clearly identified as a traditional medicine. A product that states that a claim has been scientifically proven must be supported by evidence from RCTs or other recognised research approaches.

How is this approach to evidence working out?

A good question with no simple answer. Canada was the first country to regulate NHPs as one class of products supported by different forms of evidence which is assessed by a regulator before the product is allowed to be marketed. In most cases this approach is working well, but there are definitely questions that need to be more thoroughly explored. Things such as how can traditional evidence for a product be used in a modern, self-care setting; how do you support innovation in the market place with a respect for traditional forms of health and healing; and how do you ensure people can make an informed choice about the evidence question regarding the NHP they decide to take. This is still a work in process and one that can only truly be answered by all parts of the NHP community – regulators, researchers, practitioners and consumers – working together

Where can I find out more about NHPs-focussed research?

There is a lot of research investigating all aspects of NHPs with many books and online resources available. In addition, there are many organisations focused conducting NHP research both in Canada and internationally. If you want to know more what is going on in Canada, the Natural Health Product Research Society of Canada may be a useful resource. Members of the society come from academia, industry, practitioners and government conducting world class research related to all aspects of the NHP sector. Recognising the importance of this research to the consumer, the society is committed to engaging Canadians. You can find more information about the society and its work at www.nhprs.ca

Final Thoughts

The question of appropriate evidence supporting claims for NHPs is very complex. Unlike many other countries, Canada has a regulatory framework for NHPs that aims to balance the rigors of science with a respect for traditional forms of health and healing. While the regulations function well, they are still a work in progress. It is also important to ensure that Canadians are informed and educated about the

NHP regulations; what is the evidence required to support NHP claims and how they can use this information to better navigate the shelves at their local health food store or pharmacy.

About the authors:

Michael Smith trained as a pharmacist and as a naturopathic doctor. He is recognized internationally as an expert in natural health products and complementary & alternative medicine. For more than 10 years, he worked in senior regulatory positions at the then Natural Health Products Directorate, Health Canada and the Therapeutic Goods Administration in Australia. In addition to his international work as a consultant, he is an Adjunct Professor at the National Center for Natural Products Research at the University of Mississippi, USA and an Adjunct Fellow at the National Institute of Complementary Medicine at Western Sydney University, Australia. Michael is a member of ISURA's Scientific Advisory Committee.

Dr Mary Hardy is the Founder/Director of Wellness Works and is on Faculty at the Academy of Integrative Health & Medicine in California, USA. Mary is recognized as an authority on integrative medicine and natural products. She is board certified in internal medicine, specializes in botanical and integrative medicine, and is a leader in integrative oncology. For more than 25 years, in both her practice and research, Dr Hardy has combined complementary & alternative medicine with Western medicine. Her current research interests include reviewing the evidence for the safety and efficacy of natural therapies, especially botanicals, as well as conducting clinical trials of dietary supplements and lifestyle choices to support conventional cancer treatment. Mary is a member of ISURA's Scientific Advisory Committee.