Charity Commission Consultation:
Response from the Complementary and Natural Healthcare Council

Question 1: What level and nature of evidence should the Commission require to establish the beneficial impact of CAM therapies?

As the UK voluntary regulator for complementary health practitioners, established with Department of Health support, CNHC proposes that the Commission seeks the 'best available evidence' as set out by Sackett (http://www.dcscience.net/sackett-BMJ-1996.pdf). This would mirror what happens in the provision of mainstream health and care services.

As stated by the House of Lords Select Committee for Science and Technology in its report of 1999 – 2000, cited by the Commission in Annex A of its decision about the Soteria Network, dated 29 February 2012, there is little funding available for full-scale Randomised Controlled Trials (RCTs) in the complementary health sector. This situation has not changed since that report and yet complementary approaches remain popular and widely used by the public.

Large number of hospices, cancer and palliative care centres and mental health charities provide access to complementary healthcare. Information is also provided by organisations including charities such as the MS Society, Mind, Allergy UK, Macmillan Cancer Care, Parkinson's UK and others.

Clinical studies, audits, service evaluations and patient-reported outcomes
Despite the lack of RCTs, there are wide numbers of patient-reported outcomes, clinical audits and case studies – particularly in the cancer and palliative care sector, and also in mental health services. These represent a pragmatic approach to evidence, which tie in directly with patient experience. These types of studies are often carried out by clinicians and those involved in the delivery of services in highly regulated and / or supervised environments. (See Appendix 1 for examples).

In most cases the provision of complementary therapies is demand-led by patients, hence the services provided. Approximately 40% of breast and prostate patients use complementary therapies and 20% of patients with other cancers. The evidence and audits are very patient-centred and almost always supportive of the service and what it has to offer (especially the qualitative work and audits).

Example tools in cancer and palliative care for gathering patient reported outcome measures (PROMS) include *Measure Yourself Concerns and Well-being* (MYCaW) questionnaire, an evidence-based, validated tool designed specifically for evaluating Complementary therapies in cancer care http://www.bris.ac.uk/primaryhealthcare/resources/mymop/sisters/ .

Measure Yourself Medical Outcome Profile (MYMOP) is another validated tool which enables practitioners to collate patient-reported outcomes.
http://www.bris.ac.uk/primaryhealthcare/resources/mymop/

NICE guidelines
We would also suggest that the Commission can rely on NICE guidelines where they make recommendations about complementary healthcare. For example, the recent update to the NICE guideline on low back pain and sciatica includes recommendations for massage therapy – when used as part of a treatment package including exercise, and group yoga classes, to address low back pain with or without sciatica. Another example is the reference,

in the NICE guideline for irritable bowel syndrome (IBS) in adults, to the use of hypnotherapy as one of the psychological interventions for people whose symptoms have not responded to pharmacological treatment after 12 months.

Following a consultation in January 2016 of an update to its supportive and palliative care guidelines in adults, NICE decided to keep the original guideline in place which included recommendations for complementary healthcare. Here is the link to NICE's information for the public about that guideline: https://www.nice.org.uk/guidance/csg4/resources/supportive-and-palliative-care-services-for-adults-with-cancer-pdf-2188778077 . Here is the link to the guideline itself with relevant section at section 11, page 148: https://www.nice.org.uk/guidance/csg4/resources/improving-supportive-and-palliative-care-for-adults-with-cancer-pdf-773375005

Evidence from overseas
We would also recommend a consideration of evidence and provision abroad, as happened in the decision about the Soteria Network. For example there is a lot of peer-reviewed evidence published about the use of massage in the US and Canada.

Question 1 summary:
So in summary, our suggestions are that the Commission considers:

- Best available evidence according to Sackett's hierarchy of evidence which includes:
  - Systematic reviews – where they exist
  - RCTs where they exist
  - Service audits and evaluations
  - Patient-reported outcome measures (PROMS)
  - Published case studies
- NICE guidelines where relevant
- Overseas research that is published and peer-reviewed
- Evidence of use of complementary healthcare in other countries as part of mainstream care.

Question 2: Can the benefit of the use or promotion of CAM therapies be established by general acceptance or recognition, without the need for further evidence of beneficial impact? If so, what level of recognition, and by whom, should the Commission consider as evidence?

Yes we would suggest that there are other ways of recognising the legitimacy and benefit of complementary healthcare approaches.

Government recognition of complementary healthcare
As stated above, CNHC was initially established with Department of Health support in recognition of the beneficial role that complementary healthcare plays in the UK and the need to ensure that the public has access to safe and competent practitioners.

In preparation for the establishment of CNHC, government invested considerable funding into the development of National Occupational Standards (NOS) for a wide range of complementary healthcare occupations. The NOS set out the knowledge, understanding and performance criteria required for safe and competent practice. This includes competence to identify contra-indications for the specific complementary therapy. All disciplines registered by CNHC have NOS in place.

Full details of all published NOS can be found on the Skills for Health website: http://www.skillsforhealth.org.uk/standards

Recognition of disciplines on Accredited Registers

More recently, as part of the Health and Social Care Act 2012, the government established its system of Accredited Registers.

In order to be approved as the holder of an Accredited Register with the Professional Standards Authority for Health and Social Care (PSA), organisations are required to meet PSA's robust standards as follows:

1. Hold a voluntary register of health and care practitioners
2. Be committed to protecting the public
3. Understand, monitor and control risks
4. Be financially sound
5. Inspire public confidence
6. Develop your knowledge
7. Provide strong and effective governance
8. Set good standards for practitioners on your register
9. Ensure appropriate education and training for practitioners
10. Run your register well
11. Manage complaints fairly and effectively

The detail of standard 1 is as follows:

> **Standard 1: the organisation holds a voluntary register of people in health and/or social care occupations.**
>
> The Professional Standards Authority will decide whether an occupation is 'health or social care' having regard to the definition of health care set out in the National Health Service Reform and Health Care Professions Act 2002, section 25E (8) as inserted by the Health and Social Care Act 2012, section 228.

In order to meet this standard CNHC showed that there are National Occupational Standards (NOS) for each of the disciplines we register.

NOS also exist for homeopathy and acupuncture, and these disciplines are also recognised as legitimate health professions by PSA through its approval of the British Acupuncture Council and the Society of Homeopaths as holders of Accredited Registers.

In recognition of the status of Accredited Registers, in April 2015 the General Medical Council updated its guidance to confirm that registered medical practitioners can refer patients to practitioners on Accredited Registers. The relevant section of Good Medical Practice is included below:

> Delegation and Referral
>
> 8. Where this is not the case, you must be satisfied that systems are in place to assure the safety and quality of care provided – for example, the services have been commissioned through an NHS commissioning process or the practitioner is on a register accredited by the Professional Standards Authority.[4]
>
> [http://www.gmc-uk.org/guidance/ethical_guidance/30143.asp at 25 April 2017]

In addition to this recognition by the GMC, PSA is currently involved in a joint project with the Royal Society for Public Health (RSPH) to explore the role that complementary health practitioners on Accredited Registers can play as part of the wider public health workforce. The RSPH is due to publish its report later this year.

We consider that this government recognition, combined with recognition by the Professional Standards Authority, the Royal Society for Public Health and the General Medical Council,

provide sufficient evidence on which the Commission can recognise the relevant approaches.

Question 3: How should the Commission consider conflicting or inconsistent evidence of beneficial impact regarding CAM therapies?

We recognise that this is a challenge for the Commission.

Due to lack of funding for research in this field it is likely that there will be conflicting or inconsistent evidence.

It would be helpful for the Commission to seek peer-review by relevant experts where possible, or to encourage those applying to do so. The central question must be whether there is any risk of harm. For most complementary healthcare approaches the risk of harm due to the interventions themselves is low which is why successive governments have chosen to introduce voluntary, rather than statutory, systems of regulation.

Therefore, it might be possible to tolerate a level of inconsistency or conflict if there is *some* clear evidence of benefit.

Question 4: How, if at all, should the Commission's approach be different in respect of CAM organisations which only use or promote therapies which are complementary, rather than alternative, to conventional treatments?

We suggest that the Commission acknowledges and accepts government investment over more than a decade in the development of NOS, the establishment of CNHC and the system of Accredited Registers, as recognition of the public benefit in the use of complementary therapies. Practitioners of these approaches must not claim to cure medical conditions, or suggest that clients cease existing medical care, as may be the case with practitioners of 'alternative' treatments.

Use of Codes of Conduct and Ethics

A key concern of the Commission is that members of the public might seek 'alternative' therapies instead of seeking medical attention when required. All CNHC registrants agree to abide by the CNHC Code of Conduct, Ethics and Performance which includes, for example, Standard D1 requiring our registrants to recognise and work within the limits of their own knowledge, skills and competence. This standard incorporates practitioners knowing when to seek the advice of another healthcare professional and when to refer on.

Where disciplines fall outside of the Accredited Registers system mentioned above, the Commission might want to see the contents of codes of conduct and ethics of organisations that register or hold as members, practitioners of complementary healthcare, to check standards on this matter.

The Commission might also want to check whether the organisation has a robust complaints and disciplinary procedure in place and that practitioners could be removed from membership where codes have been breached.

Question 5: Is it appropriate to require a lesser degree of evidence of beneficial impact for CAM therapies which are claimed to relieve symptoms rather than to cure or diagnose conditions?

The complementary therapies registered by CNHC provide relief from a wide range of symptoms. In many cases there are not RCTs or equivalent to demonstrate this. However,

we provide example references at Appendix 1 to give an indication that evidence does exist for the benefit of a number of approaches in a range of palliative care and other settings.

If a therapy is provided on a palliative basis only, then clearly it is a complementary, rather than 'alternative' approach and so could be considered to require a 'lesser degree of evidence' (by which we assume 'less' than RCTs is meant) in line with the hierarchy of evidence. Again it would be important to ensure that practitioners have signed up to a robust professional code of conduct and ethics, and that there is an independent complaints process in place.

The Commission could seek evidence of actual harm, as although there might not be consistent evidence of benefit, there also might not be evidence of harm, as per our response to question 3.

Question 6: Do you have any other comments about the Commission's approach to registering CAM organisations as charities?

We have reviewed the Commission's approach to the Soteria Network and this appears to be sensible and robust.

Many people seek out complementary approaches when they are already using or have been through mainstream healthcare services. Complementary health care may also be recommended by healthcare professionals when discharging people from mainstream services.

The Commission may also be interested to compare its approach to that of the Information Standard, which reviews evidence, and awards organisations a listing based on that evidence. This includes a number of organisations that provide access to complementary healthcare. https://www.england.nhs.uk/wp-content/uploads/2017/02/tis-guide-finding-the-evidence-07nov.pdf This document includes a clear articulation of the hierarchy of evidence as discussed in our response at question 1:

Appendix 1

Examples of research studies carried out in cancer, supportive and palliative care settings

Recent research / audit / case studies from the Royal Marsden NHS Foundation Trust

- Dyer J, Cleary L, McNeill S, Ragsdale-Lowe M, Osland C. 2016 The use of aromasticks to help with sleep problems: A patient experience survey. Complementary Therapies in Clinical Practice 22:51-8
- Dyer J, Cleary L, Ragsdale-Lowe M, McNeill S, Osland C. 2014 The use of aromasticks at a cancer centre: A retrospective audit. Complementary Therapies in Clinical Practice 20(4):203-6
- Dyer J, Sandsund C, Thomas K, Shaw C 2013 Is reflexology as effective as aromatherapy massage for symptom relief in an outpatient oncology population? Complementary Therapies in Clinical Practice 19(3):139-46
- Dyer J, McNeill S, Ragsdale-Lowe M, Cleary L, Cardoso M, Cooper S 2010 The use of aromasticks for nausea in a cancer hospital. International Journal of Clinical Aromatherapy 7(2):3-6
- Ragsdale-Lowe, M. 2009. Supporting a young girl through radiotherapy, following resection of a brain tumour: Case study. International Journal of Clinical Aromatherapy 6(1):23-5
- Dyer J, Ashley S, Shaw C 2008 A study to look at the effects of a hydrolat spray on hot flushes in women being treated for breast cancer. Complementary Therapies in Clinical Practice 14:273–79
- Dyer J, McNeill S, Ragsdale-Lowe M, Tratt L 2008 A snap-shot survey of current practice: the use of aromasticks for symptom management. International Journal of Clinical Aromatherapy 5(2):17-21
- McNeill, S. 2007 Essential oils and massage used to support a patient with a compromised airway: a case study. International Journal of Clinical Aromatherapy 4(1):40-2

Further references for relevant research studies below:

- Cassileth, B. R. and A. J. Vickers (2004). "Massage therapy for symptom control: outcome study at a major cancer center." Journal of Pain and Symptom Management 28(3): 244-9.
- Ernst, E 2009 Massage therapy for cancer palliation and supportive care: a systematic review of randomised clinical trials. Supportive Care in Cancer 17(4):333-7.
- Lee, S.-H., J.-Y. Kim, et al. (2015). "Meta-Analysis of Massage Therapy on Cancer Pain." Integrative Cancer Therapies 14(4): 297.
- Mackereth P Hackman E Knowles R Mehrez A (2015) The value of stress relieving techniques. Cancer Nursing Practice. 14(4): 14-21.
- Mackereth P Campbell G Maycock P Hennings J Breckons M (2008) Chair massage for patients and carers: a pilot service in an outpatient setting of a cancer care hospital. Complementary Therapies in Clinical Practice. 14:136-142.
- Samuel, A. and Ebenezer, I. (2013) ‘Exploratory study on the efficacy of reflexology for pain threshold and tolerance using an ice-pain experiment and sham TENS control’, Complementary Therapies in Clinical Practice 19, pp. 57-62.
- Seers, H.E., Gale, N., Paterson, C., Cooke, H.J., Tuffrey, V., Polley, M.J. Individualised and complex experiences of integrative cancer support care: combining qualitative and quantitative data. Supportive Care in Cancer 2009; 17(9): 1159-1167. (In collaboration with Penny Brohn Cancer Care).
- Sharp, D. Walker, M. Chaturvedi, D. Upadhyay, S. Hamid, A. Walker, A. Bateman, J. Braid, F. Ellwood, K. et al (2010) ‘A randomised, controlled trial of the psychological

effects of reflexology in early breast cancer', European Journal of Cancer, 46, pp. 312-322.

- So PS, Jiang JY, Qin Y. Touch therapies for pain relief in adults. Cochrane Database of Systematic Reviews 2008, Issue 4. Art. No.: CD006535. DOI: 10.1002/14651858.CD006535.pub2.
- Stringer J Donald G Knowles R Warn P (2014) The Symptom Management of Fungating Malignant Wounds Using a Novel Essential Oil Cream. Wounds UK 10(3):30-38.
- Stringer J Donald G (2011) Aromasticks in Cancer Care: An innovation not to be Sniffed at. Complementary Therapies in Clinical Practice. 116-21
- Stringer J, Swindell R, Dennis M 2008 Massage in patients undergoing intensive chemotherapy reduces serum cortisol and prolactin. Psycho-Oncology 17(10):1024-31.
- Tsay, S. Chen, H. Chen, S. Lin, H. and Lin, K. (2008) 'Effects of reflexotherapy on acute postoperative pain and anxiety among patients with digestive cancer', Cancer Nursing, 31, pp. 109–115.
- Wilkinson SM, Love SB, Westcombe AM, Gambles MA, Burgess CC, Cargill A, Young T, Maher EJ, Ramirez AJ. 2007 Effectiveness of aromatherapy massage in the management of anxiety and depression in patients with cancer: a multicenter randomized controlled trial. J Clin Oncol 25:532-539
- Wyatt, G. Sikorski, A. Rahbar, M. Victorson, D. and You, M (2012) 'Health-related quality-of-life outcomes: A reflexology trial with patients with advanced-stage breast cancer', Oncology Nursing Forum, 39(6), pp. 568–577.