

Homeopathy, Science and Evidence Based Medicine

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Abstract

This dissertation explores, using an extensive literature review, the evidence for homeopathy. The science that supports the homeopathic therapeutic response is examined as well as examples of high quality clinical trials involving homeopathic medicines with comparisons to current examples in conventional medicine using Evidence-based Medicine (EBM) hierarchy as a measure.

The literature review reveals plant and animal studies which demonstrate that there is a therapeutic response that cannot be attributed to the placebo response alone. Scientific research involving bio-cellular communication such as 'water memory' has been replicated on a number of occasions in the last twenty years and the use of spectroscopy allows us to 'see' sub-molecular energetic activity where we once believed there was none. In view of the scientific advances in the area of quantum mechanics, it is likely that scientific research will eventually find out how homeopathy works. This literature review shows that homeopathy clearly has a therapeutic action and anticipates that the definitive science supporting it is not far away.

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'When you have eliminated the impossible, whatever remains, however improbable, must be the truth'.

- - - Sir Arthur Conan Doyle "The Sign of Four"

INTRODUCTION

Homeopathy has fascinated people for over two hundred years attracting enormous popular support from the public and many governments (<http://www.similima.com/org10.html>, 2010). Not until the twentieth century has scientific development in the area of quantum mechanics been able to show that cellular energetic activity beyond a molecular presence is possible, a concept that is at the root of homeopathy. These scientific advances seem to suggest that beyond the realm of the physical atom there is activity of an energetic nature, which is not meaningless but which, as in the case of water, contains the energetic pattern of the original physical substance. This energetic substance appears capable of responding therapeutically as a health intervention providing a safe, inexpensive, alternative form of health treatment.

One of the common criticisms levelled at homeopathy by its antagonists is that homeopathy lacks both scientific evidence and an evidence-based medicine approach to practice. These two concerns are more of a latter day problem, homeopathic treatment having been used successfully to treat medical illnesses since Dr Samuel Hahnemann, homeopathy's founder, first used this form of treatment in the mid nineteenth century.

To-day, one hundred million Europeans have had homeopathic treatment (<http://www.homeopathy-ecch.org/>, 2010) and in 2005 €930 million was spent on homeopathic and anthroposophical medicine (Ullman, 2010). In India, 100 million people use homeopathic medicine and according to the newspaper 'India Post', homeopathy supports a growing profession of 400,000 homeopaths (India Post, 2009). Homeopathy is currently the second most popular system of healthcare in the world (Medhurst, 2009) and a large number of people from all manner of backgrounds and educational levels have tried and experienced its benefits and accept that it works.

Some scientists see homeopathy as being implausible and dismiss it as 'bad science' (Goldacre, 2007) however, for 200 years it has had a strong following of people who have felt its benefits and so

what better time than now – in this era of quantum mechanics, nano-technology, particle accelerators and accelerator mass spectroscopy – to try to discover homeopathy's scientific basis. This dissertation will discuss why some commentators feel it is necessary to describe homeopathy in terms such as pseudo-science and bad science; it will also discuss the difference in meaning between these terms.

If the science underpinning homeopathy could be unlocked, then support might be forthcoming from the scientific community, thus ushering in, in conjunction with conventional medicine, an era of safe, affordable medicine, especially for the very young, the weak, the elderly and the poor. Support from the scientific community would give validity to this system of medicine in poorer countries whose use of homeopathy in human, animals and agriculture disease, would benefit the countries socially and economically.

My interest in the scientific arguments surrounding homeopathy began in 1988 when I read an article published in the peer-reviewed journal *Nature*, of an experiment undertaken by Jacques Benveniste and his colleagues. Benveniste (1935-2004) was at that time the head of allergy and inflammation immunology at a French biomedical research agency (Watts, 2004) and submitted for publication, the results of his latest research on basophils – human white cells which contain substances including histamine, responsible for allergic response (Milgrom, 2001). In his research these basophils had been serially agitated and diluted until no molecules of the original material was left, only the water that had contained them. When this water was exposed to anti-IgE (anti-immunoglobulin) it responded in the same manner as if the water still had basophils molecules in it, by degranulation, thus showing that the water must have retained some sort of memory of the original substance (anti-IgE) despite the absence of molecules of the original substance. This was described as 'a sub-molecular organisation of water' (Ullman D. , 2009; Watts, 2004) and its significance to homeopathy is immense, as it shows that those solutions that once contained a substance, but no longer do, can still exert a biological response and therefore therapeutic action.

This underpins a fundamental tenet of homeopathy - that a substance still exerts a therapeutic action if it has been agitated and diluted during the same process.

The editor of *Nature*, John Maddox, had doubts about the proof of the principles of homeopathy (Watts, 2004), but accepted the research paper from Benveniste providing he could include an editorial reservation at the end of the paper which stated that Benveniste had accepted independent investigators to review the experiment. After publication, Maddox, anti-fraud investigator Walter Stewart and magician James Randi, went to Paris to observe the experiments (Ullman D. , 2009). The results were successfully replicated three times without blinding and then a further time with blinding, but not successfully replicated in the final three replications with blinding. Maddox and his team dismissed the successful replication with blinding as experimental error and declared the experiment confirmed that there was no evidence that micro-doses have biological action (Ullman D. , 2009). Criticism of Maddox's team was that they ignored the positive 'blinded' experiment and they did not take into account the 'variables' noted by Benveniste's team that may have had an effect on the results. Benveniste had spent five years researching sub-molecular organisation of water and Maddox had spent 2 days reviewing the experiment (Ullman D. , 2009) and left when he decided that it was refutable.

The behaviour surrounding the challenge to Benveniste's work and the lack of outrage by his scientific colleagues was curious to me. Benveniste's work was reproduced in four other laboratories around the world, with supporting experiments undertaken by still other laboratories and analysed by Louvain researchers¹. In addition, all researchers were trained in the same Paris laboratory, to maintain consistency (Fisher, 2004).

The implications of accepting the scientific findings of Benveniste would be controversial and far reaching. If they were adapted a paradigm shift would likely occur, opening up new scientific areas

¹ Co-ordinated by Professor M Roberfroid at Belgium's Catholic University of Louvain in Brussels.

of understanding. This paradigm shift would change scientific direction and thus affect healthcare provision, particularly in the area of pharmacology which would bring revision of this industry.

To answer the question 'What is the emerging evidence which may provide insight into the nature of homeopathy and its contribution to contemporary healthcare and how much evidence do we need to have for it to be valid? ', a brief exploration of what is science and how it is relevant to homeopathic practice will be conducted, referring to a range of supporting literature. EBM will also be considered, including the criteria for EBM, examples that are appropriate to the examination of homeopathy, and also the wider context of EBM.

This dissertation is relevant for two reasons. The first is that it is timely because of the recent decision by the UK government to label homeopathy as scientifically implausible (Science and Technology Committee, 2010) and secondly, to provide the reader with information for consideration when deciding if homeopathy may make a valid contribution to healthcare in the era of evidence-based medicine.

SECTION ONE

CHAPTER ONE

1.0 Homeopathic Medicine

Aude sapere (Dare to Know)

A Latin phrase originally used by Horace and later by Hahnemann at the beginning of later editions of the Organon.²

Homeopathy was founded by Samuel Hahnemann (1755-1843), a nineteenth century German doctor and linguist who became dissatisfied with medicine as it was then practised. In Hahnemann's day, physicians commonly practised medicine by blood-letting, using fever medicines (arsenic), aperients etc (Haehl, 1971). Hahnemann expressed great concern from the very beginning of his medical career about the use of poisons as medicines as it was common to use mercury and arsenic in strong doses, enough to make a person sick or die over time. Hahnemann wrote an essay in 1806 entitled 'What are poisons? What are medicines?', in which he described the fine line between a therapeutic dose and a poisonous one saying that only 'the correct and judicious preparation of the poisons could make them into medicines' (Haehl, 1971, p. 314). He made detailed suggestions for prescribing poisons and demanded that arsenic sales be prohibited. In his own practice he decided to dilute these toxic medicines to avoid their terrible effects on his patients, but as he expected they eventually stopped working.

Hahnemann decided that as it was impossible to apply the Hippocratic corpus – to which doctors pledge in deciding whether or not a proposed course of treatment might harm, rather than heal (Gill, n/d) he would rather not practice at all. He resorted to translating medical books into German to

² An instrument of thought; a system of reasoning or logic; a set of principles for use in scientific or philosophical investigation. Statement of the basic paradigm and principles of homeopathic medicine, developed by Samuel Hahnemann (Swayne, 2000)

support his large family and it was whilst he was translating Cullen's *Materia Medica* that he saw a reference to cinchona bark curing malaria – due to its bitter qualities having a tonic effect on the stomach (Haehl, 1971). This did not sound plausible to him, so he decided to administer an oral dose of crude cinchona bark to himself as *“four drams of good china, twice a day, for several days”* (Haehl, 1971, p. 37) and to his surprise he developed symptoms similar to what we know to be the illness, ‘malaria’. Hahnemann challenged Cullen's interpretation of the therapeutic action of cinchona, saying that *“Peruvian bark³, which is used as a remedy for intermittent fever⁴, acts because it can produce symptoms similar to those of intermittent fever in healthy people”* (Haehl, 1971, p. 37). Further investigation led him in 1797 to develop the ‘similar principle’ which is fundamental to the homeopathic doctrine *similia similibus curentur* or let “likes be cured by likes”.

It is uncertain how or why he started to ‘agitate’ or ‘succuss’⁵ the medicines at each step of the serial dilution process, but it resulted in a dilute yet dynamic medicine still behaving as if the original substance was present and active, yet without its toxicity.

It is known that the ‘agitation’ is still an essential part of homeopathic medicine but the science behind this process is still unclear. Hahnemann was also a hygienist and dietitian and he employed the principles of these disciplines to help his patients. He gave special attention to the ‘causation’ of disease, such as environmental factors, and ‘obstacle to cure’, such as maintaining factors – e.g. continuing to smoke cigarettes when you have a chronic respiratory illness. He was constantly looking for the minimum dose needed to excite a therapeutic response in his patients (Close, 1924) – later to be known as the ‘homeopathic minimum dose’.

The last important step in the development of homeopathy was the use of the ‘single medicine’. In a time when pharmacists were combining or compounding multiple drugs into one potion, Hahnemann spoke out against this, saying that the combination together of different drugs could

³ Also known as cinchona or china

⁴ Known today as malaria

⁵ Vigorous shaking, with impact or ‘elastic collision’ (Swayne, 2000)

have an unknown effect on the individual. He implored doctors to learn about medicines and give the best and most suitable (similar) medicine as a single medicine dose (Haehl, 1971, pp. 307-9).

1.1 Historical background to the search for evidence supporting homeopathy

In 1835 the first ever double-blind, randomised, placebo-controlled experiment, involving homeopathy, to test for a therapeutic response in a substance beyond 'Avogadro's number'⁶ was conducted in Bavaria. It was known as the 'Nuremberg Salt Test' and came about because the highest-ranking public health official in Nuremberg was annoyed by the rising in popularity in homeopathy and accusing homeopathy of having no possible therapeutic response (Stolberg 2006).

A challenge was issued by a prominent homeopath to investigate the homeopathic effects of salt in a 30c potency (the 30 centesimal potency or 10^{60} is a dilution beyond 'Avogadro's number' and has no material presence of the original substance). It is not stated definitively why salt was selected, however, it was possibly used because it was considered relatively inert, cheap and freely available. The challenge was accepted and 50 participants were selected. Great care was taken with two pharmacists following a precise trial design which was as follows:

'Following a widely publicized invitation to anyone who was interested, more than 120 citizens met in a local tavern. The minimum number needed to proceed had been fixed at 50. The design of the proposed trial was explained in detail. In front of everyone, 100 vials were numbered, thoroughly shuffled and then split up at random into two lots of 50. One lot was filled with distilled snow water, the other with ordinary salt in a homeopathic C30-dilution of distilled snow water, prepared just as Reuter had demanded: a grain of salt was dissolved in 100 drops of distilled snow water and the resulting solution was diluted 29 times at a ratio of 1 to 100. Great care was taken to avoid any contamination with allopathic drugs. The two

⁶ Avogadro, Count Amedeo (1776-1856), Avogadro's number or constant, is the number of molecules theoretically present in one mole of a substance, estimated to be 6.0225×10^{23} (Swayne, 2000)

pharmacists in charge had taken two days off before the experiment. They had taken a bath and they used new weighing scales, which had not even come close to an allopathic pharmacy.

A list indicating the numbers of the vials with and without the salt dilution respectively was made, and sealed. The vials were then passed on to a 'commission' which distributed 47 of the vials to those among the audience who had declared their willingness to participate (the report speaks of 48 vials but this included an unnumbered vial with salt dilution given to a physician by the name of Lochner). The participants' names and the number of the vial that each had received were written in a second list. Seven more numbered vials were distributed after the meeting by one of the members of the commission.

Three weeks later, at a second meeting, the participants were asked to report whether they had experienced anything unusual after ingesting the vial's content. Those who did not come to the meeting were asked to send this information in. Responses were thus obtained from 50 of the 54 participants. Those participants who had perceived something unusual described their symptoms, as required by the protocol.

Finally, the sealed lists were opened to see who had received water and who the homeopathic dilution, and a list of results was compiled' (Stolberg, 2006)

At the end of three weeks the participants responded as to whether they perceived 'anything unusual' (Stolberg, 2006). Of the eight that did so, five had received the salt solution. This result was put down to the 'fruit of their imagination' (Stolberg 2006), but nevertheless, the results of this first ever randomized blinded control trial still represents a positive research finding – that homeopathic solutions do have an effect on the human economy in ultra-high potency.

1.2 Homeopathy and the Age of Enlightenment

All truths are easy to understand once they are discovered.

The point is to discover them.

Galileo Galilei (1564-1642)

In Hahnemann's time Europe was still under the influence of 'The Age of Enlightenment'. It was a time when knowledge of philosophy, science and religion became accessible to the public (Lenman, 2004). It was a time full of exciting discoveries and inventions, such as the telescope, microscope and pendulum clock; the mathematical and scientific advances of Newton; the philosophical enquiries of Voltaire, Kant and Galileo Galilei (1564-1642), arguably one of the greatest philosophers and mathematicians. These inventors, discoverers and personalities heralded in the scientific revolution and changes to the accepted way of thinking about matter, mechanics and motion (Machamer, 2010). In Europe, the French Revolution (1789) brought social and government upheaval and change, whilst the Ottoman Empire, which had held influence in Europe since 1345 was now in retreat and had only left Germany less than 100 years before (Lenman, 2004). By the end of the eighteenth century Galenian medicine was in crisis, (Priven, 2008) as it no longer worked, resulting in a search for a new system of medicine. Johann Reil (1759-1813), director of medicine at Berlin University, believed that medicine would only become rational when it became a science, whilst his colleague, Christoph Hufeland (1762-1836), believed that the art of medicine, through strict individualisation, was the path to take (Priven, 2008). Hahnemann chose a combination of these paths – the art and science of medicine. Hahnemann was also actively involved in the debate between Reil and Hufeland (Haehl, 1971) regarding the art of rational medicine, and he entitled his first 'Organon' *The Organon of Rational Medical Science* (1810).

1.3 Homeopathy and Quantum Mechanics

With the beginning of the twentieth century, science was advancing into a new era that we now know as quantum mechanics. The discoveries of Planck, Schrödinger, Einstein and de Broglie took science from the seventeenth century classical mechanics of Newton into the dynamic and powerful world of the ultra-small to sub-molecular states. With these scientific advances, an explanation could now be postulated about the science supporting homeopathy – quantum mechanics gave a plausible scientific explanation for the action of homeopathic medicines, particularly those medicines diluted beyond Avogadro's number. Spectroscopy of ultra-high dilution provides evidence of electro-magnetic activity to support the theory that homeopathic medicines have an energetic basis for their medicinal action. In addition, solvents, such as water, also appear to retain an identity of the original substance that materially is no longer present. The documentation included in this article represents only a small number of the research papers available, selected for the rigour expected of science and to progress the knowledge of the science supporting homeopathy. The discovery of quantum mechanics in the twentieth century heralded in the greatest change in scientific thought since Sir Isaac Newton's laws of motion in the seventeenth century.

1.4 Conclusion

Hahnemann was born historically in a time that was noted for both the general public dissatisfaction of the way medicine was practised, and a time of new thought and scientific enquiry. Hahnemann experienced personal dissatisfaction in his chosen profession which eventually led him to discover the dynamic state of medicine that had been both diluted and agitated. The popular support for homeopathy in the early days brought about questions as to whether it could work in such small doses and this led to a modern forerunner of the 'Randomized Control Trial (RCT). This early RCT using salt had a positive outcome but did not silence its critics. The twentieth century heralded in

the biggest change in scientific thought since the 17th century, namely the discovery of quantum mechanics. Now, over a hundred years later, the mysteries of the sub-molecular world are still unfolding. With spectroscopy we can now measure energetic activity where once we thought there was none, thus the science supporting homeopathy is emerging.

CHAPTER TWO

2.0 Methodology

Debate, opinion and research surrounding homeopathy has been extensively written about and in recent years has again become topical. Research for this dissertation was undertaken using academic peer-reviewed articles through an extensive literature review, involving search engines such as: Academic Search Premier, AMED, EBSCO, OvidSP, ProQuest, PubMed, BioMed Central, Science Direct, Google Scholar and journal databases that are free or available via 'Athens'. These journals included publications such as: AAAS, Journal of Alternative and Complementary Medicine, Karger, Mendeley, Public Library of Science, PNAS, Sage publications, and Wiley. Published articles, older than ten years are included as the topics covered looked at the history, development and growth of homeopathy spanning more than 200 years. This older material was reviewed and was included if it was still considered relevant, despite a great difference in publication periods between documents. Some research material concerned the origins and development of concepts, such as atomic spectroscopy, or philosophical areas, such as, 'what is truth or knowledge'. As well as access to journal articles and books, relevant Internet sites, such as 'Stanford Encyclopædia of Philosophy' were accessed. Key words used in combination for literature searches were: homeopathy, science, evidence based medicine, history, philosophy, bad science, and epistemology. The subject area covered encompasses the areas of: spectroscopy; science and what we think constitutes bad science; Evidence-based Medicine and its components; philosophy, with an exploration of what is truth, knowledge and evidence relating to homeopathy, and 'can science and evidence based medicine be applied to homeopathy'.

CHAPTER THREE

3.0 Truth

3.1 The Rise of Homeopathic Truth

*Truth for which all the eager world is fain,
Which makes us happy, lies for evermore
Not buried deep but lightly covered o'er,
By the wise hand that destined it for men.*

Verse by Christian Furchtgott Gellert (1715-1769) in the introduction to the first edition of Hahnemann's "Organon of Rational Healing".

Truth is a highly-valued concept in all human endeavours; truth in science, truth in philosophy, truth in relationships. Philosophically 'truth' can mean different things to different people, so what makes something truthful (Glanzberg, 2009)? Truth is true to the perceiver and not to the disbeliever. Truth in science is upheld by the scientific method and peer review of articles on scientific discovery (Charlton B. , 2009). To begin to understand truth is to begin at the most fundamental, but contentious point. 'Truth' means 'in fact' and the word 'science' comes from the Latin *scire*, to know (Oxford English Dictionary, 2004), so in science we deal with what is known and this should be assumed then as a fact. Truth is also 'the quality or state of being true; that which is true as opposed to false; a fact or belief that is accepted as true' (Oxford English Dictionary, 2004). As a truth is 'a fact or belief that is *accepted* as true' it shows us that truth is probably a fluid concept involving the perceiver and perceived.

Knowledge and truth can be relative to the moment – as knowledge is constantly changing and evolving, so when a scientific discovery is in the process of emerging or a secondary paradigm is apparent, then truth in all its forms becomes more relative and contentious. Truth in science is upheld by the scientific method and over-viewed by the peer review of articles of scientific discovery, (Charlton B. , 2009) and when scientific ‘truth’ changes we call it a paradigm shift. When a paradigm shift occurs, the new paradigm may not be believed by all, especially those whose life’s meaning is enmeshed in the old paradigm. When primary and secondary paradigms are jostling for supremacy it seems like a battle between two truths with each believer somewhat blind to the other’s truth.

Truth may be seen as a reality that is a balance between what the mind understands and its perception of reality (The Epistemological Question, n/d). To complicate our understanding of truth, there seems to be a number of ‘types’ of truth.

Dana Ullman gives a thorough outline of the continuous animosity between conventional medicine and homeopathy in America over the last 150 years in his book ‘Discovering Homeopathy: Medicine for the 21st Century’. He paralleled what was happening with homeopathy in other parts of the world and said that homeopathy became ‘spectacularly’ successful in Europe, America and amongst royalty, which led it to becoming the object of deep-seated resentment by established medicine (Ullman, 1995). Peter Morrell quotes Kaufman’s description of homeopathy in the mid-1800s in America:

‘First, most homeopathic physicians were once orthodox practitioners, unlike the poorly educated farmers and backwoodsmen who were philosophically attracted to botanical treatment. In addition, homeopathy was based upon a scientific approach, an experimental pharmacology; in many ways it had a better claim to scientific accuracy than did the practice of bloodletting and the use of calomel....’ (Morrell, 1999).

Further examples of the degree of opposition held towards homeopathy at this time are given in two medical journals – ‘Anti-Homoeopathic Archives’ and ‘Anti-Organon’⁷. The apothecaries (pharmacists) were not happy either, as homeopathic medicine used very small doses and only one medicine at a time. In America the strongest hostility came from the newly formed American Medical Association (AMA) established two years after the American homeopaths formed the American Institute of Homeopathy, America’s first medical association. The AMA resolved to bar membership to homeopaths or to those that associated with homeopaths. This was quite serious for new homeopathic doctors as it meant working in isolation and in some American states not being affiliated to your professional body meant you could not hold a licence to practice.

Hostility towards homeopathy by the conventional medical and pharmaceutical professions was not only practised in America. Medical journals refused to publish positive homeopathic outcomes and surveys, punishing those who used other journals to do so with expulsion from their own medical society (Ullman, 1995; Morrell, 1999).

In England, homeopathy became very popular under the energetic support of Dr Harvey Quinn who had first-hand experience of being cured of a potentially fatal illness by homeopathy and subsequently became a homeopathic doctor and a staunch advocate of homeopathy. He established the London Homeopathic Hospital in 1850, which soon after became completely devoted to the care of cholera victims during the epidemic of 1854. A review of the mortality of this epidemic ordered by Parliament showed that the mortality statistics of the homeopathic hospital was 16.8%, compared to more than 50% at other hospitals. An attempt by ‘orthodox’ doctors to suppress these figures failed and these outstanding results were published in the Parliamentary Papers. Another parliamentary Bill forbidding doctors to practice any form of medicine not taught in medical schools was also defeated, with an amendment added making it illegal for doctors to be penalised for unorthodox beliefs, a statute that still stands today.

⁷ Hahnemann’s book of homeopathic philosophy.

During the twentieth century a number of interesting pieces of positive homeopathic research were also overlooked. In 1941, Drs Paterson and Boyd conducted a four case series to measure whether homeopathic high potencies were biologically active. They compared two high-potency samples of Diphtheria – ‘Diphtherinum’ and ‘Alum-Precipitated Toxoid’ – to test whether or not either of them provided immunity to diphtheria. A positive or negative ‘Schick test’⁸ was measured and the results showed that out of 33 positive Schick test participants, 20 (or 60%) later tested negative after dosing with either Diphtherinum or Alum-Precipitated Toxoid in homeopathic potency (Dean, 2004, p. 168). In 1968 and 1970 a survey was conducted comparing the effectiveness of the homeopathic nosode of influenza, with the vaccine for influenza. The results showed that 19.7% of the allopathically vaccinated group contracted influenza compared to 6.5% of the homeopathic group. Perhaps the most puzzling ‘ignored’ study was the homeopathic mustard gas trial during 1941-1942, undertaken at the height of the Second World War, to look for a preventative treatment for soldiers that might be exposed to mustard gas. Mustard gas was introduced in 1917 during the First World War as a weapon of war. This gas did not kill its victims immediately – only 5% of victims died – but caused blistering of the skin, irritation of the eye and respiratory systems, and depressed immunity. Victims usually recovered, but had health problems for the rest of their lives and were at a higher risk of developing cancers. With the start of the Second World War, concerns were expressed about the possible use again of mustard gas against British soldiers and if anything could be done to protect them from the debilitating effects of exposure to it. In the 1940s the British government sponsored a double-blind, randomized, placebo trial of a number of homeopathic medicines selected for their similarity to the symptoms of mustard gas poisoning, and the results gave a statistically significant positive response, yet this was not acted upon.

⁸ A diagnostic test for diphtheria. A positive test means that the person has no antibody cover for diphtheria and is vulnerable to getting the illness.

3.2 Truth in Science, Scientific truth and Transcendental truth

Bruce Charlton says that the ideal and ultimate truth is found outside and beyond science, the scientific method and peer review (Charlton, 2009). In the past, peer review examined scientific validity *retrospectively* whereas current usage of peer review involves using the opinion of others in the same field to review scientific validity. This has led to the emergence of so called 'experts'. Thus a shift in the entire scientific evaluation process has left it open to influence by scientists whose opinion 'became the ultimate arbiter of validity' (Charlton B. G., 2009, p. 634). Bruce Charlton says that transcendental truth is not evaluated by science, but is the proper aim of science (Charlton B. G., 2009, p. 373). Truthfulness in science has severely declined and has become a 'wishful aspiration of scientific verity found in the peer review process' (Charlton B. G., 2009). It would seem that scientific data is the new measure of truth, but this is by no means fool-proof. All parts of the scientific method that require either an interpretation of results or, in the area of systematic review and meta-analysis, choice in inclusion or exclusion, are open to manipulation and may lead to a biased conclusion (Strobel, 2007). The latter can lead to a manipulation of truth to suit the preferred outcome or ensure the researcher's values and beliefs are validated. Charlton says that with the removal of truth, we now need 'professional consensus' (Charlton, 2009, p. 373) – a characteristic that belongs to all academic disciplines, not just science. One problem identified by Charlton and the critics of EBM is that, with scientific research being increasingly funded by wealthy private sponsors – as opposed to government in the past – there may be pressure on researchers to justify their sponsors' funding by scientifically supporting a desired outcome (Charlton B. G., 2009). This approach means that individuals have to make career-defining choices in research at the cost of new science. Charlton quotes Bronowski (Charlton B. G., 2009, p. 374) saying 'that for science to be truthful as a whole it is not sufficient to aim at truth as an ultimate outcome, scientists must also be habitually truthful in the 'minute particulars', of their scientific lives'. Scientists like Newton were devoutly religious, with all their scientific discoveries being viewed as discoveries of God's work. In

the twentieth century science was seen as absolute fact, not enmeshed in belief, and scientists and indeed sceptics became increasingly atheist, as if this added some sort of credibility to their scientific credentials. Science itself has become the new God to be worshipped and adored, like a self-serving deity, and truth in science has become a relative concept that has to fit in with a new reality.

Charlton says that there have been inducements to dishonesty from outside of science – principally politics, government administration and the media – all wanting to distort truth for their own agendas (Charlton B. G., 2009, p. 634). When science stops being science it becomes something else – ‘Zombie science’ (Charlton B. G., 2009).

The search for truth in science is a challenge; Strobel says that scientific objectivity presupposes that there is one truth – a collective truth – and personal beliefs either match these beliefs or do not. He says truth results only when our belief about what is real corresponds to what is real (Strobel, 2007, p. 8). It would seem that despite the great difference between science and belief, truth only occurs when we believe it to be true.

3.3 Good science, Bad science and Pseudo science

Sven Hansson at the Stanford Encyclopedia of Philosophy describes some of the difficulties between science and pseudo-science (Hansson, 2008) and looks at this subject from a theoretical and practical perspective. The theoretical discussion contributes to the philosophy of science, whilst the practical view, he says, helps by giving guidance in decision-making in both private and public life, such as health and economic policies and education (Hansson, 2008, p. 1). Hansson says that there is a difference between research that is non-science and research that is unscientific, with pseudo science being identified as fake science. He defines pseudo science as ‘part of a non-scientific doctrine whose major proponents try to create the impression that it is scientific’ (Hansson, 2008).

Science had been described as an 'intellectual and practical activity encompassing the systematic study of the structure and behaviour of the physical and natural world through observation and experiment' and pseudo science as 'a collection of beliefs or practices mistakenly regarded as being based on scientific method' (Oxford English Dictionary, 2004).

Nick Strobel says that, to distinguish the scientific theory from the non-scientific (pseudo-science) theory, the former must be refutable in principle and that a set of circumstances must potentially exist that if observed would logically prove the theory wrong (Strobel, 2007). Strobel points out that although science uses words such as 'logic', and 'facts', the *interpretative* process used to draw conclusions can allow bias to affect the outcome (Strobel, 2007) and that inductive reasoning may not be absolute – especially if the sampling is not representative – and may lead to the wrong conclusion. Strobel also says that the 'absence of evidence for absolute proof is not evidence of absence of truth' and 'without room for doubt, there would be no room for self-correction, and we would be left with a cluttered clash of irrefutable beliefs' (Strobel, 2007, p. 4).

Most authors on this subject readily accept that it is hard to define the line between science and pseudo-science (Simanek, 2009) (Hansson, 2008) and that the term has a derogatory connotation (Hansson, 2008). The approach some authors take on this subject is to define science and all that falls outside of this definition should be examined as pseudo-science (Simanek, 2009). True science needs to be 'objective' as well as repeatable, testable and confirmable. There must be a logical link and an experimental operational link between concepts and observations, and between deductions or predictions that may be tested against observations and against precise measurements made on nature (Simanek, 2009). Simanek concludes that pseudo-science can be assumed if results cannot be tested in any way, or the research repeatedly fails the test, or the predicted results are contrary to established and tested science (Simanek, 2009, p. 2). I think it is fair to say that just because a conviction is held strongly and by many, does not make it true (LSE Web, 2009) and that this

assumption works equally for those that believe in a theory as well as those that disbelieve in its plausibility.

In recent years the expression 'Bad Science' has been used in the popular press as a derogatory adaptation of the term pseudo-science to emotively manipulate the reader to dismiss the validity of the subject without further examination. In fact pseudo-science is a term that has been applied in the past to some science that was inconvenient and not wanted or accepted – for example Nicolaus Copernicus's proposal that the earth rotated around the sun (Kuhn T. S., 1957). Although not the first scientist to propose this theory, Copernicus proclaimed his theory after careful analysis of planetary models (Rabin, 2008). He was aware of the repercussions of such a discovery contradicting the Church's then current doctrine based on Ptolemy's Geocentric Theory and that a counter-theory that challenged the infallibility of the Church's doctrine could have grave repercussions professionally and personally for him. His research was published after his death and written in Latin, the language of scholars, effectively excluding common people accessing his research. When the new theory was accepted it might have been seen from today's view as a 'paradigm shift'. Another example of a scientist persecuted for pursuing research that was against popular thought was Gregor Mendel (1822-1884), whose genetic theories were considered ideologically unsound and so labelled 'pseudo-science' (Bauer, 2003, p. 253).

One of the difficulties associated with any scientific theory labelled as pseudo-science is that to apply inductive reasoning to test it, means it needs to be examined with honest scientific enquiry. Mathematical probability is often used to describe whether a theory is scientific or not, however, Karl Popper has said that no matter how much evidence there is, the mathematical probability is always zero (LSE Web, 2009). The definition of science and pseudo-science is a contentious point, with great philosophers such as Kuhn and Popper expounding differing views. Many philosophers prefer to look at demarcation criteria (Hansson, 2008), but again that is also open to debate.

Homeopathic treatment has been used by millions of people, and on animals and plants for 200 years and has shown to provide a positive therapeutic response, including objective reports from animal and plant studies. Nevertheless little is being done to expand and develop these positive outcomes further, and contra to this observations are ignored, dismissed, or given derogatory, labels is puzzling.

Homeopathy has struggled for recognition since its inception because it has set itself outside of the medical and scientific paradigm of the day. Accepted 'truth' is cast by the majority of people on the minority. It exists within belief systems and scientific paradigms. Truth and its reality is the essence of what we have been looking at in this section. Truth, either philosophically or scientifically, is still affected by the observer. The observer in turn is influenced by their personal beliefs, social and education background. When any information is provided it will be the truth that the person recognises (as true).

Some observers may feel challenged and even threatened by new ideas that do not fit within their belief systems. Thus they may seek to contradict it (Goldacre/anti-homeopathic Archives), dispute it (Nuremberg salt test), deny it (Benveniste, Mustard gas test) or ban it (USA), in order to maintain orthodox views. These interventions are not for those who believe or have no opinion, but rather for those threatened by the presence of the alien concept.

Truth can never be denied as ultimately it will represent itself through each age until the time is right and it will be accepted. Copernicus (1473-1543) was not the first person to say that the sun was the centre of the solar system, but when the time was right it was accepted as true; nor does believing that the earth is flat, which was popular with early civilization, mean it is flat. The challenge of this section is for the reader to decide whether they are biased or unbiased when examining new and challenging information.

3.4 Conclusion

As we have shown the concept of 'truth', especially in science and philosophy is very much determined by the individual, based on their culture, up-bringing and belief system. If they are told something is true that they believe not to be true they may look for ways to deny or discredit it to preserve all the other 'truth' cherished by the individual.

Scientific and philosophical thought is similarly influenced by the interpretation of individuals as seen through their own reality. Pseudo-science today may be the new science of tomorrow as many examples from the history have shown us. Nothing changed with the science but individuals accepted it and when enough people came to the same conclusion, it became scientific truth.

All truth passes through 3 stages. First, it is ridiculed. Second, it is violently opposed.

Third, it is accepted as being self-evident.

- - - Arthur Schopenhauer (1788-1860)

SECTION TWO

CHAPTER FOUR

4.0 Science

4.0.1 Illuminating or Enlightening – the science surrounding homeopathy.

Homeopathy has been accused of being unscientific and more recently of being ‘scientifically implausible’ (Science and Technology Committee, 2010). The main argument is that there’s no science that explains the action of homeopathic medicines, but since the beginning of the twentieth century new advances in scientific theory around the presence of sub-molecular energetic activity, have produced evidence that supports the therapeutic activity of homeopathic medicines (Wolf *et al*, 2009). The key areas are: the measure of biophoton activity using spectroscopy; therapeutic activity in solutions that had once contained a therapeutic agent; the significance of the biphasic dose-response application, known as Arndt-Schultz Law, in relationship pharmacological research (Jyothis, 2005); and the research into low dose pharmacological action in the field, known as hormesis. These scientific results confirm the existence of biphasic activity of therapeutic substances at very small doses and therapeutic activity of substances in high dilution, and together form part of the science supporting homeopathic action.

4.0.2 Developmental background

Physics, originally called ‘*natural philosophy*’, is broadly speaking, the study of nature or a point of view of the natural world using a method based on general principles and disciplines. This interplay between theory and experiment was first applied to mechanics by Sir Isaac Newton (1642-1727) (Encyclopaedia Britannica, 1961). At this time the microscope, discovered by Anton van Leeuwenhoek (1632-1723), demonstrated that minute organisms existed, but it was not until the

nineteenth century that germ, or pathogenic theory of disease was developed (Cullingworth, 1905). This theory, central to modern hygiene, seemed implausible to many scientists of the day because germs were so small as to be invisible to the naked eye and it was hard to believe that something that small could be so deadly. It was not until 1861 that germ theory was accepted, when the perceptive physician John Snow (1813-1858) recognised that cholera was prevalent in an area near a particular London street pump, leading Snow to the belief in the plausibility that disease could be caused by small microbes in water. Despite resistance from his peers, he campaigned and succeeded in having the pump closed down, so ending the epidemic.

The twentieth century brought great strides in scientific understanding with Röntgen's (1845-1923) discovery of X-rays and Max Planck (1858-1947) presenting the theory of quantum mechanics, showing the hidden power of the smallest structure, the atom. He discovered that energy, like matter, is quantifiable and occurred in individual 'packets', asserting that all forms of matter emit and absorb energy called quanta (Kleppner, 2005), and that light emitted and absorbed quanta, propounding the quantum nature of radiation.

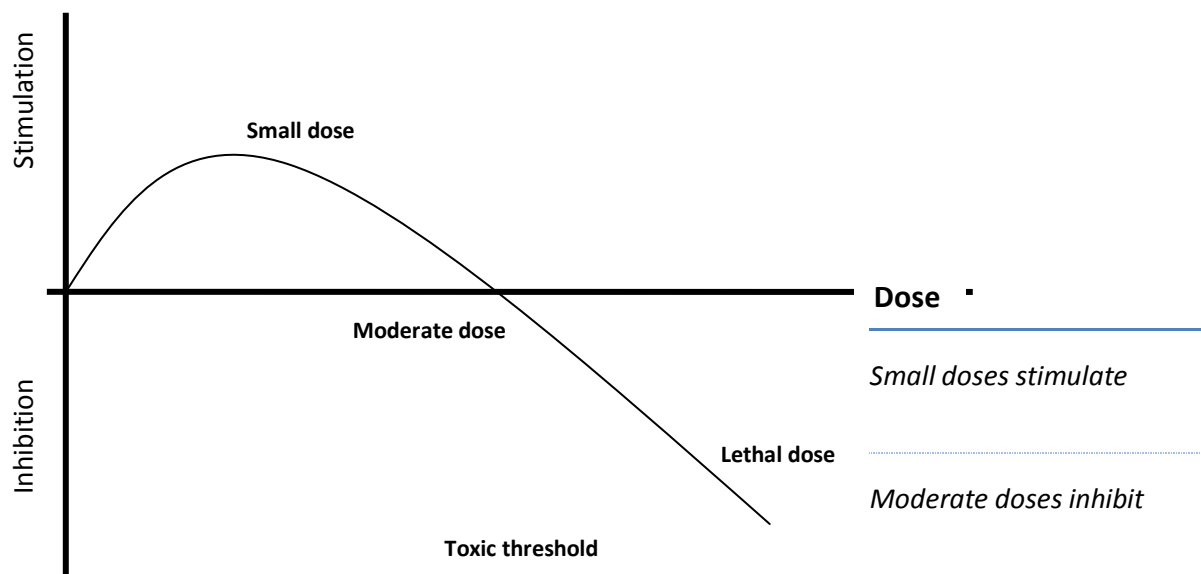
Although atoms had been identified one hundred years earlier, scepticism had prevailed due to a lack of theory to explain the properties of matter and the properties of atoms – even in the twentieth century scientists were saying that if atoms were real, then it should be possible to see them (Pojman, 2009). Albert Einstein (1879-1955) added to the theory of quantum mechanics by stating that radiation was also quantifiable (Sandhyarani, 2010). His work on demonstrating that atoms were real, was considered significant. In 1924, Louise de Broglie (1892-1987) proposed that energy and matter were similar in their behaviour and composition and used the term 'wave-particle duality', that is, matter and energy can behave as waves or particles (Sandhyarani, 2010).

Ernest Rutherford (1871-1937) discovered the nuclear atom (Encyclopaedia Britannica, 1961) and Edwin Schrödinger (1887-1961) made a substantial contribution to quantum mechanics when he proposed the uncertainty principle (Daniel & Roman, 2000).

Amedeo Avogadro (1776–1856) was an eighteenth century lawyer who became interested in natural science and began studying it in 1800. Avogadro was the first person to draw the distinction between an atom and a molecule in 1811. He believed that the molar volumes of all gases should be the same; the number of molecules to a mole is 6.0221367×10^{23} and is known as Avogadro's number, or constant, after this no molecule remain (Stephenson, 1955). Avogadro's constant has been a cornerstone of the argument against homeopathy, in that nothing is present in homeopathic medicine, so any therapeutic response must be the placebo response. However, the placebo response argument is less convincing when a therapeutic response is noted in animals and plants.

The Arndt-Schultz law gives a scientific framework for the action of low, and ultra-low, dilution of therapeutic solutions, including those used in homeopathy. Propounded by nineteenth century scientists, Hugo Schulz (1853-1932) and Rudolf Arndt (1835-1900), the Arndt-Schultz Law is the pharmacological principle of homeopathy and describes how weak stimuli accelerate physiological activity, medium stimuli inhibit physiological activity, and strong stimuli halt physiological activity (Arndt-Schulz Law, 2007). The principle was further cited in their work into cellular communication by researchers Madeleine Bastide and Agnès Lagache (Bastide & Lagache, 1998). In other words, to stimulate a maximum biological response, a homeopathic remedy needs to be in an ultra-high dilute concentration. Other names applied to this biphasic response are: Hueppe's Rule (Calabrese, 2005), bidirectional, bimodal, U-shaped, J-shaped, bell-shaped over-compensation, and the rebound effect (Calabrese, 2008). Edward Calabrese believes that the description of all these terms represents the same, or similar, biological dose-response concept (Calabrese, 2008, p. 9).

Figure 1 ARNDT-SCHULZ LAW



Spectroscopy measures radiant energy emitted as a wavelength of light. Raynor Johnson (1901-1987) described in his book *'Atomic Spectra'* that 'when an atom is placed in a sufficiently strong electric field, or is hit by a sufficiently swift electron or collides violently with another atom it may have an electron displaced from the normal orbit to an outer one. As the disturbed electron falls to an interior orbit, ultimately to the normal orbit, it will radiate this acquired energy as monochromatic light' (Johnson, 1946). The use of spectroscopy has demonstrated energetic activity in substances that are beyond Avogadro's constant and support the energetic action of homeopathic medicine, providing they have been agitated during the serial dilution process. These great scientific discoveries were later used to demonstrate the energetic action of homeopathic medicine.

4.0.3 Scientific Inquiry

Whereas the scientific method gives us a standardised process to follow, scientific inquiry starts the process and represents the impetus to know or to understand. It is where the question or

hypothesis begins, leading to further investigation that may result in a theory – the germ of curiosity precedes the scientific method.

Robert Michael quotes Gary King (Michael, 2002) as stating that there are four principles of good (scientific) research. These are:

1. Inference – the design of the scientific work is to make descriptive or explanatory ‘inferences’ based on empirical information. The gathering of facts – qualitative or quantitative evidence – alone becomes meaningless, if there’s no inference made as to what these facts mean.
2. Public scrutiny – the research results generated need to be explicit, codified and public, so that the methods and analysis can be scrutinised and assessed by interested parties and the methods and outcomes replicated, reviewed and enhanced.
3. Conclusions are uncertain – this must always be the outcome as the data is always uncertain. To infer something is to ‘imply’ that one is uncertain and therefore, any conclusions cannot be certain either.
4. Method – the method, along with the rules that apply to method, are all important in scientific research. This ‘standardisation’ helps with replication of the research and may help a little in reducing bias.

Objectivity within inquiry protects the research from personal bias. This is achieved by agreement among the experts who are evaluating the research. However by not using human values in the measurement, such as feeling and intuition, important aspect of the research may be ignored. Studies that use qualitative research methods, particularly humanistic studies and social sciences, are affected by disregarding these values (Johansson & Hamberg, 2003).

4.0.4 Scientific Method

Scientific reasoning heralded the development of the scientific method, which began in modern times in the sixteenth century with Copernicus (1473-1543) and Descartes (1586-1650). Copernicus saw inductive reasoning as a way of acquiring knowledge. Descartes later introduced 'rationalism', which began with *a priori* concepts based on innate ideas, or first principles (Naugle, 1994) and which built up a body of knowledge. By the eighteenth century, John Locke (1632-1704) was arguing an *a posteriori* view, which came to be known as 'empiricism' and which purports that knowledge comes from experience. From empiricism came the justification model: the observation flows to hypothesis and onto theory of reality, which must be truth. Towards the end of the eighteenth century, Immanuel Kant (1724-1804) questioned both rationalism and empiricism, dismissing justification. His suggestion was that the scientific method started with theory and observations made in the context of the theory; that is, our personal views must colour the way we view the world. Kant's theory is known as *idealism* (Watkins, 2009).

It is interesting to note, when looking at the progression of scientific philosophy to today's scientific method, that according to James Dye (Dye, 1996) it is almost identical to the Socratic Method described in the fourth century BCE, and perhaps we have rediscovered what had previously been known.

The scientific method usually has at least four parts (Michael, 2002). These are:

- I. Develop a hypothesis, observation and description of an event or phenomena - ask a question.
- II. Hypothesis to explain an event – this is when qualitative and/or quantitative data are used and any variables are considered – undertake background research and construct a hypothesis.
- III. Project the likelihood of further events based on these results.

- IV. Conduct research to confirm the prediction of an event – test the hypothesis with experimentation.

If the experiment confirms the hypothesis it can then be considered a theory. If the hypothesis cannot be tested and confirmed, then it must be discarded. It is reasonable to expect small random errors in replication, which do not negate the experiment, but are included as the 'standard deviation', quantifying how much error is present. After steps one to four above, it is expected that the scientist will come to a conclusion and publish this work for peer review, which is sometimes included in the steps of the scientific method.

The purpose of a precise method or set of rules that all scientists can apply is to try to reduce any experimental bias or prejudice which may occur when scientists starts interpreting outcomes from their own social and cultural backgrounds. An example of this may be drawn from Maya Goldenberg (Goldenberg, 2006) who contends that:

'the appeal to the authority of evidence that characterizes evidence-based practices does not *increase* objectivity but rather *obscures* the subjective elements that inescapably enter all forms of human inquiry. The seeming common sense of EBM only occurs because of its assumed removal from the social context of medical practice'.

Naugle (1994) in his work on the scientific method proposes that

'the theory the scientist applies to their research is always determined by the scientist's own theoretical, scientific and philosophical orientation which is unavoidable given of (*sic*)⁹ the human condition. Hence, the scientific method will bring us close to truth even though we will never arrive at truth, for we are always theory bound. Science always results in theory, not pure objective truth'.

⁹ Authors note

Some myths are related to the scientific method (Naugle, 1994), which are:

- That there's only one scientific method. The scientific method is evolving constantly and currently the predominant thought is the hypothetical/inductive method, but not the only one.
- 'Science' has become the higher order of the rational mind and will always lead to the truth when in reality it makes mistakes, can be fraudulent and quite often what is 'absolute' in one moment can be 'bad science' in the next moment.
- Science is influenced by what is perceived through the culture of the dominant group, subject to personal bias or social conditioning.

4.1 Hormesis

Hormesis was first defined by Southam and Ehrlich who noted biphasic dose response behaviour between living organism and a large number of xenobiotics¹⁰ (Bernardini & Dei, 2006). Previous to this, biphasic responses were observed and researched and given the name Arndt-Shultz law by researchers, Rudolf Arndt and Hugo Schultz (Calabrese E. J., 2009). Schulz believed that his law provided an insight into the workings of homeopathy as the 'small' doses of homeopathy represents an aspect of a biphasic response. An example to illustrate a biphasic response is the herb digitalis or foxglove which is highly poisonous at a high dose, but a therapeutic substance at a low dose.

¹⁰ Relating to or denoting a substance that is foreign to the body or to an ecological system (Oxford English Dictionary, 2004)

The homeopathic dose is a small therapeutic dose and the hormetic response confirms an important part of the homeopathic doctrine, that small doses have a therapeutic response that is similar but an opposite reaction to the larger dose and without toxic effects.

4.1.1 Biphasic action, Hormesis and Homeopathy

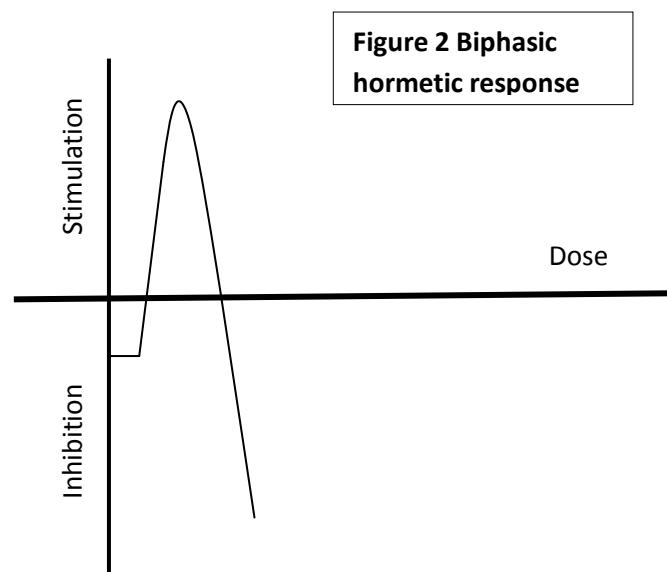
The biphasic cellular response was first noted over 150 years ago by Virchow (Calabrese, 2008) and further developed by Hugo Schultz. Mattson (2008) contends that hormesis is a fundamental concept of evolutionary theory. Some believe that the hormetic mechanism was known as far back as the sixteenth century by the Swiss chemist and physician, Paracelsus (1493-1541) (Mattson, 2008, p. 4). Rudolf Arndt and Hugo Schultz collaborated in 1888 in the discovery of the biphasic dose response law that bears their name. Since then biological, biomedical and pharmacological sciences have advanced greatly during the twentieth and twenty-first centuries with a more lineal dose-related model being favoured over a biphasic model. This has been due in part to the lack of understanding of the biphasic model, despite an abundance of research supporting a biphasic drug response (Maisonneuve *et al*, 2001; Pohorecky, 1977; Bing *et al*, 1993).

Hormesis is defined, according to the 'International Dose Response Society', quoting the Oxford English Dictionary, 2007, as:

'the phenomenon or condition of a substance or other agent having a beneficial physiological effect at low levels of exposure even though toxic or otherwise harmful at higher levels. The term hormesis is proposed to designate such a stimulatory effect of sub-inhibitory concentrations of any toxic substance on any organism. The Lancet (16/11/1963 1041/2) has described two occasions when Ps. pyocyanea appeared more resistant to streptomycin and showed hormesis with tetracycline. Another example is insecticides have been shown to stimulate growth of insects as

well as plants, and fungicides can stimulate growth of fungi as described in 1972 Science 29 Sept. 1154). In 1996 Los Angeles Times on 20 May an article tells of molecular geneticists having shown that 'hormesis', the low-level exposure of an organism to a stress agent that is harmful at higher levels, can actually extend life span in mice and fruit flies.' (Hormesis and the Oxford English Dictionary, 2007).

Edward Calabrese a prolific researcher and writer on the hormesis phenomenon, gives a brief definition of hormesis as 'a dose response phenomenon characterised by low dose stimulatory response and a high dose inhibition' (Calabrese, 2008) and as 'a phenomenon in search of mechanistic, physiological and evolutionary explanation' (Calabrese, 2005).



Mattson contends that there are thousands of published articles which include data showing biphasic responses of cells or organisms to chemicals or the changing of environmental conditions (Mattson, 2008). Calabrese (Calabrese & Baldwin, 2002) elaborates further by describing the biphasic response as an adaptive response induced by either direct acting or over compensation-induced stimulatory processes at low doses. A most recognisable example of the biphasic response is that reduced energy (caloric) intake leads to improved health (Mattson, 2008). Hahneemann

describes a similar biphasic response, in aphorism 63 and 64 of the *Organon of Medicine*, when he says that homeopathic medicines cause a primary action followed by a compensatory action which he calls secondary action or counteraction (Sarkar, 2009). Stuart Close (1860-1929) in his lectures on the philosophy of homeopathy draws an analogy to Newton's third law of motion, that action and reaction are equal and opposite, which he describes as follows:

'Closely allied to this is the so-called primary and secondary action of drugs, in which we see many drugs, in the first or primary stage of their action producing one group of symptoms, and in the second stage a directly opposite set of phenomena;' (Close, 1924, p. 184)

Arndt-Schultz law is common to both hormesis and homeopathy, but that's not to say that they're the same. They both describe small-dose response, but philosophically their application is different: Homeopathy relies on individualising the medicine specifically to the patient, whereas hormesis uses a more non-specific effect of a variety of chemically unrelated substances. Homeopathy induces responses below and above Avogadro's number, whilst hormesis looks at small doses, but still with a low material presence. Homeopathy applies a philosophy of prescribing and additionally uses small-dose medicines that have been energetically enhanced through succussion or agitation (Oberbaum & Samuels, 2005). Despite prescribing differences between hormesis and homeopathy, both provide working models of dose-response phenomena that have been observed for over two hundred years.

4.2 Science, Energy and Homeopathy

The emerging science supporting the homeopathic action is in the area of electro-magnetic energy of sub-atomic ultra-high dilutions (Rey, 2003; Demangeat, 2009; Montagnier, Aissa, Ferris, Montagnier, & Lavallee, 2009). Hahnemann recognised that powerful energy existed outside of the

physical world. He compared the power of magnetic attraction and gravitational influences in the footnote of aphorism 11 of the 6th edition of the Organon (Sarkar, 2009). He also noted in the footnote of aphorism 11:

Far more healing energy is expressed in a case in point by the smallest dose of the best dynamized medicines, in which there can be, according to calculation, only so little of material substance that its minuteness cannot be thought and conceived by the best arithmetical mind, than by large doses of the same medicine in substance. That smallest dose can therefore contain almost entirely only the pure, freely-developed, conceptual medicinal energy, and bring about only dynamically such great effects as can never be reached by the crude medicinal substances itself taken in large doses.

and

Is it then so utterly impossible for our age celebrated for its wealth in clear thinkers to think of dynamic energy as something non-corporeal, since we see daily phenomena which cannot be explained in any other manner?

Over the last 210 years this concept of Hahnemann's has been substantiated empirically and supported by significant qualitative and quantitative data (Homeopathy: the scientific proofs of efficacy, 2002) with positive evidence supporting the assertion that homeopathy works (Dean, 2004; Homeopathy: the scientific proofs of efficacy, 2002) – the task that now lies ahead is in discovering how it works. There are a number of scientific research tools that can detect energetic activity and which have shown it in properly designed replicable research. Using standardisation and scientific rigour, solvents, usually water, can retain an impression of the original substance, although no longer molecularly present. The research has been peer-reviewed and published for public scrutiny

(Rey, 2003; de Alvarenga *et al*, 2009; Wolf *et al*, 2009), thereby fulfilling Gary King's description of good scientific research (Michael, 2002).

4.2.1 Spectroscopy, Thermodynamics and Thermo-luminescence

Homeopaths contend that their medicines work by way of energetic transference of the specific individual characteristic, or 'fingerprint', of the substance from which it was originally derived, but in a dynamic state that responds to Arndt-Schultz Law. If this is so, we would expect to be able to demonstrate evidence for this. To see something energetically we need to use specific scientific equipment, such as spectrometers.

Thermoluminescence is the emission of light from a substance when it is heated – the thermally stimulated emission of light following the previous absorption of energy from radiation (van Wijk & Bosman, 2006). Thermodynamics is about the relationship between heat and other properties in a substance (Jones, 2010). Both these terms are associated with the light energy emitted from a substance. Light has particle-like properties that act like a wave in which the different wavelengths of light appear as different colours. The energy of a light wave is inversely-proportional to its wavelength. Low-energy waves have long wavelengths (such as radio waves and infrared), and high-energy light waves have short wavelengths (such as ultra-violet – UV), (Kulesa, 1997). Light is the electromagnetic wavelength detected by the human eye whilst the short and long wavelength energy waves can only be seen by a spectroscope. Spectroscopy is described as the measurement of the dispersion of an object's light (electromagnetic energy) into its component colours and analysis of the light can infer the physical properties of the object. A spectrometer is a device that analyses the spectral components of light, (electromagnetic energy), the frequencies of which differ according to the element being analysed. Homeopaths believe that an important action in the preparation of the homeopathic substance is in the succussion process, where the energy of the

original substance becomes more dynamic and is transferred to the environment in which it is diluted, usually water. Lenger proposes that because photons are magnetically bound with their characteristic properties, this information, with its intrinsic electromagnetic wave packet and different frequencies, is transformed by the preparation method (succussion) into higher frequencies at higher potencies (Kinnes, 2010), only visible using the highly sensitive technique of thermoluminescence.

In research undertaken at the Swiss Institute of Complementary Medicine, in collaboration with two laboratories in the USA, investigations were made to see whether or not homeopathic preparations would show activity when viewed with UV-spectroscopy. In a blinded randomised control experiment using homeopathically prepared substances in various dilutions, the experimental evidence showed physiochemical properties that differ from shaken solvent alone (Wolf *et al*, 2009), providing evidence that homeopathic preparations exhibit properties different from pure agitated solvent. Another study conducted by Louis Rey (2007) looked into the effect of succussion on water containing minerals, with low-temperature thermoluminescence. He used deuterium oxide, or heavy water, as his solute, as its signal is 50 times more intense than that of water, and two ionic compounds – sodium chloride and lithium chloride. Using thermoluminescence he looked at the water solution with nothing added, with the substances in dilution and succussion and with the substances in dilution and succussion above Avogadro's number. Both of these studies were conducted with the upmost scientific rigour and the results showed that both of the succussed substances – below and above Avogadro's number – showed significant thermo-luminescent glow at different dilutions (Rey, 2003).

4.2.2 Photons and Electromagnetic energy; a measure of energetic activity

Electromagnetic radiation is energy produced by an accelerating molecular charge (Electromagnetic wave theory, 2002) and comes in waves and parcels called photons, propounded by Albert Einstein (1879-1955). Max Planck (1858-1947) proposed the notion that packets of energy were released 'electromagnetic waves'. Energy, or photon waves are energy frequencies, collectively called the electro-magnetic spectrum, and are 'massless' photon particles (Lochner, 2009) travelling in a wave-like pattern at the speed of light. Each photon is a packet of electrically neutral energy, governed by the wave-like duality of quantum mechanics, which does not decay spontaneously, allowing it to be seen using spectrometers (Clugston, 2004).

The term 'photon' was first used by Gilbert Lewis in 1926 and the first description of what was later to be known as 'biophonics' was by Alexander Gurwitsch, who discovered circa 1923, ultra-weak photon emissions from living systems (plants) which he described as 'mitogenetic radiation' (History of Biophotonik or Biophotonics from the German point of view, 2003). Gurwitsch was a Russian scientist who originally trained as a medical doctor and later specialised in histology. He discovered invisible, ultra violet mitogenic rays that stimulated cell divisions in onion roots. His continued research into mitogenic radiation led to his concepts of 'field theory' (Belousov, 1997). Gurwitsch's discoveries were later verified by Italian biophysicists Colli and Facchini in 1955 at the University of Milan (Bischof, 2005) and again by Australian physical chemist, Terence Quickenden in the late 1960s, which led to the work of the current authority in the field, Fritz Albert Popp (Bischof M., 2005, p. 1). Popp rediscovered ultra-weak photon emissions from living organisms in the mid 1970s which he called 'biophotons' (Bischof, M., 2008). The phenomenon of light emission from living organisms, or quantum biology, has been repeatedly verified as well as new understandings that are currently being developed in this area (Bischof M. , 2005; <http://www.lifescientists.de/index.htm>, 2005). Popp has made a significant contribution to quantum biology – one of his later discoveries is that DNA is the main source of biophoton light from cells, which was supported by the later scientific

experiments of others (Bischof M. , 2008, p. 269). Some examples have reinforced these findings, in particular, a study conducted by Kim *et al* (2005), showing that liver damaged by carbon tetrachloride led to a temporary increase in photon emissions and delayed luminescence in the affected liver cells, similar to other experiments using human cancer cells cultures (Kim *et al*, 2005). The increased photon emission seems to be associated with the hepato-cellular proliferation response during the cell's death or repair (Kim *et al*, 2005). This model uses photon emissions to measure and demonstrate the degree of injury or repair to damaged cells in experimental models.

Karin Lenger describes experiments demonstrating the presence of photons in homeopathic potencies based on the theory developed by Popp. In experiments performed in a Faraday cage using Tesla coils, she showed that sugar globuli of homeopathic potencies – highly diluted beyond Loschmidt constant (commonly known as Avogadro's number) – attenuated the magnetic field of the Tesla-coils under condition of resonance. Lenger contended that the homeopathic remedies had the same frequency as the Tesla-coils – both Tesla-coil systems available have longitudinal waves at a frequency of 2,060 MHz or at 6.9 MHz. Argentum metallicum LMK or CMf¹¹ and Cantharis LMK, CMf possess both of these frequencies. Measuring the degree by which the photons of these remedies were separated from the sugar globuli as a consequence of the increasing electromagnetic field (increasing μV), it was found that each degree of a potency needs a characteristic field for separating the photons (Lenger K., 2010), This confirms the presence of high-frequency magnetic energy in homeopathic medicines (Lenger K., 2006).

The results of Lenger's research are confirmed by the 2008 study (Lenger *et al*, 2008, p. 139) in which it was demonstrated that a delayed luminescence signal from high potency homeopathic medicines was absorbed into sugar globuli using a modified photomultiplier¹² method. The separation of the measured photons from the sugar globuli was caused by the electromagnetic field

¹¹ LMK, CMf are homeopathic dilutions according to 'k' Korsakov or 'f' Fincke method.

¹² A device for detecting low intensities of light, even individual photons (Clugston, 2004)

of 2,060 MHz, a frequency resonant with that of the homeopathic medicines and which she says demonstrated the coherent and holistic quantum structure of these photons (Lenger, 2010).

In addition, other resonance frequencies of homeopathic medicines were also discovered and this research confirms that homeopathic medicine consists of (emits) electromagnetic energy that increases with higher homeopathic potencies (Lenger *et al*, 2008)

4.3 Water

Memory or Amnesia

In 1988, Jacque Benveniste and his team of twelve researchers published findings in the journal *Nature*. The research involved six laboratories in four countries involving blind, double-coded procedures (Benveniste, *et al*, 1988, p. 818). They found that water appeared to retain the memory (and action) of the substance it had originally held and that this 'memory' was obtained by agitation of the substance while diluting it. They also noted that despite going beyond Avogadro's number, the water still acted as though the original substance was present. They could not explain the phenomena, but suggested that water may act as a template for electric or magnetic fields. Before a peer review could take place the editor of *Nature* challenged the veracity of the results and arranged for an 'independent' investigator to observe a repetition of the experiment.

In 1999 Madeleine Ennis set about to verify the Benveniste's results, looking at the controversial area of biological action of ultra-high dilutions. The study was looking again at water containing ultra-high dilutions of histamine that caused basophil degranulation due to the inhibition of anti-IgE. The experiments were undertaken in four independent laboratories with all participants given the same training (for consistency). At the conclusion, the data confirmed the findings that histamine at very high dilutions, ranging between the 15th and 19th centesimal dilutions inhibits anti-IgE induced basophil degranulation. In this experiment the test solutions were made in independent

laboratories and the participants were completely blinded and data analysis was performed by a biostatistician who was not involved in any part of the trial (Belon *et al*, 1999).

In 2002 a BBC2 *Horizon* programme repeated the scientific experiments on whether water could in some way be changed by agitation, or even that the molecular theory of matter is wrong (Bland, 2005), as seemed to be shown by Ennis's 1999 research, in which she tried to replicate (with greater emphasis on scientific rigor) the previous work by Benveniste. Statistician, Martin Bland described that he was impressed with the blinding process in the *Horizon* experiment, but that the results were not entirely as expected. He was provided with the data samples ahead of the broadcast date and found that there was a huge and highly significant difference between the first and second half of the data. He looked at the possible explanation and chose a cube curve to fit the data and then decided 'to continue judging by eye rather than something more sophisticated, because the analysis was going to be difficult enough to explain as it was' (Bland, 2005, p. 108). Bland described variations between the different laboratories and suggested that there was a lot to be said for using the same fitting in all laboratories involved in the same research. He concluded on the television *Horizon* programme that there was no evidence of difference between the solutions that initially started off as pure water and those that started off with the histamine and so the presenter of the programme concluded that the results did not support the theory that memory of water exists. In a letter to USA homeopathic educator Dana Ullman, Madeline Ennis stated that there were many sloppy steps to the research, such as:

'He left the blood to sediment for 4 hours - this is far longer than we ever used.

He used completely different buffers including the addition of foetal calf serum.

He added in an ammonium chloride lysis step.

[NOTE: This step alone would be enough to consider this research to be junk science.

Ammonium chloride would kill all of the basophils, even before any homeopathic medicine would be administered.]’ (Ennis, 2003)

In 2004 Madeline Ennis *et al* described research investigating the action of histamine dilutions on basophil activation (Belon, *et al*, 2004) which was similar to Benveniste’s previous experiment that had been written in *Nature* in 1988. Due to the topical nature of this subject the research was divided into three study groups: study group one used a blinded multi-centre approach in four centres; study group two was to confirm the multicentric study by flow cytometry¹³ and performed independently in three laboratories; study group three examined the histamine release and activity (Hansson, 2008). The results showed that, without doubt, high dilutions of histamine did exert an effect on basophil activity (Belon, *et al*, 2004).

Allan Widom and associates (2009) believed that the outcome of Benveniste’s research and its subsequent charade left some scientists confused. They had noted that as current research showed the effect of electro-magnetic signals from biochemical systems could be transferred through water, they decided to investigate further. Their stated purpose was ‘to examine the notion of memory in water within a standard physics theoretical context of electromagnetic interactions’. The results of their research showed that water did have a significant memory capacity and this conclusion was supported by statistical thermodynamics (Montagnier *et al*, 2009).

Professor Luc Montagnier, Nobel laureate and virologist, known for his co-discovery of HIV, has also been investigating the electro-magnetic properties in highly diluted biological samples. In his research paper *Electromagnetic Signals Are Produced by Aqueous Nanostructures Derived from Bacterial DNA Sequences* (Montagnier *et al*, 2009) he was able to demonstrate that highly diluted

¹³ Flow cytometry is a technology that simultaneously measures and then analyses multiple physical characteristics of single particles, usually cells, as they flow in a fluid stream through a beam of light (Becton, Dickinson and Company., 2000).

samples (up to 10^{-18}) of bacteria and viruses had a distinct electromagnetic signature. He noted that serial dilution and agitation were 'critical' (Montagnier *et al*, 2009, p. 82) for generating the electromagnetic signal, a step that had also been stressed by Benveniste in his research (Benveniste, *et al*, 1988).

In 2009 Jean-Louis Demangeat published in the *Journal of Molecular Liquids* the results of his research arising from the use of nuclear magnetic resonance to investigate the activity of histamine when in ultra-high aqueous dilutions. The result of this research demonstrated a more organised state of water, that agitation was an important step in the preparation, and that histamine activity was able to be detected at ultra-high dilutions of less than 10^{-20} .

4.4 Conclusion

Hahnemann was convinced through observation of gravitational forces and magnetic attraction that a powerful unseen energetic state existed in sub molecular dilutions that were agitated to release this force during serial dilution. During this time Avogadro developed his law of the minimum amount of dilution that could contain a molecule of a substance. For some Avogadro's law meant that homeopathy was implausible but Hahnemann never claimed that homeopathy was simply dilution. He admitted himself, when looking for a way not to harm his patients with gross poisons, that eventually if they were diluted constantly that would stop working. Hahnemann implied that by agitation during serial dilution that an energetic transformation took place to the solution that was being used to dilute the substance. Avogadro's law is one of dilution not dilution and succussion and does not apply to homeopathy. Arndt-Schultz noted a biphasic response to substances, usually that showed that substances behave differently at different doses. The supporters of hormesis have confirmed this over and over again. Homeopathy also notes the biphasic response in its medicines. Hormesis is not homeopathy as the hormetic substance is diluted whereas homeopathic substances

are diluted, agitated to render more dynamic, and applied according to principle of similar and individualisation. Bastide and Lagache helped us to understand cellular communication in dilution and dilution and succussion (Bastide & Lagache, 1998b) and Rey demonstrated that there was energetic activity in substances diluted beyond Avogadro limit by utilizing thermo-luminescence (Rey, 2003). Lenger showed that homeopathic medicines in different attenuations have different electromagnetic fields (Lenger K. , 2006). Jacques Benveniste first described research into a solvent retaining a memory of the original substance after serial dilution and agitation and this research has been reviewed and repeated many times (Benveniste, et al., 1988; Ennis, Belon, Cumps, Mannaioni, Roberfroid, & Sainte-Laudy, 2004). In 2009 Jean-Luis Demangeat was able to show using nuclear magnetic resonance the activity of histamines in ultra high aqueous dilutions. Nobel laureate Luc Montagnier shows that there is a unique electromagnetic signal from highly diluted and poetized virus and bacteria.

The argument that homeopathy is implausible and that there is no science that supports its action is not valid. Good emerging science looking at the presence and nature of sub atomic energetic activity has been discovered, demonstrated and repeated by different scientists and laboratories. Significant scientific investigations exploring cellular communication have been researched in many ways and the results have been repeated over and over again starting from the works of Benveniste in 1988 to the most recent research of Nobel Prize laureate Luc Montagnier in 2009 into electromagnetic signals from bacterial DNA. The science supporting homeopathy is evolving and in time we will know more fully how it works; it cannot be argued that there is no science that supports its action.

SECTION THREE

CHAPTER FIVE

Another common criticism of homeopathy is that there is no clinical evidence that supports its efficacy as a medical intervention (Shang, et al., 2005). This reason alone is significant grounds for public health authority's reluctance to show support for its use or to provide government health funds to subsidise it. Other criticisms of homeopathy are that it claims that because it is from a different paradigm that it does not try to provide an acceptable evidence based approach, particularly the gold standard Randomised Control Trials (RCT) (Albietz, 2010). This chapter will look at what is evidence based medicine and at a number of homeopathic examples from the 'hierarchy of evidence' that are of a standard that would satisfy the most critical examination, if it was provided in conventional medicine. Some significant cohort studies using homeopathy to prevent disease, known as homeoprophylaxis, will be described as an illustration of the protective effect of homeopathy. Many homeopathic preventative substances originally came from deactivated morbid tissue (Mroninski, Adriano, & Mattos, 2001) similar to vaccines, and are given in very small homeopathic doses. According to Isaac Golden, an expert on this subject, homeoprophylaxis gives protective cover to certain infectious illness, free of unwanted side-effects (Golden, 2005).

5.0 Evidence Based Medicine (EBM)

The term 'Evidence Based Medicine' was first coined by clinicians at McMaster's University, Ontario (White, 2004), with the first model being described in the Journal of the American Medical Association. David Sackett describes the philosophical origins of EBM reaching back into the mid nineteenth century Paris with its modern origins evolving from several disciplines, including clinical epidemiology and critical appraisal (Placeholder1). EBM was originally described by investigators at

McMasters University, Canada as 'a systematic approach to analyse published research as the basis of clinical decision making (Claridge & Fabian, History and Development of Evidence-based Medicine, 2005)

During the mid 1990s Sackett described EBM as the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients (<http://www.cochrane.org/about-us/evidence-based-health-care>, 2010). Sackett further described EBM as the integrated, individual clinical expertise with critical appraisal of the best available external clinical evidence from systematic research (Sackett D. , 1997). Evidence-based medicine was originally applied to medicine but later EBM became both a term and a standard applied in all areas of health care.

Evidence-based medicine is an extension of this definition when applied to clinical medicine. The Journal of the American Medical (JAMA) describes Evidence-based Medicine as an approach to practicing medicine with the goal to improve and evaluate patient care (Glass, 2009). It requires the judicious integration of best research evidence with the patient's values to make decisions about medical care. This method is to help physicians make proper diagnosis; devise a best testing plan, choose best treatments and methods of disease prevention, as well as develop guidelines for large groups of patients with the same disease (Torpy, Lynm, & Glass, 2006).

Evidence based medicine is currently considered the highest standard of clinical practice in medicine (Evidence Based Dentistry, 2010) and allied health, including complementary and alternative medicine (Hadley, Hassan, & Khan, 2008). The best approach according to Stephen Buetow is the use of scientific based evidence plus the expertise and intuition of the clinician in applying the scientific evidence to the individual patient (Buetow, 2000). Sackett (1997) contends that 'good doctors' use both individual clinical expertise and the best available evidence, and neither alone is sufficient (Sackett *et al*, 1996). There is an implied devaluation of any other forms of evidence other than the so called scientific evidence in an attempt to increase the important contribution Sackett *et al* have

made. It is also possible that with the rapid development of electronic storage with its vast amount of data and the relative ease of access through internet search engines, that this new state that we know as EBM is just a natural progression of knowledge in clinical science (Doherty, 2005).

Buetow and Kenealy (2000) assert that scientific evidence assumes an objective and observable reality – a ‘truth’, but truth is in itself is a relative phenomena, involving the observer, even in science. They also propose that failure to acknowledge the dimensions of evidence other than scientific evidence denies access to insights no less important than those accessible within science (Buetow, 2000, p. 90). Relying only on one particular aspect of science that suits and reinforces a particular version of ‘truth’, disregarding other versions of science and truth, flies in the face of true scientific thought.

What is evidence? Evidence according to the Oxford dictionary it is the information that holds a belief or proposition to be true or valid (Oxford English Dictionary, 2004). EBM has refocused the practice of modern day western medicine on scientific evidence supporting clinical decisions in patient care. Some say that clinical decisions have always been made on the best scientific evidence (Lai, 2009) and that perhaps it is not so much a new way of practice but a natural evolution. Before the development of Cochrane’s (1909-1988) repository for research articles and Sackett (1934 -) advocated an evidence based approach to medicine, many committed physicians considered that they were applying patient care based on the best scientific evidence. It would be easy to argue that by the end of the twentieth century a more organised and systematized approach to reviewing evidence had to come about. Gone were the days where current information came through journal papers arriving by post, there now was a vast global collection of evidence flooded the internet and it was necessary that a method was developed to sort out what was good science (evidence based) and research that was poorly designed or flawed (Claridge & Fabian, History and Development of Evidence-based Medicine, 2005). Evidence-based medicine filled this need admirably, but not totally. Without too much effort problems can easily be identified in the area of individualized

medicine, particularly psychological and social medicine, where the individual's problem may not suit the 'best' evidence. The consumer has an important part in the choice of treatment as the patients 'values' is part of the formula. In addition many consumers are also accessing the evidence via the internet and evaluating the results for themselves and do not want to be treated on 'someone else's numbers' (Evidence Based Dentistry, 2010).

5.1 Background and Principles of Evidence-based Medicine

Modern day evidence-based medicine started in an editorial for the British Medical Journal of David L Sackett, a Canadian medical doctor. Sackett wrote his oft quoted article 'evidence based medicine: what it is and what it is not' (Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996). This article crystallised a 'new paradigm' that began a few years before in the early 1990's. Its basis was that it "de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research" (Group Evidence-Based Medicine Working, 1992) and integrating individual clinical expertise and the best external evidence (Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996). Akobeng (2005) defines evidence based medicine as the 'integration of best research evidence with clinical expertise and patient values' (Akobeng, 2005) while Woolf (2000) says EBM is 'the examination of the evidence that is comprehensive, critical and explicit'. The purpose of EBM was to avoid unsystematic and 'intuitive' methods of individual clinical practice in favour of an approach that had scientific rigor (Goldenberg, 2006) and made a significant move away from beliefs that were dictated by religious dogma or folk lore, preferring the best scientific evidence instead (Goldenberg, 2006). This implies that all evidence other than those based on scientific studies have a lesser evidential credibility as diagrammatically shown in the pyramid shaped hierarchy of evidence. Another method proposed looks at a circular model for evaluating complex interventions, which allows for inclusion of psychological and traditional healing systems. This model considers multiple methods used in a complementary manner to give a realistic evaluation of efficacy and safety. This

results in the optimum intervention for a particular question rather than the 'best evidence'. This model is suitable in qualitative research and allows for more individualised treatment that patients may prefer while producing an optimum outcome. The circular method may prove to be a more universal model that fits the homeopathic method as well as many other social science and traditional medicine approaches (Walach, Falkenberg, Fønnebø, Lewith, & Jonas, 2006). Evidence based medicine claims to improve the quality of patient care by the use of more effective and scientific based clinical interventions (Shortell, Rundall, & Hsu, 2007). Sackett (1996) emphasises that external clinical evidence should be used to help the practitioner make the best individual treatment choice for the patient. Sackett's (1996) groundbreaking article went on to describe the paradigm shift that it was proposing for patient care and looked at problems and concerns that naturally accompany any shift from the familiar.

Akobeng (Akobeng, 2005) describes clearly the principles of EBM as a five-step model:

STEPS		COMMENTS
1	<u>Formulating answerable questions.</u> proposes the questions should have the following components: <ul style="list-style-type: none"> a. The patient or problem in question (P) b. The intervention, test or exposure (I) c. Comparison of interventions (C) d. Outcome or outcomes (O) 	This can be difficult as it requires the investigator to <i>interpret</i> a clinical problem converted into an answerable question This is commonly drawn diagrammatically as PICO (P-patient or problem, I-intervention, C-comparison and O-outcomes)
2	<u>Finding the evidence.</u> Electronic data bases are of great value. <ul style="list-style-type: none"> a. Generate a key word from the clinical question b. Choose a data base, conduct the search 	Source information from traditional areas such as journals and books (often out of date), ask colleagues (not reliable) search internet data basis, the best but requires time and computer skills.
3	<u>Critical Appraise the evidence</u> <ul style="list-style-type: none"> • user to be competent at critical appraisal 	Tools such as Critical Appraisal skills programme (CASP) are helpful
4	<u>Look at validity,</u> importance and application to the patient. Appraising the validity of the information can be tricky so a hierarchy of evidence has evolved to assist.	Integration of good evidence, clinical expertise, and patient values. Decision should also include cost and availability.
5	<u>Evaluating performance</u>	Auditing of performance to assess value of intervention

TABLE 1: Principles of EBM as a five-step model

'Hierarchy of Evidence' is a term used to describe the type of research and the importance placed on this research. This hierarchy can vary according to different authors, however the order below is considered as standard (Phillips, et al., 1998):

- 1 Systematic reviews (SR) of RCT.
- 2 SR of Cohort studies
- 3 SR of Case controlled studies
- 4 Case series
- 5 Expert opinion

The aim is to utilize the hierarchy of evidence and associated levels of evidence or grades of reliability of evidence in order to guide the practitioner and patient to make the best choice in health treatment. In today's world the best choice may also be viewed from benefits versus risk associated with treatment, for very few treatments are risk free (Glasziou & Irwig, 1995).

Systematic Reviews allow the practitioner to consider published research or clinical treatments from peer journals. The best known example of a collection is the 'Cochrane Collaboration'. The highest standard for EBM is the systematic review of randomized controlled trials (Pai, McCulloch, Enanoria, & Colford, N/D; Hemingway & Brereton, 2009).

The Randomized Control Trial (RCT) is considered the highest level of 'evidence' due to the rigorous scientific methods that are required and its ability to test hypothesis (Akobeng, 2005, p. 840). In this process there is a 'random' assignment of participants to prevent bias. Areas to consider in evaluation of RCT are (Akobeng, 2005, p. 841):

- Validity of methodology used
- Size and precision of the treatment effects
- Application of results to the patient or population.

Apart from the systematic review of RCT (gold standard) (Carini & Sim, 2003) , systematic reviews have arisen from the tradition of health care professionals writing narrative reviews in peer reviewed journals. The risk of bias was obviously higher here. This method was followed by the systematic review which applied scientific strategies, a critical appraisal and also relevant studies that addressed a specific clinical question (Akobeng, 2005, p. 845). Meta analysis may follow a systematic review to analyse the collected data. The first part of the meta-analysis considers the efficacy of treatment and the second part looks at the meaning of the results considering costs and risk benefits (George, 2001). The critical point in the meta-analysis is the correct phrasing of the question before the analysis starts (What is EBM, 2009).

TABLE 2 EXAMPLE OF HIGH QUALITY RESEARCH DEMONSTRATING EFFICACY OF HOMEOPATHY

Type of Research	Year	Number/type of studies reviewed	Area of research	Positive/negative outcome	Comments
Systematic Review (SR) of RCT	1991	105 trials	Early SR of homeopathic RCT- poor research design Allergies and URTI Childhood diarrhoea Influenza Post-operative ileus Rheumatic disease Seasonal allergic rhinitis vertigo	81 positive Positive 9 of 23 positive	The British Homeopathic Association noted that a 1996 joint study comparing conventional and homeopathic medicine commissioned by European commission and conducted by the Homeopathic Medicine Research group, involving 184 trials with 2,001 found positive evidence that homeopathy was more effective than placebo. In 1997 a Lancet published meta-analysis of the highest standard showed homeopathy was greater than placebo. (British Homeopathic Association, 2010)
RCT	Up to end 2009	142 published	A total of 74 conditions, including Fibromyalgia Osteoarthritis sinusitis	63 positive 11 negative 68 not statistically conclusive	Many of these trials were replicated with the same positive outcome (British Homeopathic Association, 2010)
Meta-analysis	1997 1991	Galphimia (Medhurst R. , 2010) Survey of GP (Netherlands)	11 studies (hay fever) General	The homeopathic medicine significantly superior Overall positive	

Cost effective	2009	Study comparing cost of homeopathic complex and conventional treatment for sinus	Survey over 22 days showed saving of 274 euros	positive	(British Homeopathic Association, 2010)
Clinical observations		70.7% of 6,544 patients at Bristol Homeopathic Hospital		50.7% record improvement	
	1994	160 patients (prospective survey) UK		Very positive outcome 73%, some effect 27%, No effect 0%	
	1998	37 patients suffering psychological complaints(prosp ective survey)UK		Very satisfied 81%, satisfied 16%, not satisfied at all 3%	
	1995	Retrospective survey (Denmark)		73% stated improved	

TABLE 2 Example of high quality research demonstrating efficacy of homeopathy

Information from the British Homeopathic Association (British Homeopathic Association, 2010), Brauer Dispensary News (Medhurst R. , 2010), *An Overview of Positive Homeopathy Research and Surveys*, (Chatfield & Viksveen, 2007)

5.2 Cohort and Case Studies

There have been a number of cohort studies naming the benefits of homeopathic treatment in epidemics and in preventative medicine (homeoprophylaxis). The London Cholera epidemic of 1854, for example, was a well known and documented cohort study involving homeopathic treatment of cholera patients. In this epidemic the records show that patients treated in general hospitals had a mortality rate of 46% and untreated had a mortality of 50%. This compared with those patients with the same degree symptoms being treated in the London Homoeopathic Hospital and treated homeopathically having a mortality rate of 18.4% (Dean, 2004).

Francisco Eizayaga in his book *Treatise on Homoeopathic Medicine* (Eizayaga, 1991) records an event in Guaratingueta, Brazil, in 1974 where a 'terrible' epidemic of meningitis struck. 18,640 children from poor families, out of a population of 78,000 inhabitants, were given inactivated strains of meningococcal A and C in a 10c homeopathic potency (10^{-20}) while 6340 children were not homeopathically vaccinated. Of the 18,640 children who received the homeopathic vaccination there were four cases on meningitis and in the unvaccinated group there were 32 cases. The results of this larger study demonstrated a 95% success rate in the vaccinated group (Eizayaga, 1991, p. 285).

Following this impressive result a further study very large was done in 1998 in an area in Brazil where meningococcal disease was endemic (Mroninski, Adriano, & Mattos, 2001), and conventional vaccination had resulted in a poorer outcome in children less than two years of age. Over a period of three days, volunteers (aged less than twenty years) were drawn randomly from members of the public responding to press notification of the trial, and given one dose of meningococcal 30c (10^{-60}). A total of 65,828 participants took the vaccination while 25,058 participants did not receive it, totalling 90,886 participants in the study. The outcome was that in the homeopathic vaccinated

groups, three contracted the illness, while in the unvaccinated group; thirteen became ill with meningococcal disease. Results were analysed using the Fischer Accurate test and the results showed 95% effectiveness in the first six months, falling to 91% by twelve months (Mroninski, Adriano, & Mattos, 2001, p. 232).

In Havana, Cuba in 2008, a convention was held which focussed on homeoprophylaxis in third world countries. The Cuban experience of a mass homeopathic vaccination campaign from the previous year was discussed. In November 2007 after heavy rains and much flooding resulting in damage to the sanitary system, the Finley Institute¹⁴ identified a high risk to about 2,000,000 people from being infected with leptospirosis bacteria. The institute donated homeopathic vaccination for this illness. Leptospirosis is one of the most infectious diseases in the world. The organism enters through the skin, infecting the host (man or animal) and can lead to serious health problems as sequelae to acute infection (Green-McKenzie, 2010). Using *Leptospira nosode 200c*, the homeopathic prophylaxis was given to 2.4million people twice, a few days apart. The results of the intervention were reported: (Campa, et al., 2009)

The epidemiology surveillance after the intervention showed a dramatic decrease of morbidity two weeks after and a reduction to zero of mortality of hospitalized patients. The number of confirmed leptospirosis cases remains at low levels and below the expected levels according with the trends and rain regimens

This study has been published in *Homeopathic Links* by Isaac Golden (Golden, 2009)

Homeopathy has been criticized for not producing sufficiently high quality research and a cursory look at the Cochrane Collection appears to support this, with only eight papers available. The view appears to confirm for some that there is no evidence to support homeopathy. Part of the problem has been the type of research design acceptable as good research in allopathic medicine does not

¹⁴ Finlay Institute is a scientific organization dedicated to vaccine research and production.

easily transfer to the more individualised treatment that homeopathy provides. One of the premises of homeopathy is that it treats people (with diseases) not diseases; and double blind studies and RCT do not suit this type of treatment intervention (Clinical trials, 2010).

“Case Controlled Studies” are comparisons between a group that already has an outcome of interest and a control group. Acute diarrhoea, for example, is considered to have the highest morbidity and mortality in children worldwide (Jacobs J, 1994). Childhood diarrhoeal illness is an acute condition seen more commonly in underdeveloped countries in poorer communities who cannot afford medical treatment. One example of this problem using homeopathy for childhood diarrhoea illness was a randomized, double blind; placebo controlled study involving 126 children with diarrhoea, less than five years old in Nepal, in 2000. This was a replicated double blind, placebo controlled study of a previous study involving 81 children with diarrhoea in Nicaragua in 1994 (Jacobs J, 1994). The results showed a statistically significant effect between the two groups and confirmed previous findings (Jacobs, et al., 2000). The importance of these studies is that they are a replicated study using a double blind, placebo controlled method, with the second study confirming the first study results. This may have important implications in the provision of inexpensive and effective healthcare in countries with under-resourced health systems.

Another pertinent case study is those having homeopathic treatment for pruritus in patients receiving haemodialysis for renal failure. End stage renal failure (ESRF), a secondary health problem, usually to diabetes, is increasing the need of haemodialysis (HD) in the western world. Pruritus is an ‘itch’ and in renal failure it is manifested as uraemic pruritus (UP) which, although of poorly understood aetiology, is a common complaint in those receiving HD. Despite being a common problem with 50%-90% of patients complaining of UP and significant compromising their quality of life (Keithi-Reddy, Patel, Armstrong, & Singh, 2007), there are few interventions that have proven to help these patients. A homeopathic double-blind, placebo-controlled randomised clinical trial was conducted in 2003 involving 28 patients who had not responded to common interventions for UP.

Patients were given the homeopathic appropriate medicine or placebo. The results showed a significant reduction (49%) in intensity of symptoms as reported by the verum group (AMS Cavalcanti, Rocha, Carillo Jr, LUO Lima, & Lugon, 2003). With diabetes increasing in the western world resulting in increase in conditions such as ESRF (Tuller, 2008), these results are important as they provide patients needing haemodialysis, who do not respond to the usual treatment of UP, an alternative treatment for the distressing condition.

The final case study to be considered here is a randomised, double blind, placebo controlled trial involving 51 patients on five sites testing the results of three previous homeopathic interventions in perennial allergic rhinitis. In this trial nasal inspiratory peak flow and visual analogue scales were used to measure outcomes, with the homeopathic intervention group having a significant improvement in the nasal inspiratory peak flow (Taylor, Reilly, Llewellyn-Jones, & McSharry, 2000).

The important question here is whether these results are valid and whether the three studies selected have the scientific rigor needed to be accepted, based on the same criteria that is applied to case studies in conventional medicine.

Cost effectiveness of homeopathy shows better clinical outcomes for similar or lower costs. In a study of 493 patients diagnosed with a chronic illness and using homeopathy or conventional medicine, the outcome showed a greater improvement in those receiving homeopathy with both costing similar amounts. Most costs associated with homeopathy are the practitioner's fees with the homeopathic medication being very inexpensive. Generally consultation times and fees for homeopathic medicine are less than conventional medicine. A survey of 233 patients by the National Health Service (NHS) in the UK, in a one year period showed a reduction of 70% in visits and 50% in medication when homeopathy was available at the clinic (An Overview of Positive Homeopathy Research and Surveys, 2009).

Clinical observation studies of follow up patients treated at Bristol Homeopathic Hospital for a broad range of chronic medical conditions showed that 70.7% of 6,544 follow up cases displayed positive health changes especially in children (Spence, Thompson, & Barron, 2005). Another study in Switzerland in 2003-2003 involving 3126 patients, showed that patient satisfaction was considerably higher than conventional medicine and homeopathic treatment was considered low risk and with fewer side-effects (Marian, Joost, Saini, Ammon, Thurneysen, & Busato, 2008)

These cohort and case studies demonstrate by patient satisfaction surveys and statistical outcomes that homeopathy works.

5.3 Placebo response; Animal and Plant Studies

According to *Introduction to Research in the Health Sciences* by Polgar and Thomas (2008),

placebo effect is defined as:

The phenomenon where an otherwise worthless intervention in a study nevertheless induces an improvement in the patients condition or perception of the condition, perhaps due to the expectations of participants in the study.

Positive homeopathic research is often attributed to the placebo effect as the only rational explanation for the positive research outcome (Shang, et al., 2005). This view is not substantiated by an intervention review of the influence of placebo in clinical conditions, conducted by Asbjørn Hróbjartsson and Peter Gøtzsche for the 'Cochrane Collaboration (Hróbjartsson & Gøtzsche, 2010). The study examined the claim that 'placebo' effect accounts for observer and patient improved outcomes. They assessed placebo interventions and placebo treatments in 'trials and concluded

that placebo treatment had no major health benefit, and only a modest impression on patient's perception in such areas as pain relief and nausea.

Homeopathic research using animal and plant studies address the claim that positive results are a placebo response. These studies also provide important scientific information as well as beneficial economic outcomes for farmers and agronomy. Animals generally have environments that are stable and similar for all the animals in the group (Scientific Framework of Homeopathy, 2009). Research using stringent research methods and involving animal cohorts renders results free from potential accusation of the placebo effect and negate the argument for 'placebo' effect in positive research results. In animals, there is often no discernible difference in their daily pattern of behaviour whilst the research is carried out and as plants are not considered sentient in any way, the homeopathic intervention should not attract a placebo response. One such example is research done by Dr Christopher Day on mastitis in dairy cows in the UK (Day, 2007). This was a double-blind placebo controlled study into bovine mastitis using a control and treatment group numbering 41 cows in each. The outcome of the research showed that 47.5% of cows in the control group experienced moderately severe mastitis yet only 2.5% of the treatment group experienced any symptoms and these were of mild mastitis. It follows that if homeopathy was routinely used as an initial treatment in bovine mastitis there would be considerable savings for individual farmers from reduced veterinary medical costs. There would be less need for milk withholding periods thus providing overall benefit to the individual farms and local economy.

In 2005 a study was undertaken by Varshney and Naresh comparing the two systems of medicine in mastitis in Indian cows (Varshney, 2005). They discussed the economic implications of mastitis in dairy animals throughout the world and the need for a 'safe, efficacious and eco-friendly approach to containment' of bovine mastitis (Varshney, 2005, p. 1). The research results in cows diagnosed with fibrosed mastitis showed 66.6% cured with homeopathy and 67.7% cured with conventional antibiotic treatment. In the non-fibrosed group 93.3% cured with homeopathy and a cure of 36.4%

with intra-mammary administration, improving to 52.8% with the addition of parenteral antibiotics but also with a considerably greater cost. The overall efficacy of homeopathic treatment was 86.6% compared with 59.18% in the antibiotic treated group.

With the demand for scientific proof of homeopathy a constant call and the difficulty in obtaining research funding a constant obstacle, the use of plants in homeopathic research seems an achievable solution to the problem. No longer do we need to concern ourselves about the placebo effect, ethical approval or significant costs, the plants will deliver the scientific results (positive or negative) to allow an evaluation of homeopathic response. In 2003, Betti *et al*, published research evaluating the homeopathic treatment of tobacco mosaic virus inoculated onto tobacco plants. The research was a blind, randomised trial using tobacco leaf disks and homeopathic arsenic trioxide, water and a control group. The water and the arsenicum trioxide were prepared in 5x, 5c, 45x (10^{-45}) and 45c (10^{-90}) potencies (Betti, Lazzarato, Trebbi, Brizzi, Calzoni, & Nani, 2003). The results showed that arsenic in both decimal and centesimal strength acts on resistance and variability whilst the higher centesimal seems to affect variability. This research demonstrates efficacy of ultra high dilutions, commonly used therapeutically in homeopathy.

Another plant study, also published in 2003 examined the effects of gibberellic acid in homeopathic potency on the germination of barley plant seedlings (Hamman, Koning, & Lok, 2003). In this research gibberellic acid was chosen for its known effects on stimulating germination in seedlings and was made into a number of homeopathic potencies ranging between 4c and 200c (10^{-400}), gibberellic acid 0.5g/L and a control (water). All the seeds germinated under the effect of gibberellic acid in both the material and the potency doses. There was little difference between the germination of the potency and material doses even the 200c potency (beyond Avogadro's number) (Hamman, Koning, & Lok, 2003, p. 143). It was also noted that the material dose had an inhibiting effect on root growth while the weaker 15c strength of gibberellic acid appeared to have a stimulating affect on root growth, which supports Arndt-Schultz Law (Hamman, Koning, & Lok, 2003). The researchers

concluded that solutions of gibberellic acid in homeopathic potencies demonstrated a biological response on germinating and developing barley seedlings.

The importance of both animal and plant research is that it addresses the critics who accuse homeopathy of being purely a placebo response. It reinforces the fact that homeopathy gives a measurable therapeutic response. The challenge is to find the science behind this therapeutic action. With a scientific answer to this therapeutic response, homeopathy could make an important contribution to impoverished economies by providing cheap and effective interventions for animal and crop disease in an ethically sound research framework.

5.4 In vitro studies

In vitro studies are studies done in a laboratory rather than a day to day environment (*in viva*). The strength of such research is that it yields good quantitative data and it is less likely to be affected by the internal or external validity. *In vitro* research results are generally reproducible and more cost effective than *in viva* studies. The importance of the *in vitro* research in homeopathy is that it demonstrates that homeopathy can and does have high quality measurable and reproducible laboratory research to support its epistemology, and also its application underpinnings.

A systematic review of in-vitro studies done in Germany in 2007 by Witt *et al*, demonstrated a positive result to remedies even when applied in high potency. Witt et al posited that there was a lack of standardization and homogeneity in the research, and, as a consequence, not all studies were reproducible. However, three-quarters of those reproduced were positive. Higher consistent standards of research should lead to a higher number of positive replicated results (Witt, Bluth, Albrecht, Weißhuhn, Baumgartner, & Willich, 2007).

In another in-vitro study of homeopathic medicines in high dilution, three plant based medicines and one sample of cancer cells were tested for their apoptosis response to human breast

adenocarcinoma cells, with a control of normal human mammary epithelial cell. The results showed positively cytotoxic effects due to an altered expression of cell cycle regulatory proteins resulting in cell cycle delay or death (Frenkel, et al., 2010).

5.5 Reproducibility

Reproducibility is an important requisite of scientific research and the criticism of homeopathy is that it is difficult to reproduce previous research. In evidence-based medicine it becomes even more difficult to reproduce trials due to the individualisation of the homeopathic medicine to the patient's individual symptom, rather than prescribing for a named medical condition. In 1994, David Reilly *et al*, challenged this assumption by describing research that reproduced two previous trials. All three trials produced the same results which showed that the effects of homeopathy differ from placebo. All trials were done with the highest scientific rigor with analysis showing an absence of random factors proving the reproducibility of homeopathic trials under independent conditions. Reilly comments that this is not an isolated event and that an independent criteria-based review of over 100 published controlled homeopathic trials had 77% positive outcomes (Reilly, et al., 1994). We can say therefore that homeopathic studies are reproducible.

5.6 Homeopathic Research and the Traditional Bio-medical Model

The emergence of the bio-medical model of clinical research in the twentieth century as the only authentic model of medical research had a severely inhibiting affect on progress of homeopathic research and validity. At the beginning of the twentieth century virtually all homeopaths were trained in conventional as well as homeopathic medicine resulting in an effort by homeopathic doctors to combine the bio-medical model and traditional homeopathic principles. This resulted in

some interesting research and the emergence within homeopathy of a more illness based model of prescribing, especially during the mid twentieth century. Dean (2004) describes twenty separate trials in 10 publications in 2 languages involving 3 countries over a nearly 40 year period. Diseases treated were then commonly of a serious nature, such as tuberculosis and whooping cough. These early research trials were often not conducted according to modern day standards, but, for the most part use a placebo control. The results were generally positive and highly significant for homeopathy as a science (Dean, 2004)

5.7 The problems of evidence

Sackett describes the importance of the scientific evidence, the practitioner's skill and the patient's choice, but little is made of the importance of the latter two, with greater credence given to the 'science' in decision making.

It should be noted that EBM is premised on systematic reviews of a high standard as a cornerstone to finding the best evidence to help the practitioner make the most relevant and reliable selection for the patient. If the information obtained to make the selection is not absolutely trustworthy then processes become flawed.

Flaws can occur if the study or sample size may be too small and as a result, 'blinding' is faulty. More insidious still is the manipulation of information that the unsuspecting clinician may access to determine the choice of treatment for the client. This manipulation can occur through the inclusion or exclusion of research trials in peer reviewed publications, the selection of published articles for inclusion in meta-analysis, or the use of ghost writers or the creation of 'experts' by those with a vested interest in the outcomes. There is also a problem of extrapolation and interpolation of data where the researcher assumes and takes data from the findings which were not relevant or finds meaning into the results which were not intended (Grimes & Schulz, 2002).

Peter Gøtzsche reminds us of how important it is to check the veracity of all trials especially if they are included in a meta analysis (Gøtzsche, 1989). Meta-analysis of Randomized Control Trials is considered highly in evidence-based medicine but can be open to bias if the RCT's selected are tainted with bias, resulting in flawed evidence that is hard to recognize. With a great many of our drug trials being done by or financed by pharmaceutical research dollars, the risk is that outcomes may be influenced. It is these published results that the diligent practitioner uses in evidence-based practice. Gøtzsche says that bias are hidden and not detectable by looking at the report, or may be overt but contained in the abstract and the conclusion, thus, to Gøtzsche reading these is worse than reading nothing (Gøtzsche, 1989, p. 51).

An example to illustrate the problem of research influenced by pharmaceutical companies is the question on the efficacy of SSRI antidepressants, notably 'Prozac'. Prozac and other SSRI soared to popularity in the treatment of mild to moderate depression in the late 1980s as a drug that made the person feel better and was less dangerous than the older class of antidepressants, the tri-cyclic group. In 2008, Turner *et al* published a re-examination of the American Federal Drug Administration (FDA) reviews on 12 studies, involving 12,564 patients. The research was a systematic literature review of 74 studies to identify and review matching publications. The results showed that 31% were not published, 37 studies with positive results were published; 11 appeared positive but were questionable, 22 studies with negative results were not published with 3 exceptions and one positive study was not published. The authors concluded that this led to bias due to selective reporting (Turner, Matthews, Lindaratos, Tell, & Rosenthal, 2008). Also in 2008 a meta-analysis on the efficacy of SSRI antidepressants showed that they had a very small affect on severely depressed patients and virtually none on moderately depressed patients. When the unpublished research articles were included, the benefits fell below what was considered to be clinically significant (Kirsch, Deacon, Huedo-Medina, Scoboria, Moore, & Johnson, 2008). Whether these two studies are considered 'absolute' in their research, the question has to be asked about the use of systematic reviews if the material is biased and therefore inaccurate, and why do we continue to use interventions that have a

query over both the research and evidence. If these two problem areas aren't discussed then EBM has a fundamental flaw and that can only lead to flawed outcomes in Evidence-based practice.

5.8 Intuition and Experience.

'Risk-Benefit' is a term often used when there is competing evidence on a particular intervention. This expression, without clear qualification, is likely to impact negatively the elderly, a growing and vulnerable population group, for which health services and governments are concerned that the cost of the best care may be prohibitive, while a risk-benefit ratio is an acceptable compromise for the organisation rather than for individuals. Treatment cost and risk benefits often influence the clinical decision when applying an EBM approach

Andreas Gerber (2005) presents an interesting view on the adoption of evidence based medicine, not from a scientific perspective but from a religious/cultural viewpoint, is discussed by. Gerber notes that it is only cultures with ready access to computers and the internet that have embraced EBM. He points out a very salient fact that a call made over a 150 years ago for more scientific evidence in determining patient treatment was ignored and the old method of 'diagnosis, prognosis and therapeutics' was sufficient until recently (Gerber, Lungen, & Lauterbach, 2005, p. 1035). Gerber suggests that the historical origin of EBM lies in protestant "Enlightenment" thinking and says that only those countries that have a strong protestant background have embraced EBM (Gerber, Lungen, & Lauterbach, 2005).

Proponents of EBM must acknowledge its shortfalls. If only medicine that has a 'strong scientific evidence base' is considered a valid approach for patient care then how are traditional forms of medicine to be accommodated? Critics of other forms of evidence or more traditional forms of medicine propose that EBM is superior. On consideration, EBM might be just a good formula for focusing the practitioner on a range of considerations. Goldenberg refers to Guyatt (Goldenberg,

2006, p. 2614) where she says ‘The formal methods promoted by EBM to replace so called “traditional” medicine’s over reliance on intuition, habits, and unsystematic clinical experience appears to repeat the misplaced effort to separate science from values.

Another consideration is the way evidence is measured. It is a great tool for quantitative outcomes, but less serviceable for assessing qualitative outcomes. However, arguing that evidence based medicine is valid because it is scientific, also poses some challenges. Maya Goldberg describes in an article in *The Lancet* in 1995 where a research team disagreed so completely on the interpretation of their research trial results that they published both (Multicentre Acute Stroke Trial—Italy (MAST-I) Group, 1995). In this case the data supported both differing interpretations of results (Goldenberg, 2006). She goes on to say that there are a number of points of contention that can occur, some of which are; design of the study, measurement error, contamination of solution, equipment malfunction, poor design or bias and interpretation of statistical results (Goldenberg, 2006, p. 2624).

In the above example can both studies be right? On a lighter note, to illustrate why EBM results should not be taken out of context or over reliance only on ‘science’ over ‘common science’ there was an article in the British Medical Journal which conducted a systematic review of randomized control trials of the use of parachutes to prevent death or major trauma related to ‘gravitational challenge’. The purpose of the article was to illustrate that those EBM protagonists who are critical of observational studies might want to be involved in a ‘double blind, randomised, placebo controlled crossover trial of the parachute’ (Smith & ell, 2003). The article demonstrates that, rigidly applying the hierarchy of evidence is not always the best practice.

Harald Walach (2006) describes a different model of evaluation of the best medical intervention that evaluates internal validity balanced by external validity in a circular model. This model allows for multiple individual considerations to help inform the practitioner’s decision. This would allow more consideration to individualised, patient centred approach to care, more conducive to homeopathic qualitative research (Walach, Falkenberg, Fønnebø, Lewith, & Jonas, 2006).

5.9 Conclusion

Homeopathy has shown that it can compare very well in the area of Evidence-Based medicine by utilizing the placebo controlled randomized control trial. Although the quantity of research needs to increase, the quality is generally comparable to conventional EBM research. Homeopathy is represented in all areas on the hierarchy of evidence. Some interesting results have emerged in the area of cohort studies looking at inexpensive and effective interventions in the area of preventative medicine. Research using animals and plants leading to positive outcomes must question the cry that homeopathy is only a placebo response while also demonstrating the cost-effective contribution homeopathy can make to agriculture and farming.

Anomalies and deficiencies in the evaluation of EBM shows us that although this is good advancement in providing a consistently high level of standardised healthcare, there needs to be a review to ensure that it is still adhering to its original principles and it works. Homeopathy can fit into the current system of EBM without any difficulty but the use of a circular model of evaluation of medical evidence based on a balance between internal and external validity would be a better measure for homeopathy care.

DISCUSSION

Homeopathy has received considerable criticism about its lack of scientific plausibility. Consequently any positive research has been dismissed or attributed to the placebo effect. It has also been accused of not having any evidence to support a therapeutic response. This dissertation has addressed these two areas of criticism and shown that homeopathy can now claim emerging new science in the modern scientific field of quantum mechanics and impressive research in the area of evidence-based medicine. Homeopathic research involving plants and animals shows that it can make a significant contribution to farming and agriculture as well as addressing the accusation that any positive research is the placebo response.

In order to address these two major issues, it was necessary to discuss the nature of 'truth'. This is difficult to discuss because it is such a subjective area yet much of what we do in the scientific world is based on 'hard' science, and contains components of subjective reasoning which imparts the outcome. These issues require an unprejudiced mind. To develop an understanding of the problem in each of these areas this dissertation considers how science supports the 'homeopathic response'.

Avogadro's law, which was developed in the eighteenth century, stated that there is no molecular presence in a dilution beyond 10^{23} . It was shown that this fact alone is the reason for much scepticism relating to the 'science' of homeopathy. While accepting Avogadro's law it must be kept in mind that there have been more recent discoveries of molecular activity: sub-atomic particles that exert an influence on their environment. One of the issues explored in this dissertation is the growing amount of new scientific evidence supporting the belief that electro-magnetic energy has an energetic influence in its environment and therefore relevance for energetic medicines such as homeopathy as a powerful yet economical form of health intervention.

Nobel laureate Luc Montagnier described how solutions containing the DNA of virus and bacteria are able to emit low frequency radio waves that induce the adjacent water molecules to become nano-structures. This would explain how water can retain a memory of the substance it originally contained (Montagnier, Aissa, Ferris, Montagnier, & Lavallee, 2009). French immunologist Professor Jacques Benveniste published new scientific research demonstrating the sub-molecular organisation of water in 1988 which appeared to indicate that water may be able to retain some sort of impression of a substance that it had contained, particularly if it was agitated at each step of a serial dilution. This original research was duplicated at four other laboratories around the world (Benveniste, et al., 1988). Irish immunologist Professor Madeline Ennis found Benveniste's earlier research interesting but doubted that it was possible decided to repeat the experiment for herself only to also have positive results (Ennis, Belon, Cumps, Mannaioni, Roberfroid, & Sainte-Laudy, 2004) These three scientists of high repute have found energetic activity that defies classical science but demonstrates repeatedly that there is a unique response from water that has previously held a substance and that, when this substance has been serially diluted and agitated, is able to pass a memory or influence the sub-molecular organisation or structure of the solution it is contained in, demonstrating the digital memory that remains after the physical presence has gone. This would explain how solutions can act in a therapeutic manner beyond Avogadro's constant. Karin Lenger (2008) demonstrated that electromagnetic fields differed with different homeopathic potencies in ultra high dilutions, demonstrating a cohesive and holistic quantum structure. Louis Rey was able to show using spectroscopy that a thermoluminescence glow was able to be seen on succussed substances below and above Avogadro's number (Rey, 2003), whilst Wolf demonstrated using spectroscopy that highly diluted homeopathic medicines differ from simply shaken pure solvents (Wolf, Wolf, Heusser, Thurneysen, & S, 2009).

Arndt-Schultz law has been keenly used as an explanatory model of homeopathic actions. This law describes the biphasic response of therapeutic agents; what causes a response at one solution

strength can cause the opposite at another. A field of medicine looking at this response is hormesis. Large amounts of high grade research into hormesis have demonstrated repeatedly this biphasic action, the same action that is applied to homeopathy (Calabrese E. J., 2005). Certainly the application is significantly different so it should not be confused with homeopathy but it does demonstrate an important tenet of homeopathy.

This dissertation has argued that Evidence-based medicine is an important change to the way modern medicine is practised. It allows the user to apply a hierarchy of evidence, starting with systematic reviews of randomized controlled trials at the top and expert opinion at the bottom. Vast repositories of information can be accessed with relative ease meaning that scientific research pertaining to the best and most suitable information is readily available. The same hierarchy was applied to homeopathic research and found examples of research that met these standards. Earlier research during the twentieth century often failed to provide the level of internal and external validity required in current standards, a point which is equally applicable to all other areas of medical research.

Placebo control in research is an area of focus to prevent accusations of bias and is important in research of the highest standards. Both medical and homeopathic research utilizes placebo control. Because homeopathic medicine is used in very low dilutions any positive response is considered by some to be placebo as the only reasonable explanation. It is rather implausible to believe that the millions of people who use homeopathy can only be having a placebo response. In order to test this supposition the author looked at homeopathic scientific research involving animals and plants where unquestionable positive research outcome were discovered which negates homeopathy being a purely placebo response (Varshney, 2005; Bonamin & Endler, 2010). Finally, in-vitro research involving homeopathy was also shown to provide positive results.

In summary, this dissertation has shown that while the science behind homeopathy is still being defined, the homeopathic response has been demonstrated to conform to scientific laws and the standards expected for an evidence-based medicine. The challenge for those that may have adopted a particular view without investigating the veracity of this stand is to re-examine the evidence and science supporting homeopathy. It is timely to reflect that even in science and EBM we are called on to make judgements and interpretations which are drawn from our inner realities and beliefs, our social customs, norms and mores. Changing what we believe as individual scientists and practitioners to be true has huge ramifications for the future of science, scientific thought, research and also for homeopathy.

For those that have not kept up with modern scientific advances of the twentieth century, Homeopathy still remains implausible. The association with homeopathic principles, even remotely has lead to ridicule and devaluation for some valid areas of research, such as hormesis, leading to plea by their followers that hormesis is not to be confused with homeopathy. Both hormesis and homeopathy share the principles of Arndt-Schultz law that Schultz claimed supported homeopathy. This prejudice and criticism influences reasonable people to remain quiet about supporting homeopathy. If in the future there is a place for homeopathy in the scientific research arena surely it is in the world of sub-molecular activity and digital bio-communication. Homeopathy research should be funded adequately so that independent scientifically research of the highest rigor can be evaluated and explored.

Kuhn quotes Planck saying, "a new scientific truth does not triumph by convincing its opponents and making them see the light, but rather because its opponents eventually die, and a new generation grows up that is familiar with it" (Kuhn T. , 1962, p. 151)

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