

# H:MC21 Critique of the Assessment of the Swiss Health Technology Assessment (HTA) by Professor Hylands

Professor Hylands states that the purpose of his report is “To assess whether the Swiss HTA report and the conclusions it draws are sound.” We are concerned that his assessment is based on some serious inaccuracies and omissions.

Professor Hylands states of the HTA that

The main conclusion concerning efficacy was drawn from a meta-analysis of qualifying trials which demonstrated efficacy for the interventions of conventional medicine and phytotherapy, but no significant difference from placebo for homeopathy. (p. 1)

He references as the source for this statement the meta-analysis “A Shang, K Huwiler-Müntener, L Nartey, P Jüni, S Dörig, J A C Sterne, D Pewsner and M Egger (2005) Are the clinical effects of homeopathy placebo effects? Comparative study of placebo-controlled trials of homeopathy and allopathy *Lancet* **366**: 726-732”.

This statement is unsatisfactory for a number of reasons, including the following:

1. No “main conclusion” of the HTA could be based on the Shang meta-analysis, since the authors of *Homeopathy in Healthcare* specifically state that its approach conflicted with that of the HTA. They describe it as “a smaller quantitative sub-study, which – contrary to the implicit intention of an HTA – had evaluated only experimental trials (randomised double-blind trials)” (*Homeopathy in Healthcare*, p. 2).
2. The Shang et al. meta-analysis is discussed in chapter 5 as an example of general problems with clinical trials in research. In chapter 13 the following statement is made about this study:

A study – conducted and published as part of the PEK programme – on the quality and results of homeopathic trials in comparison to conventional medical trials, which gave rise to heated discussion (Shang et al. 2005), has been largely invalidated by the research of Lüdtké & Rutten (2008) and Rutten & Stolper (2008). (*Homeopathy in Healthcare*, p. 201)

3. The HTA’s actual analyses of the effectiveness and efficacy of homeopathy are dealt with in chapters 9 and 10 of *Homeopathy in Healthcare*, and further discussed in chapter 13.
4. The Shang meta-analysis makes no mention of phytotherapy.

In brief, Professor Hylands has ascribed an authority to Shang et al. in the HTA which is not justified by the evidence. He has also made a statement about phytotherapy, which is not supported by the reference supplied.

Professor Hylands goes on to discuss Shang et al. further, claiming that

The 2011 book included a reworking of the analysis of the data in the Shang *et al.* article largely by considering only the therapeutic studies (by removing data for prevention studies). Considering the therapeutic studies only the number of significant trials *versus* non-significant becomes 28 *vs* 23, instead of 32 *vs* 33 in the original publication. This is described as

... a truly remarkable result in favour of homeopathy ...

by the editors of the book in their introduction but the same authors in their own contribution describing their own reworking of the data state more cautiously

While the above argument does not allow [us] to draw the reverse conclusion that homeopathy is effective, it does support the claim that the Shang et al. (2005) study does not prove the ineffectiveness of homeopathy. (pp. 1-2)

(N.B. The omission of “us”, the position of “(2005)” and the underlining in this latter quotation are as the text appears in Professor Hylands’ assessment.)

These statements are highly unsatisfactory.

1. The reworking of the analysis of the data in the Shang et al. article was not done “largely by considering only the therapeutic studies (by removing data for prevention studies)”, but by considering a whole range of issues, of which the difference between therapeutic and prevention studies is only one. The issues include:
  - Failure to adhere to the QUORUM guidelines<sup>1</sup> (p. 40);
  - Failure to explain the assessment of issues of external validity (p. 40);
  - The inappropriateness of the research tools used to assess the data (p. 40);
  - Failure to take into account variable placebo effect sizes (p. 40);
  - The risk of the results being due to chance because of the very small sample size of only 8 homeopathic studies and 6 conventional medical studies (p. 40);
  - The questionable validity of some trials as genuine homeopathic practice (including 2 of the 8 studies) (p. 42);
  - The fact that some of the conventional medical studies were based on homeopathic thinking (p. 42);
  - The fact that the selected 8 studies of homeopathy and 6 studies of conventional medicine were not comparable (p. 42);
  - The “extreme heterogeneity” of the selected studies (p. 42).

None of these other issues are mentioned by Professor Hylands.

2. The figures quoted by Professor Hylands are at no point offered in *Homeopathy in Healthcare* as a definitive argument, but solely as an example of how the exclusion of some trials with questionable external validity affects the balance of significant trials to non-significant trials. As a subsidiary point, *Homeopathy in Healthcare* points out the significant failure of Shang et al. to provide adequate data (which is why only 65 of the 110 studies are considered in this comparison):

Without a more detailed knowledge of the 110 studies it is not possible to decide whether the analysis would yield a different overall conclusion if these external validity criteria were taken into account. Removing the prevention studies – which are unusual in homeopathy – from the comparison certainly changes the ratio of significant to non-significant trials, although a vote count is not adequate for a synthesis of results.” (p. 43)<sup>2</sup>

3. Professor Hylands’ quotation of the statement “... a truly remarkable result in favour of homeopathy ...” is taken completely out of context. It does not refer to the effects of “removing data for prevention studies”, but to fundamental issues of validity.<sup>3</sup> The full sentence reads:

It [“the present, corrected and partly revised book”] especially re-evaluates Shang et al.’s (2005) quantitative analysis, taking into consideration criteria of external and model validity as well as of

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<sup>1</sup> It is curious that the meta-analysis was published by *The Lancet* despite the fact that the journal had adopted these guidelines,

<sup>2</sup> The authors explain the inadequacy of a “vote count” as follows: “It is like drawing the conclusion, after observing 2 black swans and 5 white swans, that there are no black swans, as  $2 - 5 = -3$ . This happens in a simple vote count or in other statistical additive procedures without thematic differentiation.” (*Homeopathy in Healthcare*, p. 197, note 2)

<sup>3</sup> The definitions of ‘internal validity’, ‘external validity’ and ‘model validity’ are given on p. 32 of *Homeopathy in Healthcare*.

internal validity – with a truly remarkable result for homeopathy – and adds it to the original text. (*Homeopathy in Healthcare*, p. 3)

The “remarkable result” in question is almost certainly related to a discussion of the questionable external validity of 2 of the final 8 homeopathy studies. The relevant passage concludes:

If we remove both studies from the evaluation because of their low external validity we end up with a much higher effectiveness for homeopathy that is almost comparable to that of conventional medicine. (*Homeopathy in Healthcare*, p. 42)

From this it can be seen that the conclusions of Shang et al. are not robust, and that strong evidence in favour of homeopathy can be masked by the use of questionable trials and a “vote count” approach to the assessment of the data.

4. The second quotation presented by Professor Hylands has nothing to do the exclusion of prevention studies either. It is a reflection on the nature of Shang et al. as a whole (rather than on one particular aspect, as in the previous quotation). The full context is as follows:

In summary, we can say that there is considerable risk of bias if formal criteria are over-rated and there is no differentiation of content or consideration of external validity and model validity criteria, as is frequently the case with meta-analyses. Due to retrospective selection and lack of confounder control, meta-analyses are also not protected against overt or hidden bias. ‘If one evaluated an RCT with these means, it would fail the Cochrane test’ (Wegscheider 2005).

While the above argument does not allow [us] to draw the reverse conclusion that homeopathy is effective, it does support the claim that the Shang et al. study (2005) does not prove the ineffectiveness of homeopathy. (*Homeopathy in Healthcare*, pp. 43-44)

In brief, Professor Hylands presents a picture of *Homeopathy in Healthcare* which is not supported by the evidence. His claim about the nature of the “reworking of the analysis of the data in the Shang *et al.* article” is seriously at odds with the facts, excluding virtually all of the issues actually discussed. He uses two quotations as if they addressed a single issue, when in fact they relate to separate issues, neither of which are the issue he alleges they refer to.

Professor Hylands goes on to state

This encapsulates the crux of the argument between those in favour of homeopathy and those against: different things are being compared. The evidence of the efficacy of homeopathy established by the conventional criterion of robust randomised clinical trials is lacking and so this is used by detractors against. Conversely, studies which include effectiveness may show benefit, and so naturally those in favour of homeopathy tend to cite and give prominence to those studies. The problem with this is of course that identical positive effectiveness could be caused by a response due to the placebo effect alone. (p. 2)

Unfortunately, he has overlooked certain facts brought out by the authors of the HTA: “robust randomised clinical trials” of homeopathy may be robust in terms of internal validity, but may not actually be trials of homeopathy at all. Shang et al. identified that of the 110 studies

48 (44%) concerned clinical homeopathy, 35 (32%) complex homeopathy, 18 (16%) classical homeopathy, and eight (7%) isopathy. For the remaining trial, the nature of the homeopathic intervention was unclear. (Shang et al., p. 729)

At the very least, then, four different approaches were being studied, not one, and the invalidity of any of those approaches would be interpreted as an invalidity of homeopathy, rather than of that particular approach. In fact, only one approach met the full definition of homeopathic treatment:

Classical homeopathy was defined as comprehensive homeopathic history-taking, followed by the prescription of a single individualised remedy. (Shang et al., p. 727)

This issue is not discussed by Shang et al., but is thoroughly discussed in the HTA.

It is no coincidence that the largest group of studies in Shang et al. “concerned clinical homeopathy”, where “no comprehensive homeopathic history was taken and all patients received a single, identical remedy”. This is a type of study appropriate to conventional medical practice, but anathema to homeopathy as a system. The next largest group, “complex homeopathy” also ignored individualisation of treatment, a cornerstone of the homeopathic system. Despite the fact that up to 82% of the studies in Shang et al. did not fully apply homeopathic principles, the researchers still reported that “there was weak evidence for a specific effect of homeopathic remedies” (Shang et al., p. 726). What the authors of *Homeopathy in Healthcare* have shown is that when these issues are taken into account the success of homeopathy “is comparable to that of conventional medicine” (*Homeopathy in Healthcare*, p. 42).

On the same issue, Professor Hylands ends by stating that (his italics)

This reviewer emphasises the clear distinction between the establishment of efficacy (by the established gold standard criterion of randomised controlled trials of a *single defined* product) and considerations of effectiveness, studies of which are wide ranging and include a range of social criteria and economic considerations as well [as] ‘simple’ efficacy. (p.3 )

This ‘gold standard’ has been identified as only 51% effective as a measure even in trials of specific drugs for specific conditions under specific conditions.<sup>4</sup> Its effectiveness in testing a whole system of medicine, such as homeopathy, is not obvious. Indeed, the analysis of the various approaches to treatment which were all categorised as ‘homeopathic’ in Shang et al. shows that it can readily cease to have the specificity necessary to provide evidence about a system as a whole. As a result, meta-analyses based on such trials can be deficient:

‘If one evaluated an RCT with these means, it would fail the Cochrane test’ (Wegscheider 2005). (*Homeopathy in Healthcare*, p. 43)

In emphasising the criterion of “a *single defined* product”, Professor Hylands raises the question of what this means in terms of homeopathic trials. If, by “a *single defined* product”, he means individual homeopathic medicines tested without regard to the system within which they are intended to be used, then such trials will not test homeopathy for efficacy. If, by “a *single defined* product” he means the rigorous application of homeopathic principles, then Shang et al. does not meet this standard. Whichever position he may take, it has to be explained and justified, and he does not do this, whereas the authors of the HTA were at pains to explain the complexities and to justify the position they took in their study (*Homeopathy in Healthcare*, chapters 5, 9, 10 and 13). Professor Hylands’ failure to clearly state his own position or to report on the discussion of this issue in the HTA are serious omissions.

Professor Hylands goes on to claim that in trials of effectiveness “identical positive effectiveness could be caused by a response due to the placebo effect alone” (p. 2), an assertion which is wholly unsubstantiated. He also suggests that all trials of effectiveness “... are wide ranging and include a range of social criteria and economic considerations as well as ‘simple’ efficacy.” (p. 3). This is at the very least disingenuous on a number of counts. If efficacy were “simple”, 51% of RCTs would not be inconclusive.<sup>5</sup> If all trials of effectiveness included “economic considerations”, there would be a substantial body of evidence about the cost-effectiveness of homeopathy, whereas few trials of clinical effects actually consider the cost issues: only 3 out of the 29 analysed in the HTA, for example (*Homeopathy in Healthcare* chapter 10). It is also unclear as to what Professor Hylands means by the vague reference to “social criteria”.

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<sup>4</sup> See the previously submitted document ‘El Dib. pdf’.

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Finally, Professor Hylands raises another interesting point when he states that

The report was undertaken to address the context in Switzerland where the practice of homeopathy is more established than it is here. (p. 3)

No explanation is given as to what his basis of measurement is. Homeopathy was included in the Swiss health insurance scheme for the first time 1998, but was withdrawn in 2005. In 2009 the Swiss people nationally voted in favour of a constitutional article granting authority for the state and cantons to take complementary medicine (including homeopathy) into consideration in the public health insurance scheme. Homeopathy was then re-instated in the public health insurance scheme in 2012. In contrast, homeopathy has been part of the National Health Service in the UK since 1948. In both countries homeopathy has been practised since the early nineteenth century.

In conclusion, Professor Hylands has not provided the ASA with a reliable report on the Swiss Health Technology Assessment as published in *Homeopathy in Healthcare*. Many of his statements cannot be substantiated on the basis of the evidence, and even conflict with the evidence. Much of his report is actually concerned with the marginal issue of the Shang et al. meta-analysis, as if this were central to the HTA, which it is not. At the same time as he gives Shang et al. undue weight in this context, he also fails to take into account the full extent of the criticisms of this meta-analysis detailed in *Homeopathy in Healthcare* and elsewhere. He provides no secure grounds on which “To assess whether the Swiss HTA report and the conclusions it draws are sound.”