

the Nightingale Collaboration

Response to NHS Lanarkshire's consultation:

*Should NHS Lanarkshire
refer patients to the
Centre for Integrative Care
(Glasgow Homoeopathic Hospital)?*

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Challenging misleading healthcare claims

Contents

Introduction	3
About the Nightingale Collaboration	3
Current referrals to GHH	4
Evidence	4
Assessments	4
Dr Kohli	4
House of Commons S&T Committee Homeopathy Evidence Check	4
National Health and Medical Research Council	5
The Swiss homeopathy report	5
Summary	6
Dr Leckridge	6
Specific and non-specific effects	7
Care plans	7
Summary	7
Alternative approaches and support	7
Submissions from homeopathy supporters	8
Petition in support of the GHH	8
Patient choice	8
Advertising Standards Authority	9
Conclusion	9
Appendix A — Conditions referred to the GHH	10
References	12

Introduction

We welcome the opportunity to respond to your consultation on the referral of patients to the Glasgow Homeopathic Hospital (GHH).

We believe this is an ideal time for NHS Lanarkshire to end the practice of referring patients to the GHH for unproven and disproven treatments.

We outline our reasons below.

About the Nightingale Collaboration

The Nightingale Collaboration is a consumer pressure group set up to challenge misleading claims in the promotion of healthcare therapies to the public.

Most misleading claims that appear in marketing aimed at the general public are in the promotion of complementary and alternative therapies and products. This is where our experience lies and where we therefore focus our attention.

We challenge questionable claims by referring them to the appropriate regulatory bodies.

Laws, rules and regulations are in place for the protection of consumers but we are concerned that some of them are being widely ignored by manufacturers, practitioners and advertisers.

When misleading claims are made, we are denied the ability to make a fully informed choice in our healthcare decisions. There are many examples of tragedies that have resulted from people basing their healthcare decisions on flawed information and delaying or forgoing effective treatments (see www.whatstheharm.net). Even if there is no direct harm to health, there are still the financial repercussions of buying products and services based on misleading claims.

However, we do not make any of the laws, regulations or rules governing the provision of the healthcare products and services; nor do we set standards — all decisions are made by the regulatory bodies we submit complaints to. They decide whether their rules or regulations have been breached, not us. However, we have a track record of having the vast majority of our complaints upheld.

If there are misleading claims in advertising of conventional medicine — or indeed any other area — then we believe these too should be challenged to help protect the public. The information we carry on our website will help others do that.

We are currently funded solely with a grant arranged by Simon Singh and we receive no commercial funding whatsoever.

Note

We use the term ‘homeopathic medicine’ to be consistent with the language used in various EU Directives and therefore by the Medicines and Healthcare products Regulatory Agency (MHRA). However, we believe this phrase and the word ‘remedy’ — as frequently used by homeopaths — are misleading terms, implying as they do, that they have medicinal or remedial effects when we understand there is no good evidence for any such effects. We believe this is consistent with the stance of the MHRA on the evidence.

Similarly, we refer to ‘treatments’ and ‘therapies’ as in everyday usage but without accepting that there is necessarily any good evidence of efficacy or effectiveness.

Current referrals to GHH

According to the consultation document, the following treatments at GHH were given to GHH-referred patients:

- The prescribing of homoeopathic medicines
- Mindfulness-based cognitive therapy, which is used to help patients with chronic fatigue syndrome, chronic pain or chronic mood disorders
- HeartMath which teaches a person how to create a greater degree of coherence in heart rate variability and helps deal with stress
- Self-management programmes
- Art therapy
- Yoga and breathing
- Music therapy/ movement therapy
- Acupuncture for patients with musculoskeletal problems causing chronic pain and stiffness
- Neural therapy which is an injection technique used in the management of pain and neurological conditions such as multiple sclerosis
- Mistletoe therapy for patients with cancer

From the response by NHS Lanarkshire to our Freedom of Information (Scotland) Act request, we know that 53 categories of conditions were referred to GHH — see Appendix A. We note that these include a wide range of different cancers and many other serious medical conditions.

Evidence

We understand that there is some evidence for the efficacy of a few of these treatments referred, but no good scientific evidence for the efficacy of homeopathy, HeartMath, neural and mistletoe therapies and that the evidence for acupuncture for the conditions listed is not compelling.

Although we don't know which treatments were requested or provided for the 53 conditions listed, we do not believe that there is much good evidence, if any, for those conditions for many of the treatments on offer at the GHH.

Assessments

We would like to comment on the points made by Drs Kohli and Leckridge.

Dr Kohli

In general, we agree with the views expressed by Dr Harpreet Kohli in his assessment of homeopathy and with the conclusions of the Lanarkshire Homeopathy Review Project Group in its assessment of the five therapies listed in the consultation document. While those conclusions are brief, we believe they are broadly in line with all the best available scientific evidence.

We note that the conclusions of the Review Group are backed by citations of trials, meta analyses and systematic reviews, and we would seek to underline the view expressed by Dr Kohli that these represent the best available evidence.

It is because of this lack of compelling evidence for the treatments that we believe that referrals should be ended.

House of Commons S&T Committee Homeopathy Evidence Check

We concur with Dr Kohli's comments on the House of Commons Science and Technology Committee Homeopathy Evidence Check¹, set up specifically to test if the Government's policies on homeopathy were based on sound evidence.

We note that the report concluded:

20. For patient choice to be real choice, patients must be adequately informed to understand the implications of treatments. For homeopathy this would certainly require an explanation that homeopathy is a placebo. When this is not done, patient choice is meaningless. When it is done, the effectiveness of the placebo—that is, homeopathy—may be diminished. We argue that the provision of homeopathy on the NHS, in effect, diminishes, not increases, informed patient choice.

We concur particularly with the comments that not giving patients the full facts about homeopathy restricts patient choice.

It also concluded:

23. The Government should stop allowing the funding of homeopathy on the NHS.

The key question here is whether or not homeopathy should be funded by NHS Lanarkshire and the House of Commons Evidence Check report has already answered that conclusively.

National Health and Medical Research Council

The National Health and Medical Research Council (NHMRC) have recently completed their evaluation of the evidence for homeopathy and have published their draft report.²

Their objective was:

...to summarise the evidence from systematic reviews regarding the effectiveness of homeopathy as a treatment for any clinical condition in humans.

Results:

A total of 57 systematic reviews were identified that met the criteria for inclusion within this Overview Report. The relevant reviews tended to have one of three main objectives (i) to review a variety of complementary and alternative medicines (CAM), including homeopathy, for the treatment of a particular clinical condition or specific clinical area, (ii) to review homeopathy for the treatment of one clinical condition, or (iii) to review homeopathy for the treatment of a variety of clinical conditions. The reviews examined the evidence for a total of 68 clinical conditions and included seven clinical conditions for which no relevant primary studies were identified. Of the remaining 61 clinical conditions, the total number of participants included in the trial(s) was less than 150 for 36 of the clinical conditions examined. The total number of participants included in the trial(s) was between 150 and 499 for 15 clinical conditions. The evidence base for 10 clinical conditions collectively comprised 500 or more participants. There were 31 clinical conditions for which only one Level II or Level III-2 study was identified.

We believe this to be the most comprehensive and authoritative investigation of the evidence and note they concluded:

There is a paucity of good-quality studies of sufficient size that examine the effectiveness of homeopathy as a treatment for any clinical condition in humans. The available evidence is not compelling and fails to demonstrate that homeopathy is an effective treatment for any of the reported clinical conditions in humans.

The Swiss homeopathy report

Although not mentioned by Dr Kohli, we believe that this report may also be cited by supporters of homeopathy in their submission. Wrongly described as a Health Technology Assessment (HTA), it was originally commissioned by the Swiss Government to look into the evidence for homeopathy so they could decide whether to continue the temporary reimbursement for it in their national health insurance scheme. This was part of a wider investigation into homeopathy,

anthroposophic medicine, neural therapy, phytotherapy (herbal) and Traditional Chinese herbal therapy (TCM). The well-known Shang *et al.* analysis³ of homeopathy was also commissioned as part of this same assessment.

It should be noted, however, that the version of the report published in English⁴ was not the report prepared for and submitted to the Swiss Programm Evaluation Komplementärmedizin (PEK) commission set up to oversee the investigation. According to Dr Felix Gurtner of the Federal Office of Public Health FOPH, Health and Accident Insurance Directorate, Bern, Switzerland:

This review was declared to be an HTA by the authors (the final PEK [5] report does not classify the literature reviews as HTA reports) and published later as a book [7] under their responsibility without any consent of the Swiss government or administration. The book by Bonhöft and Matthiessen was later translated into English and published in 2012 [2]. (His original references)⁵

The report has been roundly criticised as being biased, written mainly by supporters of complementary therapies. One academic went as far as to call it:

a case study of research misconduct⁶

The authors 're-interpreted' the conclusions of many previous reviews of homeopathy, making them more favourable towards homeopathy. However, this was criticised by the PEK (unofficial translation from German):

For all five assessments, it is very obvious that all or some of the authors have a positive attitude towards the treatments in question or are convinced about their efficacy. Unquestionably, strict proponents of the usual hierarchy of evidence will regard the presented evaluations as scientifically untenable and unreasonably positive (except for some specific aspects of phytotherapy). Even less skeptical academic doctors will regard many interpretations as very optimistic and not scientifically convincing.

And:

The positive interpretation of the current evidence seems understandable, as long as one does not require especially high evidence standards, given the low plausibility of homeopathy in the light of established scientific knowledge. Very skeptical people will regard the reviewed evidence as not very convincing.

The PEK review panel downgraded all the reports in their view on efficacy and, as a direct of the reports, ended the reimbursement for all therapies investigated, including homeopathy.

It was only after a subsequent national referendum and campaigning by supporters of the therapies that the Swiss Government decided to allow a second temporary period of reimbursement for these therapies. That period ends in 2017 unless new scientific evidence can be presented by 2015 that they meet the Government's criteria of 'efficacy, appropriateness and cost-effectiveness'.

Further details of the report can be found in a blog post I wrote⁷, which includes links to the original source documents so that they can be verified.

Summary

We strongly recommend that NHS Lanarkshire take note of these findings and end the funding of referrals to the GHH for homeopathy and other therapies including anthroposophy.

Dr Leckridge

We note that the statement by Dr Bob Leckridge in support of continuing referrals makes no attempt to refute any of the points raised by Dr Kohli. Nor does he provide evidence to refute

any of the Review Group's conclusions or evidence in support of any other of the treatments his hospital provides, eg acupuncture.

Although patient satisfaction rates are important, we strongly believe that they are inadequate as a base for determining whether a treatment is effective or efficacious. These can only be ascertained by robust, independent trials.

We find his claims about the safety of the GHH to be misleading; it can only be disingenuous to compare the GHH with a General Hospital setting that deals with a completely different profile of patients, including life-threatening, emergency and trauma cases.

Specific and non-specific effects

Dr Leckridge focuses solely on the *non-specific* effects of treatments (eg the consultation, the personalised approach, a person-centred service), yet says nothing about the *specific* effects of any treatment, that is, whether the treatment itself has any demonstrable effects.

The distinction between specific and non-specific effects is crucial: while the non-specific effects may elicit strong placebo responses, they cannot be used to validate non-existent specific effects eg of homeopathy.

There is little doubt that patients' well-being can be improved by a lengthy, comprehensive consultation, particularly if they are carried out in inviting, relaxed, modern comfortable surroundings.⁸ This is as much applicable to conventional treatments as it is to treatments provided by the GHH and is not a differentiator.

Similarly, Dr Leckridge talks about a consultation being 'holistic' as if that is something unique to the treatments the GHH provides when it is something that all doctors strive to provide.

In many cases, Dr Leckridge simply states truisms and standard phrases (eg 'all patients are unique', 'individualised care plans') as if these were unique to the GHH. However, he gives no indication of why he believes what the GHH does is different or results in any improvements in outcomes, nor offers any evidence to substantiate his assertions.

Care plans

While we cannot disagree with what Dr Leckridge says about care plans in terms of patient education and the acquisition of new skills and practices, he again does not say what he believes is unique about these from a GHH perspective. We believe the GHH is not necessary for that and that these could be provided locally, possibly by existing NHS Lanarkshire staff.

We are concerned at his suggestion that treatments such as homeopathy and mistletoe therapy could be 'clinically indicated'. We are not aware of any compelling evidence that these particular treatments confer any specific therapeutic value, therefore cannot see under what circumstances they could be clinically indicated.

Summary

Considering the above, we do not find Dr Leckridge's arguments in favour of continuing referrals at all compelling.

Alternative approaches and support

We generally concur with the views expressed by Nurse Consultant Janette Barrie about the provision of other approaches and support for those with long-term conditions. We believe NHS Lanarkshire should investigate the provision of these locally, giving greater control and flexibility whilst reducing the need for patients to travel to the far side of Glasgow and a reduction in concomitant travel expenses whether this is borne by the patient or reimbursed by NHS Lanarkshire.

However, we were disappointed to see the suggestion that acupuncture be used short-term pain relief. Although we understand there is some evidence that it is useful for some types of lower back pain, we are not aware of any compelling evidence that it is any more effective than other forms of pain management. However, this is an issue for NHS Lanarkshire to address.

Submissions from homeopathy supporters

We suspect that many of the reported 3,000+ responses already received by NHS Lanarkshire⁹ will have been from supporters of homeopathy. We also suspect many of these will be from supporters outside the UK and many will contain anecdotes of how they believed homeopathy had helped them.

Whilst these may be sincerely held beliefs, for many well-known and well-understood reasons they cannot be a proper and reliable basis on which to decide about continuing referrals to the GHH.

Patients deserve treatments that have good evidence behind them; and this applies to conventional treatments as much as CAM therapies.

Petition in support of the GHH

We are aware of a petition to save the GHH¹⁰ and expect this to be mentioned in responses by supporters of homeopathy and the concerted campaign by many homeopathy lobby groups, trade bodies and individual homeopaths and supporters.^{11,12,13,14,15,16}

This petition is addressed to, amongst others, Ian Ross, Acting Chief Executive of NHS Lanarkshire.

To date, the petition has gathered approximately 25,000 signatures. However, we note that many of these give their location as outside the UK, outside of Scotland and outside of Glasgow.

We do not have access to the full list of signatures, but we have been able to sample 2,123 (9%) of them, taken up to 21 March 2014. Of these, only 39% gave the UK as their location. 15% of the sample gave an identifiable Scottish location and just 6% gave Glasgow as their location. Assuming our sample to be random, we believe we can extrapolate this sample of 9% of the total number of signatures to the total petition population with a confidence interval of $\pm 2\%$, to a confidence level of 95%, giving the overall UK signatures as 9,590 (9,109–10,071, 95% CL); Scotland: 3,651 (3,298–4,003, 95% CL); Glasgow: 1,465 (1,229–1,700, 95% CL).

We believe this gives a more realistic indication of support by those directly within the GHH's 'catchment' area, but it must be borne in mind that it cannot be known whether or not any of these 1,465 from Glasgow have been, are currently, or might be in the future, patients of the GHH.

However, we do not believe that fundamental decisions about healthcare should be influenced by a popularity vote, but on the best available evidence.

Patient choice

We also suspect that responses will encourage you to continue to refer on the basis that stopping will reduce patient choice. The concept of patient choice is frequently raised by homeopathy supporters, but while this is important, medical professionals have a duty to ensure that their patients are properly informed about any treatment before a decision can be made.

The framing of choice as purely something of a personal preference can completely ignore inconclusive or negative scientific evidence for that choice. This cannot be in the patient's best

interests and usurps the role of the medical profession and responsible prescribing within financial restrictions.

For homeopathy and other most other treatments provided by the GHH, they are not exclusive to the GHH — the vast majority of these treatments are available privately. Homeopathic medicines, for example, are available over the counter from many pharmacies and health food stores and there are a number of homeopaths in Lanarkshire and nearby that patients wishing to continue to use homeopathy could consult.

Advertising Standards Authority

The GHH are currently being investigated by the Advertising Standards Authority (ASA) over claims they make on eight pages of their website¹⁷ and in a leaflet. We are the complainants and we believe many of the claims made by the GHH are not capable of substantiation.

Our complaint covered claims made about homeopathy for a variety of medical conditions, including serious medical conditions, claims about mistletoe/Iscador™ and cancer, claims about acupuncture, HeartMath™, emotional freedom technique and anthroposophic medicine. We note that many of these claims are about treatments for which NHS Lanarkshire has been referring patients.

We note that the ASA has already ruled on many similar claims and has issued guidance on many of these treatments advertised by the GHH.

For example, the ASA's *Guidance for Advertisers of Homeopathic Services* was published in 2011:

To date, the ASA has have not seen persuasive evidence to support claims that homeopathy can treat, cure or relieve specific conditions or symptoms. We understand this position is in line with other authoritative reviews of evidence.

We therefore advise homeopathy marketers to avoid making specific claims of efficacy for treatments where robust evidence is not held to substantiate them.¹⁸

We believe the GHH's advertising does not comply with this and we do not find it credible that the GHH were not aware of the ASA's advertising requirements on homeopathy and other treatments they advertised.

However, we cannot pre-empt the ASA's assessment of the evidence that might be supplied by the GHH and we await the ASA's adjudication on the matter.

Conclusion

1. There is no compelling evidence for the majority of therapies currently provided by the GHH.
2. Patient choice is meaningless without being informed of the lack of compelling evidence and medical professionals have a duty to ensure their patients are properly informed about any treatment.
3. It cannot be in the best interests of patients to be referred for treatments that have inconclusive or negative evidence.
4. There are therefore no compelling reasons why NHS Lanarkshire should continue to fund treatments at the GHH or at their outpatients clinic.
5. It is likely that replacement treatments — and ones backed by good evidence — could be provided locally, saving both NHS Lanarkshire and patients, time, money and unnecessary travel.
6. We urge NHS Lanarkshire to end their referral of patients to the GHH.

Appendix A — Conditions referred to the GHH

List of conditions for which NHS Lanarkshire referred patients to the GHH as stated in a Freedom of Information (Scotland) Act response dated 07 March 2014:

The conditions they were referred with have been recorded as follows:-

- Abdominal and pelvic pain
- Abnormal involuntary movements
- Adverse effects, not elsewhere classified
- Asthma
- Cellulitis
- Chronic ischaemic heart disease
- Chronic kidney disease
- Congenital malformations of the musculoskeletal system, nec
- Convulsions, not elsewhere classified
- Crohn's disease (regional enteritis)
- Depressive episodes
- Dorsalgia
- Endometriosis
- Epilepsy
- Headache
- Infantile cerebral palsy
- Malignant neoplasm of colon
- Malignant neoplasm of breast
- Malignant neoplasm of other and unspecified parts of tongue
- Malignant neoplasm of ovary
- Malignant neoplasm of pancreas
- Malignant neoplasm of skin
- Malignant neoplasm of stomach
- Mesothelioma
- Migraine
- Multiple sclerosis
- Non-insulin dependent diabetes mellitus
- Osteoporosis with pathological fracture
- Other anxiety disorders
- Other arthrosis
- Other chronic obstructive pulmonary disease
- Other diseases of digestive system
- Other disorders of the brain
- Other disorders of the urinary system
- Other headache syndromes
- Other inflammatory spondylopathies
- Other joint disorders, not elsewhere classified
- Other polyneuropathies
- Other rheumatoid arthritis
- Other sex chromosome abnormalities, male phenotype, nec
- Other soft tissue disorders, not elsewhere classified
- Other symptoms and signs involving the nervous and musculoskeletal systems
- Other systematic involvement of connective tissue
- Pain, not elsewhere classified
- Pain and other conditions associated with female genital organs and menst cycle

Paraplegia and tetraplegia
Parkinson's disease
Psoriasis
Sarcoidosis
Spinal muscular atrophy and related syndromes
Spondylosis
Systemic sclerosis
Tuberculosis of other organs

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