

Release of NHMRC Homeopathy Review 2012: Questions and Answers

• Why does this First Report matter?

The First Report¹ was funded by the Australian taxpayer, yet its existence was never disclosed by NHMRC, let alone its 'encouraging' positive findings for five medical conditions.

Patients suffering from these conditions deserve to know that research suggests homeopathy may help them. This draft report found encouraging evidence for the effectiveness of homeopathy for fibromyalgia, otitis media (ear infections), upper respiratory infections in adults and post-operative ileus (first time to flatus after surgery), and for side-effects of cancer treatment (prevention of acute dermatitis during radiotherapy and chemotherapy-induced stomatitis).

Researchers also need to know which avenues are most promising in terms of identifying new clinically effective treatments; reports such as this are extremely important for identifying which medical conditions and treatments have been found to be effective in some studies and are therefore worthy of further investigation.

Research requires significant funding and resources. NHMRC's false claim in the 2015 Homeopathy Review that no good trials have found homeopathy to be effective has unfairly damaged the reputation of homeopathy, making it far harder for new research studies in this field to be carried out due to the misperception created that it is a 'therapeutic dead end'.²

The 'encouraging' evidence that exists for some medical conditions, some of which was already evident in 2012, is simply not consistent with the premise that homeopathy is 'impossible' – it indicates that homeopathy warrants further research.

• Why are there no annotations from the author defending their work?

NHMRC released their annotated copy of the First Report into the public domain without notifying the author, giving her no opportunity to reply to the critical comments they have added to the document.

• Who wrote the First Report on homeopathy for NHMRC?

The 2012 report was written by Prof Karen Grimmer, a highly experienced researcher who worked with the University of South Australia for 22 years. As well as authoring multiple academic papers, Prof Grimmer was Director of the International Centre for Allied Health Evidence (iCAHE) for over 20 years. Under her guidance, iCAHE became a regular provider of evidence reviews and scientific policy advice to government organisations and universities in Australia, Hong Kong, the Philippines, South Africa and New Zealand.

Most notably, NHMRC recognised Prof Grimmer's status as an expert in research methodology when they recruited her to become part of the team who created the NHMRC 'FORM' methodology.³ From 2009-2018 this method was the recommended NHMRC approach for assessing

the quality of a body of clinical evidence being used to create clinical recommendations. Prof Grimmer used the FORM method to assess the evidence for homeopathy in the First Report.

• Is this first report finally scientific 'proof' homeopathy works?

The first report is in draft form and so it cannot be quoted as part of the published scientific literature. It should also be noted that as the first report was produced in 2012, it is incomplete, missing all studies published during the past seven years.

The report does not provide definitive proof that homeopathy works – rather it has identified some positive evidence that suggests homeopathy could be beneficial for certain medical conditions. Evidence bases need to be built, one study at a time, until the amount of data is sufficient to be considered conclusive. More research is needed to build the evidence base for these (and other) specific medical conditions from 'encouraging' to 'definitively positive'.

• In what way did NHMRC 'bury' the First Report?

The existence of the First Report was only discovered from documents obtained through Freedom of Information requests (FOIs). Internal NHMRC documents examined during an investigation into the inaccurate 2015 Homeopathy Review mentioned an unknown earlier 2012 report.

NHMRC did not disclose the existence of the First Report in any public documentation relating to the 2012-15 Homeopathy review process, nor on its website.

The NHMRC Administrative Report, which is supposed to provide a full account of the Homeopathy review process, also omits any mention of the First Report.

Finally, the NHMRC Annual Reports do not mention the First Report by UniSA, nor the public expenditure on this project.

Stakeholders first sought access to the First Report in September 2015. NHMRC offered restricted and supervised access to the document at their offices, conditional on stakeholders signing a legal non-disclosure preventing any further reference to the report or its contents. Stakeholders declined this offer.

From 2016 to 2019, NHMRC refused to release the First Report despite a series of FOI requests sent by multiple independent parties, as well as questions raised in the Senate about its release.

In 2019 legal steps were in progress to challenge NHMRC's refusal to comply with the FOI request in order to force release of the report.

On 23 July 2019, NHMRC responded to Senator Derryn Hinch: "NHMRC has no plans to release what is referred to as the 2012 draft report. It is an incomplete draft of an overview of systematic reviews that was commissioned by NHMRC but was not finalised because the contract was terminated by mutual agreement between NHMRC and the contractor. As the contractor never finalised the draft, it did not undergo NHMRC's usual quality assurance processes, and was not considered by the Council of NHMRC. It is not NHMRC's standard procedure to release incomplete or unfinished documents or those that have not been through quality assurance processes."

Four weeks later NHMRC released the annotated copy of the First Report.

• What evidence do we have that the First Report was buried because it found the 'wrong result' not because it was poor quality?

The First Report is in draft form and as such it is not a 'perfect' finalised document. However, the report was sufficiently well-formed to have undergone peer review. FOI requests revealed that a member of NHMRC's committee overseeing the review process considered the first review to be high quality saying, "I am impressed by the rigor, thoroughness and systematic approach given to this evaluation [....] Overall, a lot of excellent work has gone into this review and the results are presented in a systematic, unbiased and convincing manner."⁴ (Professor Fred Mendelsohn, NHMRC Homeopathy Working Committee).

• Are NHMRC's annotations accurate and appropriate?

The First Report is an unpolished draft, so inevitably some of the annotations relate to normal corrections e.g. typographical errors and reasonable suggested improvements. However, in many cases the comments unfairly cast doubt on the validity of Prof Grimmer's work and/or suggest changes which would have weakened the findings of this report had they been implemented in a finalised version.

For example, NHMRC repeatedly criticise the report for not providing sufficient reference to 'risk of bias' assessments (a way of assessing study quality/reliability). Most strikingly, on page viii, NHMRC undermines the credibility of Prof Grimmer's finding that there is 'encouraging evidence' for five conditions by commenting that: "the FORM evidence matrix [a summary table] for each of these conditions has little or no mention of risk of bias – an integral criterion for quality of the evidence".

This gives the impression that Prof Grimmer has not given sufficient consideration to the quality of the evidence being reviewed – a remarkable claim given her expertise and experience in using the FORM approach. In fact, risk of bias is one of the factors the author would have considered when assigning a 'grade' to the evidence base for each medical condition (grading it from A-D). Risk of bias is therefore integrated within the report's findings throughout, as well as being presented directly in the main text of each chapter.

Another example of unjustified criticism can be seen on page 26 of the First Report where Prof Grimmer has described the systematic reviews she was assessing as 'focused' or 'unfocused'. She states clearly that this refers to the clinical focus of the review i.e. whether it covers a single condition or multiple medical conditions, and whether it considers only homeopathy or multiple complementary therapies (Table 3, p.25). NHMRC's comments that this section is "poorly expressed", and that unfocused "means poor quality" or "there were no quality studies" (p.26) is therefore incorrect and misleading.

It is concerning that such comments have been put into the public domain without giving the author the opportunity to respond directly to NHMRC's criticisms of her work.

• Who wrote the second report on Homeopathy?

The 2015 Homeopathy Review⁶ published by NHMRC was based on an evidence review conducted by external contractor OptumInsight, under the direction of the NHMRC Homeopathy Working Committee (HWC). Membership of the HWC was largely unchanged from when they worked with Prof Grimmer on the First Report.

Meeting minutes obtained under the Freedom of Information Act show that the HWC/NHMRC were responsible for the final interpretation of the evidence as published in the 2015 report, having made significant changes to the original draft text submitted by OptumInsight.

This included changing the findings for some conditions from inconclusive to negative e.g. OptumInsight's proposed conclusion for migraine was: 'There is no conclusive evidence that homeopathy is effective'; the HWC/NHMRC changed this wording for the final published report to: 'homeopathy is not more effective than placebo for the treatment of people with migraine'.⁷

• How did the second report get such a different result?

NHMRC's 2015 Homeopathy Review reached such a different conclusion by introducing a new rule that all trials with less than 150 participants and/or a quality score less than 5/5 on a trial quality rating scale would be considered "unreliable" and their findings would therefore be dismissed. This rule, which has never been used before or since by any research team, including NHMRC, reduced the number of trials from 176 to 5.

References

- 1. <u>Draft-annotated-2012-homeopathy-report</u>, The Effectiveness of Homeopathy, An overview review of secondary evidence
- 2. https://blogs.bmj.com/bmj/2016/02/16/paul-glasziou-still-no-evidence-for-homeopathy/
- 3. Hillier et al. FORM: An Australian method for formulating and grading recommendations in evidencebased clinical guidelines. BMC Medical Research Methodology, 2011; 11:23
- 4. <u>2012.07.12 HWC (Fred Mendelsohn) feedback on UniSA review FOI 2016-17 016-12</u>. 15 July 2012. NHMRC FOI 2014/15 021-08
- 5. <u>2012.04.04 NHMRC Official Order (UniSA contract & Statement of Requirement. NHMRC FOI 2014</u> 15 <u>021-04</u>), Page 7, point 1.5.
- 6. <u>Overview Report: Effectiveness of Homeopathy for Clinical Conditions: Evaluation of the Evidence</u>, NHMRC, 11 March 2015
- 7. <u>2013-03-18 FINAL ENDORSED Minutes 18 Mar 2013 Redacted FOI 2015-16 007-03</u> (our use of underline).
- 8. https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/review-of-natural-therapies-for-private-health-insurance

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