The Potential Value of Homoeoprophylaxis in the Long-Term Prevention of Infectious Diseases, and the Maintenance of General Health in Recipients

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ABSTRACT

Homoeoprophylaxis (HP) is the use of homoeopathically prepared substances to prevent targeted infectious diseases in recipients. Its first use in an epidemic of Scarlet Fever was documented in 1801. It has been used throughout the world since then for both short-term and long-term preventative purposes.

The effectiveness and safety of Golden's long-term HP program using homoeopathically prepared substances to prevent targeted infectious diseases in recipients was tested through two research projects.

The effectiveness of the program could not be established with statistical certainty given the limited sample size and the low probability of acquiring an infectious disease. However, a possible level of effectiveness of 90.3% was identified subject to specified limitations. Further research to confirm the effectiveness of the program is justified.

Statistically significant results were obtained that confirmed the safety of the program both in absolute terms as well as compared to all other methods of disease prevention studied.

It also appeared possible that a national immunisation system where both vaccination and HP were available to parents would increase the national coverage against targeted infectious diseases, and reduce the incidence of some chronic health conditions, especially asthma.

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STATEMENT OF ORIGINALITY

This Thesis contains no material that has been submitted for the award of any other degree or diploma in any University or other institution, except where due reference is made in the text of the thesis. To the best of my knowledge and belief, this thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

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DEFINITIONS

Note: Chapter references in brackets show where the term was first used.

The **Effectiveness** of a homoeopathic preventative program is the proportion of those using the program who did not acquire the targeted disease, to the total number of persons using the program. Where possible, the figure for effectiveness is refined by identifying those users of the program who were exposed to the targeted disease, and using that total in the proportion. (Chapter 2.5.1)

The **Genus Epidemicus** is the remedy chosen during an outbreak of an infectious disease that best matches the common symptom picture of the disease. The remedy is selected after analysing the symptoms of a number of patients with the disease. (Chapter 2.3)

Homoeoprophylaxis (HP) is the use of homoeopathically prepared potentised substances in a systematic manner to prevent the development of the characteristic symptoms of infectious diseases. (Introduction)

An **Isode** is a remedy prepared from the patient's OWN diseased material, e.g., a remedy prepared from a whooping-cough patient's own sputum. (Chapter 3.2.4)

Immunisation is taken to mean any method that reduces the likelihood of the recipient acquiring a targeted infectious disease if exposed to the disease. (Introduction)

The **Law of Similars** states that a substance that is capable of causing a group of symptoms in a healthy person is capable of removing a group of **similar** symptoms in a sick person. (Chapter 2.2.2)

A **Nosode** is a homoeopathic preparation (potency) of diseased tissue, e.g., a remedy prepared from the sputum of a number of patients with whooping cough. (Chapter 3.2.4)

Potentisation is the method used in homoeopathy to prepare remedies. The original material is subjected to a series of dilutions and succussions (violent shaking of the diluting medium against a firm surface), or triturations (grinding of insoluble substances). (Chapter 2.2.2)

Provings are controlled experiments where doses of the substance being tested (usually in potentised form) are given to healthy volunteers, who record new symptoms produced by taking the substance. The Master Prover (the person supervising the proving) then extracts those symptoms that are common to a number of provers, and this information is entered into the Materia Medica. (Chapter 2.2.2)

Recipients are those persons using the HP programs being studied. (Title)

Succussion is the process used in the preparation of homoeopathic remedies in liquid form where the container holding the medicinal solution is repeatedly shaken firmly with vertical movements against a firm surface thus violently agitating the medicinal solution. (Chapter 2.2.2)

Trituration is the process used in the preparation of homoeopathic remedies in solid form where the active substance and a medicinally neutral powder, often sugar crystals prepared from maize or milk, are ground together using a mortar and pestle. Usually trituration is used only until the mixture is soluble. (Chapter 2.2.2)

Vaccination is defined as the administration, usually orally or by injection, of attenuated antigenic material together with preservatives and adjuvants to stimulate the production of antibodies in the recipient. (Introduction)

The **Vital Force** is defined as a person's self-balancing (healing) energy that is present from birth, and which acts to maintain homoeostasis on the mental, emotional and physical levels of the person's being. (Chapter 2.2.2)

PART 1: INTRODUCTION

1 Introduction to the Thesis

In most developed countries the prevention of specified infectious diseases is generally undertaken through the use of comprehensive vaccination programs from birth. Mass vaccination has been accepted public health policy for over 100 years.

Whilst published research in orthodox medical journals has strongly supported community-wide vaccination programs, the procedure has been shown in the same journals to be neither totally safe, nor totally effective (Golden 1998, pp. 3-29).

There are a number of ways to boost a person's level of immunity to specified infectious diseases. One way is to boost overall immunity to all diseases by raising general health through good diet and nutrition, through a balanced lifestyle, and possibly through "constitutional" treatment programs such as homoeopathic or herbal treatment to improve the overall vitality of the person.

Common sense suggests that healthy people tend to recover better from any illness, and are more resistant to specified diseases. However clinical experience shows us that even very healthy people contract infectious diseases.

The second way to boost a person's level of disease-specific immunity is to target the specified disease with disease-specific preventative methods. Such methods have demonstrated levels of protection that are significant, although less than 100%.

There are two known methods of disease-specific immunisation – one is vaccination, and the second is the use of homoeopathically selected and prepared substances, a procedure known as *homoeoprophylaxis* [HP].

HP was first described in 1801, and has been used throughout the world since then. Its supporters claim that it is comparably effective to vaccination but completely non-toxic and therefore safe (Golden 1986, p.70).

However, the orthodox medical community regards HP with great suspicion because it is not consistent with the orthodox paradigm which relies on a modified antigenic stimulation of antibody levels in vaccinated persons. There has been practically no orthodox research into HP for that reason, and its community-wide use is generally opposed by orthodox medicine.

In practice, although the method of immunisation supported by orthodox medical authorities (vaccination) is neither perfectly effective nor perfectly safe, the use of an alternative method of immunisation (HP) that claims to be comparably effective and completely non-toxic is rejected without objective testing.

The aim of this thesis is to determine whether HP can safely prevent targeted infectious diseases. The consequent implications for national health policy will be considered.

Chapter 2 provides a general introduction to homoeopathic medicine and its use for both treatment and prevention. The historical development of HP and its current use and support within the homoeopathic profession are also examined.

The conceptual basis of HP and its mechanism of action are examined in Chapter 3. A minority of homoeopaths believe that it is best for the long-term health of an individual to acquire an infectious disease and then treat homoeopathically, rather than prevent the disease using HP (Golden 2002a, p.29). Some of these practitioners believe that HP may cause a long-term weakening of an individual's overall wellbeing. These and other aspects of the use of HP that are questioned within the homoeopathic community are also examined in Chapter 3.

For the purpose of this thesis, two research studies have been undertaken to analyse the effectiveness and safety of HP, and a third study has been conducted to examine the use of HP by Australian homoeopaths. The relationship between these three research projects and the chapters of the thesis is shown in Table 1.1-1 below.

The research methods used in both projects are described in Chapter 4. The results of the research are presented in Chapter 5.

The first project described in this thesis examined the long-term effectiveness and safety of a HP program established by the author in the context of his homoeopathic practice. The research component of this program involved a 15-year collection of 2,342 questionnaires, each one covering one year of the life of a child using HP. It represents the largest long-term trial of HP ever published, and provides the reference point for the second project undertaken as part of this thesis.

The second project researching the safety and effectiveness of HP involved a general health survey of 781 children aged between 4 and 12 years. General health was assessed using the incidence of asthma, eczema, ear and hearing problems, allergies and behavioural problems; the incidence data were then compared with, among other factors, the type of disease prevention used. In addition to examining the absolute effectiveness and safety of HP, the data allowed a comparison of HP to other methods of disease prevention to assess its relative strengths and weaknesses.

In Chapter 6 the effectiveness and safety of HP are discussed using all available material.

Final conclusions are presented in Chapter 7 regarding the ability of HP to safely prevent infectious diseases. Some recommendations for national health policy are made based on the evidence and arguments presented in earlier chapters.

Table 2.1-1: Outline of Research, and Relationship to Thesis Chapters

Background	*Chapter 2* *Chapter 3*
Study of Long-term Homoeoprophylaxis	*Chapters 4.1, 4.2, 5*
Practitioner Survey	*Chapter 2.4*
General Health Survey	*Chapters 4.3, 5*
Review of Homoeopathic Literature	*Chapters 2.3, 2.5, 4.3*
Discussion	*Chapter 6*
Conclusions	*Chapter 7*

PART 2: BACKGROUND TO THE THESIS

2 The History of and Use of Homoeoprophylaxis

2.1 Overview

This chapter will explain what Homoeoprophylaxis (HP) is, the extent of its use worldwide and its use in relation to that of homoeopathic medicine in general. In Chapter 3 the conceptual basis of HP is outlined, aspects of HP that are contested by some homoeopaths are discussed, and a mechanism of action suggested.

This chapter begins with a brief explanation of homoeopathy. The origin of HP is then explained, and an outline of its historical use is given. References to the effectiveness and the safety of HP in the homoeopathic literature are reviewed. The current use of HP by Australian homoeopaths is examined, as well as the use of HP by overseas practitioners.

2.2 An Explanation of Homoeopathy

2.2.1 Introduction

Homoeopathy is a therapeutic system founded by German physician Dr Samuel Hahnemann in the late 1700's and the early 1800's. Homoeopathy has been used for 200 years in most countries around the world with the main exceptions of China and Japan. It is used extensively by medical doctors, as well as by practitioners who are not medical doctors. In Australia, as in many other countries, the use of homoeopathy was much greater in the late 1800's and early 1900's, with homoeopathic hospitals in some states, such as the old Prince Henry's Hospital in Melbourne.

The widespread use of homoeopathic medicine declined in the early 1900's with the advent of antibiotics, anaesthetics, and other advances in orthodox medicine. These developments brought with them massive growth in the financial strength of the major pharmaceutical houses around the world. Exceptions were in India and some European countries where use of homoeopathy remained strong. The trend in use changed again over the last 20 years in many countries, including Australia, as growing numbers of people choose to rely more on non-pharmaceutical methods to treat themselves and their families.

As evidence of this trend, there are homoeopathic medical associations in 41 countries (Diamantidis 1990, pp. 286,7). Over 40% of French medical practitioners use homoeopathic medicine, in England there are five homoeopathic hospitals registered under the National Health Service, and 42% of British medical practitioners who responded to a *British Medical Journal* survey referred patients to homoeopaths (Wharton and Lewith 1986, p. 1498).

In Germany, homoeopathy is taught in medical schools and 20% of German doctors use homoeopathic medicines at times in their practice (Ullman 1991a, p. 118). In India, the majority of medical practitioners use homoeopathic remedies, and since 1973 homoeopathy has been regulated under an Act of Parliament (Dutta 1979, pp. 18,19).

Homoeopathy is used in a number of South American countries, in South Africa and in the United States (Ullman 1995, p. 15). Although figures are not readily available, there has been widespread use of homoeopathy in the old Eastern bloc countries since the early 1800's (Kotoc 2000, p. 27).

2.2.2 Homoeopathic Treatment - A General Explanation

Hahnemann was both a physician and pharmacist. Because of his fluency in languages, including Greek, Latin, German, French, English, Hebrew and Aramaic, he

was able to read and study both ancient and contemporary healing texts from many developed countries.

Hahnemann was the first physician to make full practical use of a Law of Nature known to ancient healers such as Hippocrates. This was the **Law of Similars,** which states that a substance that is capable of causing a group of symptoms in a healthy person is capable of removing a group of **similar** symptoms in a sick person. In fact Hahnemann coined the word "homoeopathy" from two Greek words meaning "similar suffering".

Hahnemann realised the value of this Law when he was translating Dr Cullen's Materia Medica of medicines from English into German. He disagreed with the author's description of the effects of overdoses of Peruvian bark, an herb that was used in the treatment of malarial fevers.

Hahnemann, being a true scientist, experimented by taking small doses of the Peruvian bark and found that he developed a fever **that was very similar to a malarial fever.** The fever ceased when he stopped taking the Bark. He took some more, and the fever started again. It again ceased soon after he stopped taking the Peruvian bark.

This was a practical example of the Law of Similars, i.e., Peruvian Bark was capable of producing in a healthy person a fever **similar** to a condition it could relieve (cure) in a person unwell with Malaria. In orthodox medicine, Peruvian bark, or Cinchona, is the material from which Quinine is produced, and which continues to be used in the treatment of malarial fevers.

Another example of the Law of Similars is the homoeopathic use of Ipecac. The syrup is often used in orthodox medicine to induce vomiting in cases where a patient may have swallowed a poisonous substance. When used in homoeopathic **potency** (see explanation below) it may be used to treat nausea and vomiting in patients whose symptoms are similar to the characteristic symptoms of Ipecac.

In order to find the potentially curative properties of many substances, homoeopaths from Hahnemann onwards have conducted **homoeopathic provings** of nearly 3,000 substances. This has built a substantial Materia Medica from which medicines can be selected to apply the Law of Similars.

Unlike most drugs testing, properly conducted homoeopathic provings use healthy volunteers called **provers** who take the substance being tested, usually in potentised form, using a strictly defined protocol. The provers report their resulting symptoms on the mental, emotional and physical levels. Those symptoms that are experienced by a number of provers are very carefully and systematically compiled into a summary of symptoms that the substance can cause in healthy provers.

Symptoms in sick patients can be removed by the use of the remedy, given in homoeopathic potency, which has produced the “most similar” symptoms in provings to the symptoms of the patient.

A properly conducted proving exhibits all the characteristics of a double-blind, placebo-controlled trial. Provers do not know what substance is being tested. Neither does the **master prover**, the person directing the experiment. A placebo is given to a randomly selected part of the proving group. The provers are directed not to communicate the symptoms they develop with other provers until the trial is completed.

At the end of the trial the master prover collects the symptoms recorded by all participants, and extracts those that are experienced by most provers, excluding any that may have been experienced by many in the placebo group. Only then is the name of the remedy being tested revealed to the master prover and the proving group.

The fact that a significant proportion of provers of a potentised substance in a properly conducted proving independently produce very similar symptoms suggests that potentised substances are indeed medicinally active, are different from a placebo, and their effects are observable, measurable and repeatable.

The homoeopathic **Materia Medica** is a systematic collection of remedy information constructed primarily using data collected from homoeopathic provings from Hahnemann's time to today. Relevant information from records of poisonings and repeated examples of cured symptoms are also included in the remedy information in the homoeopathic Materia Medica.

Over the last 200 years many of the remedies first tested in the early 1800's have been re-proved. Whilst some new symptoms are usually uncovered as the numbers of provers completing the collective proving increases, the accuracy of the information collected by the early homoeopaths has been repeatedly confirmed. This long history of consistency revealed in records of provings must be weighed against recently expressed concerns with any form of clinical trial in homoeopathy (Walach, 2003, p.10). In the end, the weight of consistent results is considerable.

Thus when treating a patient who presents with a particular collection of symptoms, homoeopaths consult the Materia Medica and choose that remedy whose proving symptoms are **the most similar** to the symptoms of the patient. It is then prescribed in the minimum dose necessary to produce a healing response.

Using the example of Ipecac given above, a homoeopath would consider giving a homoeopathic preparation of Ipecac to a patient who presented with continued nausea and vomiting. However, hundreds of other substances also can cause nausea and vomiting. So Ipecac would be chosen only if the patient presented with other symptoms that are characteristic of Ipecac. Confirming symptoms would include the state of the patient's tongue (clean or uncoated) and mouth (increased salivation), because in provings, Ipecac not only caused continued nausea and vomiting but also produced a clean tongue with increased salivation in most provers.

Hahnemann determined that most disease initially occurred on a deeper, inner level with physical symptoms arising as a result of the subsequent disturbance to the person's **vital force** or essential inner self-healing energy. He saw the vital force as the God-

given subtle energy that maintained homoeostasis in each person's mental, emotional and physical system.

He concluded that since disease arose on this subtle energetic level, prevention or cure would need to take place on the same level. He also was concerned with the toxic effects of the strong material doses of the medicines used at that time.

Hahnemann did not state how he arrived at his method of preparing remedies by **potentising** substances until all that remained of the particular substance was the dynamic (healing) energy that is latent in every substance.

Potentisation is achieved by repeated dilutions and **succussions** (vigorous striking of the bottle containing the diluted material against a firm support). When preparing insoluble solids, **trituration** or grinding is used instead of succussion. Most homoeopaths use the "centesimal scale" of potentisation, where one drop of the mother tincture of the medicinal material is added to 99 drops of a neutral medium and succussed vigorously. This is the first, or "1c", potency. One drop of this solution is added to 99 drops of neutral medium and succussed to create the second, or 2c potency. These steps are repeated to create potencies as high as 100,000c, referred to as "100M". One drop of 6c potency, for example, contains only 1/1,000,000,000,000th part of the original material. However, clinical use has shown that the potentisation process releases a healing energy latent within the chosen substance.

Avogadro's Law indicates that once medicines have been prepared to the 12c potency they will contain no molecules of the original substance. The use of substances prepared in this manner has caused homoeopathy to be scorned by many in orthodox medicine, who cannot believe that a substance containing no molecules of the original material can have any medicinal effect. In fact, homoeopaths generally accept, in agreement with orthodox theory, that simple dilution without succussion or trituration does not produce an active medicinal substance.

Homoeopathy cannot presently be explained in terms of current orthodox science. This will no doubt change as further orthodox research is conducted into subjects such as the memory of water, sub-atomic particles, and measurements of the energy latent in substances. The history of orthodox medicine itself is full of examples of the use of medicines and methods that have not been fully understood or proven, such as the action of Asprin that was used for decades without its action being fully understood. However, its use was justified because it produced results that were consistent, predictable, repeatable and observable. The same test can reasonably be applied to HP.

The purpose of the research described in this thesis is to test whether the use of HP can be justified on the basis of practical results that are consistent, predictable, repeatable and observable.

Returning to the development of homoeopathy, the homoeopathic historian Ullman (1991b, p. 2) has stated that 'probably the most important reason that homeopathy developed such immense popularity was its success in treating the various infectious epidemic diseases that raged throughout America and Europe during the 1800s'. Some early examples are:

- In 1813, Hahnemann achieved a success rate of 100% in treating 183 Typhus patients; at that time Typhus was considered incurable (Hahnemann 1830, p. 401).
- Scarlet Fever was effectively treated and prevented by Hahnemann using the remedy Belladonna (Hahnemann 1801, p. 377).
- During the European cholera epidemics of the mid 1800's, the death rate among all patients was between 40% and 60%, while the rate amongst persons who received homoeopathic treatment was between 5% and 16%. (Shepherd 1967, p. 15).
- During the 1849 cholera epidemic only 3% of 1,116 homeopathic patients treated by Cincinnati homoeopaths died, while between 48-60% of those under orthodox medical treatment died (Coulter 1975, p. 268).

Such experience continued throughout the world into the 1900's. For example, during the 1918-1920 Influenza (Spanish Flu) epidemics in the United States, the mortality rate was around 30%; the general mortality rate among individuals treated homoeopathically was less than 1% (Shepherd 1967, p. 51).

Homoeopathy can also be used to treat deep-seated chronic illness as well as acute disease. It is a primary care treatment in some countries, as noted above, and is used as either complementary or alternative medicine in many other countries.

Some orthodox scientific research into homoeopathic treatment has been undertaken with varying results. Three major reviews of published research have been conducted, all of which found some positive results for homoeopathy, despite the authors' finding its mechanism of action to be implausible (Kleijnen et al., 1991, pp. 316-323 ; Linde et al., 1997, pp. 834-843 ; Cucherat et al., 2000, pp. 27-33).

The greatest difficulty with orthodox research into homoeopathy is that methods used to test molecular reactions and responses are not necessarily appropriate to test non-molecular reactions (Bellavite and Signorini 1995, pp 78-83).

Thus there remains considerable scepticism within the orthodox medical community concerning the use of homoeopathic treatment. Possibly the main reason for this scepticism is that the method of action of potentised substances does not fit the orthodox model of how material substances interact.

While the current orthodox research paradigm does not (yet) have access to a methods with which to assess the effectiveness of homoeopathy, homoeopaths claim that 200 years of clinical experience shows that homoeopathy does offer an effective method of treating most conditions. Clinical experience reported in following sections also shows that it also offers a consistently effective method of infectious disease prevention.

2.2.3 Homoeopathic Prevention of Infectious Diseases - A Brief Introduction

The scepticism by orthodox practitioners regarding homoeopathic treatment is even more pronounced when considering homoeopathic prevention of infectious diseases. There is, in fact, great hostility by many orthodox authorities to anyone who suggests that homoeopathic disease prevention is even possible.

Hahnemann believed that prevention of potentially serious diseases was far superior to treatment. He wrote; 'Who can deny that the perfect prevention of infection from this devastating scourge, and the discovery of a means whereby this divine aim may be surely attained, would offer infinite advantages over any mode of treatment, be it of the most incomparable kind soever?' (Hahnemann 1801, p. 377).

As mentioned earlier, a practical example of both the treatment and prevention aspects of the Law of Similars may be found in Hahnemann's experience when treating patients with scarlet fever. 'The remedy capable of maintaining the healthy uninfectable by the miasm of scarlatina, I was so fortunate as to discover.', Hahnemann wrote. He continued, 'I shall now relate the mode in which I made the discovery of this specific preventative remedy'.

He then described his successful use of potencies of the remedy Belladonna, chosen on the basis of the Law of Similars, to treat patients with Scarlet Fever, and how he also found that potencies of Belladonna would prevent scarlet fever, once again chosen on the basis of the Law of Similars (Hahnemann 1801, pp. 374-383).

Hahnemann again refers to HP in the 6th edition of his *Organon of the Healing Art* in note 73b to aphorism 73, which discusses acute miasmic disease. Here he discusses his use of Belladonna for the prevention of scarlet fever and Aconite for prevention of roodvonk (purpura miliaris) (Hahnemann 1843, p. 161).

In *The Chronic Diseases* he identifies Bryonia and Rhus Tox as two specific remedies used in 1813 for the treatment of typhus. These acute specifics represent early

genus epidemicus preventative remedies chosen by examining the characteristic symptoms of a number of people suffering the same condition (Hahnemann 1828, p. 8). The use of HP by other homoeopaths followed Hahnemann's lead, and is described below.

2.3 The Historical Use of Homoeoprophylaxis

Traub (1994, pp. 50-61) and Hoover (2001, pp. 168-175) presented reviews covering the use of HP over the last 200 years by homoeopaths from every continent.

In *Homoeoprophylaxis - A Practical and Philosophical Review,* Golden listed a few of the many thousands of references that have appeared in the homoeopathic literature worldwide describing the use of HP by different practitioners (Golden 2001, p. 28-34). Some references from this list are provided in chronological order to indicate the historical development of HP.

Boenninghausen **(1848,** p. 3) found that 'The decidedly favourable results caused me not only to use the same remedy with all the following small-pox patients, but to also use the same remedy in several houses where small-pox had broken out, as a prophylactic, and lo! also here the result was favourable, and no case came to my knowledge where, after using Thuja, any other member of the family had been infected.'

Boenninghausen **(1849,** p. 303**)** noted that '... we homoeopaths are convinced that we possess prophylactics which have the power of preventing the outbreak of cholera. Of course, these are and can be only such remedies as are able to cure the disease after it has broken out …. Although the circumstance that thousands of men have through the use of these homoeopathic prophylactics escaped cholera, as has been actually proved, does not incontestably prove that these afford an absolute protection, since it might have been that these very persons might have been the ones who would in any case not have been touched by the disease, nevertheless these facts speak at least very much for the probability of such a salutary action.'

Burnett (**1884**) wrote ‘It seems to me that the requirement of the age is to systematise the prevention of disease according to the Law of Similars, and in dynamic dose.’(p. 115).

‘Strewn about in literature there are examples of small-dose homoeoprophylaxis’.

‘The vaccine 'lymph' - pus - has been dynamised more homoeopathico and given as a prophylactic against small-pox in epidemic times, and apparently with effect. Thuja Occidentalis has been used in like manner by more than one homoeopathic practitioner, and they claim that it is effective. ... Speaking for myself, I have for the last nine years been in the habit of using vaccine matter, in the thirtieth homoeopathic centesimal potency, whenever small-pox was about, and I have thus far not seen any one so far treated get variola.’(p. 114).

Kent (**1900**, p. 229) stated ‘We must look to homoeopathy for our protection as well as for our cure’. ‘Now you will find that for prophylaxis there is required a less degree of similitude than is necessary for curing. A remedy will not have to be so similar to prevent disease as to cure it, and these remedies in daily use will enable you to prevent a large number of people from becoming sick.’

Eaton (**1907**) said that ‘We must not do Homoeopathy the injustice of giving this, one of its most successful and useful outgrowths, a partial and equivocal recognition, just because it happens to be strange to us. This splendid piece of practice is not new; it has its roots in the past, though we may not have known it. And we must not injure the cause by refusing to recognise its value just because we happen not to have been conversant with it.’

Close (**1920**, p. 20**)** wrote that ‘Homoeopathy is opposed to the methods of vaccine and serum therapy, although it is claimed by many that these methods are based upon the homoeopathic principle. It has been proven experimentally and clinically that such methods are unnecessary, and that the results claimed by their advocates can be attained more safely, more rapidly and more thoroughly by the administration of the homoeopathically indicated medicines in sub-physiological doses, through the natural

channels of the body, than by introducing it forcibly by means of the hypodermic needle or in any other way.'

Sankaran (**1961**, pp. 11-24) produced a very thorough literature review, sourcing 92 practitioners and hundreds of examples of HP. He explained, 'Though the effectiveness of the Homoeopathic prophylactic remedies for various conditions has not been proved by controlled studies and statistical records, yet generations of homoeopaths have used these remedies to prevent these conditions and they claim to have done it successfully. So their effectiveness may be accepted on the basis of this experience even if it is not proved.'

Shepherd (**1967**, p. 15) stated that 'Inoculation with any type of serum in any of these infectious diseases is harmful and can easily and safely be replaced by a remedy or remedies, proved according to our Law of Similars that "likes cures like" on healthy individuals. Nosodes or disease products of the actual disease are often most active preventatives.' Shepherd gave many practical examples of how HP reduced attacks of infectious diseases in English boarding schools that she attended, and other examples from her long and distinguished career.

Again in England, Blackie (**1976**, p. 184) wrote, while discussing HP, 'The same is true of the homoeopathic oral flu vaccine. Clinical experience proves that protection is given in individuals, yet there is no increase in antibodies to the influenza virus. ... One cannot ignore clinical observation but we have no way of measuring true reasons - it just works. The results, therefore, of Homoeopathy in preventative medicine are justifiably based on experience rather than experiment.'

Mathur (**1979**, pp. 50,53) wrote 'Dr Hahnemann found that remedies can act as prophylactic medicines, when the homoeopathic remedy in its provings brings out symptoms similar to a particular disease. It was experienced that the genus epidemicus when given to the members of the family who were not suffering from the epidemic disease were protected from developing the disease.' Mathur then quoted Dr Pierre Schmidt from an address given in Geneva on HP: 'The most noble role of medicine is

unquestionably prophylaxy. There homoeopathy asserts its superiority over the existing methods. It can prevent disease without endangering the organism, without incurring the disappointments of the prevailing school of medicine.'

Speight (**1982**, p. 3) discussed HP, stating: 'In homoeopathy there is no immunisation as such, but there are remedies that can build up immunity to infections. They can also act as curative agents where a disease has developed. These remedies carry no risk of detrimental effects, they are absolutely safe.' 'Dr A. Pulford wrote, "No disease will arise without an existing predisposition to that disease. It is the absence of the predisposition to any particular disease that makes us immune to it. Homoeopathy alone is capable of removing these predispositions"'. Speight then gives examples of HP in nine common diseases.

Eizayaga (**1991**, pp. 283) wrote that 'An ideal socio-medical system should assist all individuals before they contract any disease, whether acute or chronic ... In acute diseases: with the remedy of the epidemic genius and with the aetiological Nosode of the disease.' 'In homoeopathy, with the Nosode of each of the acute diseases we could fulfil a job similar to the one achieved by the vaccines which are known, without any of their inconveniences. While the non specific resistance of an individual to an infection is increased with the homoeopathic remedy, a higher specific immunity against a given germ is obtained with the Nosode'.

Dr Paul Chavanon, writing in Paris in 1932, mentions in his book, *La Diptherie*, about the immunisation of 45 children with Diptherotoxinum 4M and 8M, one dose by mouth, some needing a second dose of 4M:

'Chavanon demonstrated that as regards Schick's reaction, the Nosode negatives it or makes it inactive during a first period, as well as immunising without the presence of antitoxins or antibodies. After a short time, one to two months, antitoxins which can be measured in the blood appear and a real vaccination exists ... the respective immunisation lasts just the same as the one provoked by the antitoxin in substance, without any of its disadvantages'. ' Horacio Roux reported these same experiences in 1946 and obtained like results.' (p. 284). Dr Eizayaga then describes his own substantial and successful experience with HP.

Sethi (**1991**, pp. 22, 47, 56, 78) reviewed the experience of homoeopaths around the world. Some of the examples he gives of the use for HP for specific diseases are:

> 'Diphtherinum. Allen says that he had used it for 25 years as a prophylactic and has never known a second case of diphtheria to occur in a family after it has been administered. He challenges the profession to test it and publish the failures. ...Tyler writes that for nearly three years, Diphtherinum in high potency has been used in the London Homoeopathic Hospital to protect nurses and patients exposed to the infection, with perfect success.'
>
> 'Morbillinum. As a prophylactic given to those who are, or may be, exposed to infection.'
>
> 'Lathyrus Sativa. Homoeopathic physicians are satisfied that they have a really safe and better polio preventative in Lathyrus Sativa when properly given'.

Amongst the many examples of HP given by Sethi, he then quotes the experience of Drs Smith, Grimmer, Bond, and Foubister:

> 'Whooping Cough. Dr John H Clarke strongly recommended Pertussin in whooping cough. In practice the results of Pertussin have been verified by Dr Dorothy Shepherd. Children who were given this medicine escaped the disease.'

Lessell (**1993**, p. 14) published a comprehensive travel manual giving advice as to both the treatment and prevention of dozens infectious diseases. He wrote that, 'Those Nosodes utilised for immunisation, correctly given, are immensely safe, virtually free from side effects, and may be given in pregnancy and lactation. Alternatively, a remedy other than a Nosode may be given preventatively which would be used to treat the disease in question (e.g., malaria). Such remedies are also generally very safe. Safety and lack of side-effects thus characterise the homoeopathic method. Homoeopathic remedies would seem to work by actively stimulating the immune system of the body in some way. The manner in which this occurs, however, has not been totally elucidated.' Lessell followed with numerous examples of the use of HP remedies against diseases that travellers may face.

The above review, citing practitioners from different continents, shows that HP has been supported and used throughout the 200 year history of homoeopathy. However these references do not quantify the extent of support for HP among practicing homoeopaths. Research assessing the support for HP among Australian practitioners will be used to indicate the support for HP in general.

2.4 Current Attitudes to and Use of Homoeoprophylaxis

2.4.1 Introduction

The use of potentised substances for protection against infectious diseases (homoeoprophylaxis) is still a matter of debate among some homoeopaths. Some believe that patients should be allowed to contract infectious diseases and then be treated. They believe that the patient's long-term health will benefit most from this approach. Some express a concern that HP, whilst not being toxic, may still have some suppressive effect on the immune system. These issues will be examined in Chapter 3 following.

The following research described in the next section examines how common these opinions are among Australian practitioners, and quantifies the level of support for and use of HP by Australian homoeopaths.

2.4.2 Current Attitudes to and Use of Homoeoprophylaxis by Australian Homoeopathic Practitioners

In order to ascertain how homoeopathic practitioners view the use of HP, a survey of all Australian specialist homoeopathic associations was undertaken in 2001, and reported to the profession the following year (Golden 2002a, page 26).

It was decided not to survey naturopathic associations, who have relatively few members who specialise in homoeopathy, because results might have been significantly influenced by a great number of responses from non-specialist homoeopaths whose knowledge of HP would have been much less than those practitioners whose qualifications allowed them to join a specialist homoeopathic association. The specialist associations surveyed are shown in Table 2.4-1. They all require dedicated training in homoeopathy, typically leading to a Diploma or Advanced Diploma qualification in homoeopathy. Batchelor Degrees in homoeopathy have only been taught in Australia in the last few years, and a national competency standard only recently implemented.

Practitioners were surveyed via their associations, as mailing lists are confidential, and the associations usually have up-to-date addresses. In all, 532 questionnaires were sent out. Practitioners who belonged to more than one of the associations surveyed received multiple questionnaires. It was impossible to determine the exact number of multiple questionnaires sent to these practitioners, as Associations did not disclose membership lists. However, an allowance has been made for the 5 multiple responses found in the responses received. Further, associations tended to order questionnaires in rounded figures, and it is likely that some questionnaires would not have been used due to over-ordering.

By 31.12.2001, 210 responses were received, representing a response rate of 39.5% of questionnaires sent. The effective response rate would thus have been greater than 40% given multiple association membership and the over-ordering by associations.

Nationally, the response rates were varied. NSW, Victoria and Tasmania recorded responses over 50%, whilst responses from WA and Queensland were below 30% and the response from SA was 8%.

Responses from different associations were also very mixed. Response rates exceeding 40% were received from members of the Australian Medical Faculty of Homoeopathy and the Australian Homoeopathic Association. Less than 20% of members of the Australian Association of Professional Homoeopaths Inc responded. A third of all members contacted who belonged to the Homoeopathic Education and Research Association [HERA] responded. The latter association was the only one whose executive did not assist the researcher, and members of HERA were identified in Yellow Pages listings and contacted directly. This may have affected the response rate.

In order to analyse a “majority” view (i.e., States where more than 50% of eligible practitioners responded), the data were examined in three batches: (1) all 210 responses; (2) 156 responses from N.S.W., A.C.T., Victorian and Tasmania (States where the

response rate was above 50%); and (3) 54 responses from Queensland, W.A. and S.A. (States where the response rate was below 50%).

In addition, two other profiles in the data were examined, (1) 100 responses from experienced homoeopaths who had been in practice for eight or more years; (2) 48 responses from practitioners who were not certain about their use of HP, or who said they would not use HP.

The questionnaire sent to practitioners is shown in Table 2.1-1, and the covering letter to professional associations in Table 2.1-2 in Appendix 2. A schedule showing responses to the survey is shown in Table 2.4-1, and a summary of highlights is shown in Table 2.4-2.

The following conclusions may be drawn from these results:

1. **Knowledge of HP**. Whilst just 3% of respondents have never learned about HP, only one third **had** read Hahnemann's essay first describing his use of HP. Interestingly, of the 8 respondents who said they would never use HP, 6 had not read Hahnemann's essay. Further, of the 5 respondents who said it was not appropriate for a homoeopath to assist in the prevention of infectious disease if requested by a patient, none had read Hahnemann's essay.
2. **Use of HP**. Half of all respondents currently use HP; three quarters intend to use it in the future with 19% being unsure concerning future use.
3. **HP and the Law of Similars**. A majority of respondents believed that HP is based on the Law of Similars, 17% were unsure, and 24% believed it was not. Of the 51 respondents who believed HP was **not** based on the Law of Similars, 38 had not read Hahnemann's essay on HP.
4. **Type of Prevention.** Two thirds believed that HP should be used for both long-term and short-term prevention, 16% would use it only for short-term prevention, and 3% would never use it in any circumstance.
5. **Opposed to any use of HP.** 11 respondents (5.2% of the total respondents) answered "yes" to at least one of the following questions in the survey, thus

indicating their opposition to the use of HP. They were respondents 13, 14, 72, 110, 123, 135, 142, 147, 151, 186, and 196.

(i) Never use HP in any circumstances (Question 6)

(ii) It is not appropriate for a homoeopath to assist in the prevention of infectious disease if requested by a patient (Question 7)

(iii) A homoeopath should only treat infectious diseases once they have appeared, and should never assist in the prevention of infectious diseases (Question 8)

Four of these eleven respondents answered "yes" in two of the three questions, and one in all three. Of these eleven, one said he currently used HP, five said they would prevent diseases if requested, and four of these said they would prevent and not just treat.

Thus only four practitioners were unambiguously opposed to the use of HP under any circumstances. They were respondents 72, 110, 142 and 151.

It is clear that HP enjoys considerable support among Australian homoeopaths, and is used by a majority of practitioners who completed the survey.

2.4.3 Attitudes of Other Homoeopathic Practitioners to the Use of Homoeoprophylaxis

As shown in section 2.3 above, homoeopaths from around the world have expressed positive opinions concerning HP. All of the authors quoted in section 2.3 are well known to homoeopaths, and some are among the most highly regarded practitioners in the history of homoeopathy.

The actual level of use of and support for HP in countries other than Australia has not been quantified. In countries where the practice of homoeopathy is open to all persons who have undertaken professional training, it is possible that attitudes to HP would be similar to those in Australia. It is possible that in those countries that allow only orthodox doctors to practice homoeopathy some differences in the use of HP may

exist. Only empirical research in other countries would be able to confirm actual levels of support.

However it is clear that HP has been part of mainstream homoeopathy from its very beginning, that it has been used by the founder of homoeopathy as well as it's most distinguished practitioners. It has been shown in Australia that HP enjoys considerable support and a high level of use. It is probable that the experience in many other countries is similar.

Despite two centuries of using HP, and considerable support and clinical experience reporting its value, there has been relatively little research quantifying the level of effectiveness and safety of HP. The existing research (in English) will now be reviewed to provide a starting point for the original research described in Chapters 4 and 5.

Table 2.4-1: Schedule of Questionnaires Sent and Received

QUESTIONNAIRES SENT							**Multiple**
Association	**State**	**Approached**	**Date Sent**	**Questionnaires Sent**			Associations
AHA	Vic	5/1/01	03-May-01	60			3
AHA	Tas	5/1/01	04-May-01	11			
AHA	NSW	5/1/01	18-May-01	175			2
AHA	WA	5/1/01	10-May-01	38			
AHA	SA	5/1/01	16-Jul-01	25			
AHA	Qld	5/1/01	16-Jun-01	100	409	Total AHA	2
HERA	Vic	5/4/01	27-Aug-01	23			
Aust. Assn. of Prof Hom Inc	Qld	5/22/01	16-Jun-01	80			
Aust. Med. Faculty of Hom.	NSW	5/22/01	12-Jul-01	20			
Prof Assn. of Classical Hom. (SA)	SA	5/22/01					
TOTALS				**532**			**7**
QUESTIONNAIRES RECEIVED - BY ASSOCIATION							
	9/14/01		**SENT**	**% of Total Sent**		**% received**	
AHA	173	82.4%	409	76.9%		42.3%	
HERA	8	3.8%	23	4.3%		34.8%	
Aust. Assn. of Prof Hom Inc	14	6.7%	80	15.0%		17.5%	
Aust. Med. Faculty of Hom.	8	3.8%	20	3.8%		40.0%	
Other homoeopathic	1	0.5%	0	0.0%		0.0%	
Multiple Homoeopathic	1	0.5%	0	0.0%		0.0%	
Other	4	1.9%	0	0.0%		0.0%	
Not Stated	1	0.5%	0	0.0%		0.0%	
TOTALS	**210**	**100.0%**	**532**	**100.0%**		**39.5%**	

QUESTIONNAIRES RECEIVED - BY STATE							
STATE	**RECEIVED BY 9/4/01**		**SENT**	**% of Total**		**%**	**Multiple**
	#	**%**	**#**	**Sent**		**Received**	**Questionnaires**
						By State	**Sent**
NSW	102	48.6%					
ACT	4	1.9%					
	106		195	36.7%		54.4%	2
VIC	40	19.0%	83	15.6%		48.2%	3
QLD	43	20.5%	180	33.8%		23.9%	2
WA	11	5.2%	38	7.1%		28.9%	
SA	2	1.0%	25	4.7%		8.0%	
TAS	6	2.9%	11	2.1%		54.5%	
	0	0.0%	0	0.0%		0.0%	
NOT STATED	2	1.0%	0	0.0%			
TOTALS	**210**	**100.0%**	**532**	**100.0%**		**39.5%**	**7**

QUESTIONNAIRES RECEIVED - BY STATE AFTER ADJUSTING FOR MULTIPLE RESPONSES						Actual	
	RECEIVED BY 9/4/01		SENT	% of Total		No. of	Adjusted
	#	%	#	Sent		Members	% received
NSW	102	48.6%					
ACT	4	1.9%					
	106		195	36.7%		193	36.8%
VIC	40	19.0%	83	15.6%		80	15.2%
QLD	43	20.5%	180	33.8%		178	33.9%
WA	11	5.2%	38	7.1%		38	7.2%
SA	2	1.0%	25	4.7%		25	4.8%
TAS	6	2.9%	11	2.1%		11	2.1%
	0	0.0%	0	0.0%			0.0%
NOT STATED	2	1.0%	0	0.0%			0.0%
	210	**100.0%**	**532**	**100.0%**		525	**100.0%**

Table 2.4-2: Comparative Summary of the Most Significant Practitioner Responses to Questions Concerning Their Attitude to and Use of Homoeoprophylaxis

SURVEY OF THE ATTITUDES TO, AND USE OF HOMOEOPROPHYLAXIS (HP) AMONG QUALIFIED HOMOEOPATHS						
SUMMARY OF HIGHLIGHTS - %						
Number of Respondents	**156**	**54**	**210**	**100**	**48**	**9**
	Majority	**Minority**	**Combined**	**In Practice**	**Uncertain**	**Dissatisfied**
	Response	**Response**	**Response**	**8+ Years**	**Use of HP**	
	(1)	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**
Question 1: Did you first learn about HP either						
During your homoeopathic course	82.1	77.8	81.0	74.0	70.8	66.7
Never learnt about HP	2.6	3.7	2.9	2.0	8.3	11.1

Number of Respondents	**156**	**54**	**210**	**100**	**48**	**9**
	Majority	**Minority**	**Combined**	**In Practice**	**Uncertain**	**Dissatisfied**
	Response	**Response**	**Response**	**8+ Years**	**Use of HP**	
	(1)	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**
Question 2: Have you read Hahnemann's 1801 essay "The Cure and Prevention of Scarlet Fever"						
Yes	38.5	22.2	34.3	37.0	31.3	22.2
Question 3: Describe your use of HP.						
I currently use HP	48.7	50.0	49.0	56.0	4.2	11.1
I have previously used HP	28.8	27.8	28.6	33.0	35.0	22.2
I have never used HP	22.4	22.2	22.4	11.0	60.4	66.7

	Majority Response	Minority Response	Combined Response	In Practice 8+ Years	Uncertain Use of HP	Dissatisfied
Question 4: Do you intend to use HP in the future?						
No	3.8	3.7	3.8	1.0	16.6	44.4
*				(0.5)	(3.8)	(1.9)
Not sure	17.3	24.1	19.0	20.0	83.3	55.6
*				(9.5)	(19.0)	(2.4)
*	(% calculated on total sample of 210)					
Question 5: Do you believe that HP is based on the Law of Similars?						
No	19.9	37.0	24.3	22.0	52.1	88.9
Don't know	17.9	13.0	16.7	19.0	25.0	0.0

	Majority Response	Minority Response	Combined Response	In Practice 8+ Years	Uncertain Use of HP	Dissatisfied
Question 6: Do you believe that it is appropriate to use HP (where requested either						
For both long and short term prevention	71.8	55.6	67.6	68.0	22.9	0.0
Only for short term (epidemic) disease prevention	13.5	22.2	15.7	14.0	33.3	22.2
Never use it in any circumstances	3.8	0.0	2.9	2.0	12.5	55.6
Other	10.3	20.4	12.9	16.0	29.2	0.0

Question 7: Do you generally believe it is appropriate for a homoeopath to assist in the prevention of infectious disease if requested by a patient?						
Yes	96.2	92.6	95.2	95.0	79.2	33.3
	Majority	**Minority**	**Combined**	**In Practice**	**Uncertain**	**Dissatisfied**
	Response	**Response**	**Response**	**8+ Years**	**Use of HP**	
Question 8: Do you believe that a homoeopath should only treat infectious diseases once they have appeared, and should never assist in the prevention of infectious diseases?						
Yes	3.2	1.9	2.9	1.0	10.4	55.6
*				(0.5)	(2.3)	(2.4)
*	(% calculated on total sample of 210)					

Please state the professional association(s) you belong to						
AHA only	34.6	48.1	38.1	33.0	54.2	44.4
AHA + other	51.9	22.2	44.3	49.0	18.7	22.2
Other	12.8	29.6	17.1	17.0	27.1	33.3
	Majority	**Minority**	**Combined**	**In Practice**	**Uncertain**	**Dissatisfied**
	Response	**Response**	**Response**	**8+ Years**	**Use of HP**	
Other Associations (not AHA)						
HERA	6.9	3.6	6.2	10.4	18.2	14.3
AMFH	5.9	7.1	6.2	10.4	18.2	28.6

AAPH	1.0	46.4	10.8	7.5	27.3	0.0
OTHER HOMOEOPATHY	1.0	0.0	0.8	1.5	0.0	11.1
MULTIPLE ASSOCIATIONS	1.0	0.0	0.8	0.0	0.0	0.0
OTHER NON HOMOEOPATHIC	83.3	42.9	74.6	68.7	36.3	42.9
	Majority	**Minority**	**Combined**	**In Practice**	**Uncertain**	**Dissatisfied**
	Response	**Response**	**Response**	**8+ Years**	**Use of HP**	

How many years have you been practicing homoeopathy						
				*		
1 - 3	23.8	37.0	27.1	0.0	31.3	55.6
4 - 7	24.4	25.9	24.8	0.0	22.9	11.1
8 - 10	20.5	11.1	18.1	18.1	22.9	0.0
11 - 15	15.4	16.7	15.7	15.7	10.4	11.1
16 - 20	9.6	7.4	9.0	9.0	10.4	22.2
Over 20	5.8	1.9	4.8	4.8	0.0	0.0
				*		
*	(% calculated on total sample of 210)					

2.5 Historical Measures of the Safety and Effectiveness of Homoeoprophylaxis

2.5.1 Statistical Analyses of the Effectiveness of HP

As shown in section 2.3 above, many homoeopaths have recorded their clinical experiences using different types of HP programs, including those for both short and long term prevention, and using both *genus epidemicus* and Nosode remedies. However, most authors have not systematically collected data showing the effectiveness of HP.

Some studies have examined the results of using HP for animals (MacLeod 1974, p. 30; Day 1987, p. 58; MacLeod, 1994). It was decided, with one exception, to exclude these studies from this analysis as the research findings in Chapters 4 and 5 relate solely to humans, and animal studies may not directly relate to this experience. Further, the aim of this thesis is to determine not only the effectiveness of HP, but also its safety. The measures used for safety in the human experiments are not directly comparable to those made in animal studies. It is recommended that the study of HP in animals be made the subject of a separate analysis.

The following material summarises nine references published in English that have quantified a level of effectiveness for HP in humans. A summary of these nine studies is shown in Table 2.5-1. A tenth study is excluded for the reasons explained below.

[1] Ten doctors used Belladonna as a preventative against Scarlet Fever on 1,646 children, with only 123 cases of the disease arising, an effectiveness of **92.5%.** The disease had a reported attack rate of around 90% (Dudgeon 1853, p, 541).

[2] Eaton (1907, p. 5) collected the following figures from the Smallpox epidemic in the USA in the early 1900's (from which he deliberately excluded his experience with his own patients):

Persons given *Variolinum* 30	2806
Definite exposures after taking *Variolinum* 30	547
Smallpox cases after taking *Variolinum* 30	14
Effectiveness (proportion 14/547)	**97.5%.**

[3] Taylor-Smith (1950, p. 65) investigated the use of the *genus epidemicus* remedy *Lathyrus Sativus* in the prevention of poliomyelitis. He followed two groups of patients comprising both children and adults. The first group comprised 82 healthy individuals, the second 34 individuals who were already sick.

Within the originally healthy group, 12 children were definitely exposed to infection through direct contact with cases that had been later proved to have had the disease. None of the 82 healthy individuals in the healthy group acquired the disease indicating an effectiveness of **100%.**

[4] An investigation of systematic studies of the effectiveness of Influenzinum triple nosode by 21 homoeopathic physicians in three countries revealed a composite level of effectiveness of **86%** (Gutman 1963, p. 185). A combined total of 385 persons were studied.

[5] In August 1974 there was an epidemic of meningitis in Guarantingueta, Brazil. 18,640 children were given Meningococcinum 10CH, and 6,340 children were not covered. The following results were reported (Castro and Nogeira 1975, p. 211):

18,640 protected homoeopathically	4 cases
6,340 not protected	32 cases
Effectiveness	**95.7%***

* [(32 x 18640/6340)-4]/(32x18640/6340)

[6] A pilot study of 61 children over five years on the effectiveness of Pertussin 30 showed a range of effectiveness from **95%** based on confirmed cases of whooping cough down to **82.0%** if unconfirmed cases were included (Fox 1987, p. 70).

[7] Another pilot study of Pertussin 30 examined responses concerning 694 children who were given the remedy every three months during the first year of life, then at 18, 24, 36, 48 and 60 months of age. The study used whooping cough notifications in a local district health authority as a control. There were 59 definite cases (8.5%) and an additional 31 cases where diagnosis was uncertain, making 90 cases in total (13.0%). Thus effectiveness ranged between 87.0% and 91.5%. Additionally, doctor-diagnosed cases where children were given the whooping cough vaccine or the vaccine plus Pertussin 30 were compared. However the author suggested that 4,000 subjects would have been needed to give a statistically acceptable result. (English 1987a, p. 65; 1987b, p. 68)

[8] In another test of the remedy Meningococcinum, the remedy was given in a 30CH potency, to 65,826 people from 0 to 20 years of age in Blumenau, Brazil. Another 23,539 people in the area did not receive the remedy. The rates of protection found in the group using HP were **95%** in six months and **91%** in 12 months.

The authors noted that their use of Meningococcinum was not new and cited 12 references to its use from 1966 to 1996 (Mroninski et al., 1998, p. 234).

[9] In 1997 Golden published the analysis of over 10 years of research into HP. During this period 1,305 questionnaires were collected from the parents of 593 children. Each questionnaire covered one year of a child's life, and some parents returned questionnaires for up to 8 years. Reports of disease were compared to the level of disease exposure reported by the parents of the children studied. An average effectiveness of **88.9%** was found in the study group.

[10] The final study to be reviewed was reported as part of the Cochrane Review of randomised trials with placebo controls of the use of homoeopathic *Oscillococcinum* for preventing and treating influenza and influenza-like syndromes. The researchers examined three short-term studies undertaken during the flu season.

The researchers concluded that 'Current evidence does not support a preventative effect of homoeopathy in influenza and influenza-like syndromes', and 'There is some

evidence the prophylactic use of homoeopathy may lead to adverse events'. Because none of the studies they examined are available in English, and because the actual levels of effectiveness were not recorded by the researchers, no data from these trials can be recorded in Table 2.5-1 (Vickers and Smith 2001, p. 2).

[11] In a different type of experiment, 142 laboratory mice were challenged with a potentially fatal dose of *Francisella tularensis,* a rapidly lethal organism.

The experimental design was carefully constructed, and the results were rigorously analysed reporting a **22%** effectiveness of HP compared to a control group. A vaccinated group showed a 100% effectiveness (Jonas 1999, p. 39).

The Jonas study has been described as "the best constructed study of homoeoprophylaxis" (Hoover 2001, p. 173). This study, however, produced a result that demonstrated a level of effectiveness of HP significantly below that of vaccination, and significantly different to most other studies of HP. For this reason it is examined more closely.

Despite his excellent study design, Jonas' experiment contained one major flaw that probably caused a reduction in the level of protection given to the HP group of mice--the mice were given the HP remedy three times a week for 4 weeks before and 4 weeks after the challenge with *Francisella tularensis*.

Administration of the Nosode 12 times in the month before exposure is higher than generally accepted homoeopathic practice. For example, Golden recommends no more than two doses a week for three weeks when there is definite exposure to pertussis, but less for other diseases (Golden 1998, p.139). Twelve doses may have caused a "proving" effect in the mice (producing symptoms similar to the common symptoms of infection with *Francisella tularensis*), something that could have lowered the susceptibility of the mice prior to challenge.

Administration of the Nosode repeatedly after challenge is regarded as counter-indicated by experienced homoeopaths, since the Nosode generally is not the

appropriate (or "most similar") remedy to be used in treatment of the acute phase of an illness. The "similimum" (the remedy producing symptoms most similar to the symptoms of each individual patient) is the remedy that should be used in acute treatment. It is quite possible that these doses further weakened the immune function of the mice.

Possibly Jonas believed that "more is better" when it came to administering doses of the Nosode because "nothing was in it". However, experienced homoeopaths know that this is not the case with homoeopathic remedies, and in fact "more is worse" is often found to be true. It would have been interesting to see what the fate of the vaccinated mice would have been in Jonas' experiment if they had been given 24 doses of the conventional vaccine material before and after challenge.

Jonas would need to re-run his experiment using one or maybe two doses of the Nosode in the month prior to challenge, and no doses following challenge, for the experiment to satisfy standard HP protocols.

The human studies reported above show an average effectiveness of around 90%. This figure is consistent with the anecdotal evidence reporting a high level of effectiveness (Chapter 2.3 above).

Despite the relevant criticisms of experimental design and statistical analysis reviewed in 2.5.3 below, and despite further weaknesses in some of the studies relating to the uncertainty of exposure to the disease, these results represent a considerable body of data that consistently suggests a strong measurable prophylactic effect of HP.

The figure of 90% effectiveness may be used as a benchmark against which to compare the results of the two pieces of new research conducted as part of this thesis, and reported in Chapters 4 and 5, where all of the flaws in the experiments reported in 2.5.3 below will be addressed, with varying degrees of success. Whilst the 90% figure is not definitive, it is useful as a comparative figure against which to measure new results.

Table 2.5-1: Measures of the Effectiveness of Homoeoprophylaxis – Summary of Literature Review

Year	Researcher	Number of Participants	Length of Survey	Ages Surveyed	Definitely Exposed	Type of Remedy Used	Effectiven %
1853	Dudgeon	1,646	< 1 year	Children		G.E. remedy	92.5
1907	Eaton	2,806	< 1 year		547	Nosode	97.5
1950	Taylor-Smith	82	< 1 year	adults and children	12	G.E. remedy	100.0
1963	Gutman	385	< 1 year	Adults		Nosode	86.0
1975	Castro & Nogeira	HP 18,640 Not HP 6,340	< 1 year			Nosode	95.7
1987	English	694	2 years	Children		Nosode	87.0 – 91.5
1987	Fox	61	5 years	Children		Nosode	82.0 - 95.0
1998	Mroninski et al	HP 65,826 Not HP 23,539	6 months 12 months	0 – 20 years		Nosode	95.0 91.0
1997	Golden	593 children 1,305 questionnaires	10 years	1-5 years	304	Nosode and GE	88.8
1999	Jonas	142 mice	< 1 year		142	Nosode	22.0

2.5.2 Statistical Analyses of the Safety of HP

The safety of any method of disease prevention may be assessed by examining adverse health effects that result from use of the method.

There are very few analyses of the safety of HP for a very simple reason - homoeopathically prepared remedies contain no molecules of the original substance, and while some reactions may occur, there is no chance of toxic damage from using HP (unless there is some unexpected biological contamination of the remedy). This does not mean that reactions do not occur, but they cannot be reactions that result from toxic levels of exposure to the prophylactic substance.

This view certainly has support from well-known homoeopathic practitioners, as the following excerpts demonstrate:

Shepherd (1967, p. 51): 'Inoculation with any type of serum in any of these infectious diseases is harmful and can easily and safely be replaced by a remedy or remedies, proved according to our Law of Similars.'

Eizayaga (1991, pp. 283): 'In homoeopathy, with the Nosode of each of the acute diseases we could fulfil a job similar to the one achieved by the vaccines which are known, without any of their inconveniences.'

Lockie (1989, p. 17): 'homoeopathic immunisation has never damaged anyone.'

Lessell (1993, p. 14): 'Those Nosodes utilised for immunisation, correctly given, are immensely safe, virtually free from side effects, and may be given in pregnancy and lactation.'

The Cochrane Review study reported in 2.5.1 above, in contrast, noted some reactions to short-term HP remedies. It noted 'The reported effects were mild (e.g.,

headache) and transient, and might be described by homoeopaths as a "proving" phenomenon.' (Vickers and Smith 2001, p. 7).

The only published reference quantifying the level of reactions to a long-term HP program was by Golden (1997, p. 12), who reported reactions to HP of around 8.1% of people using his 1986 program, and 13.7% using the new program that was introduced in 1991. This would translate to a reaction rate of around 1.4% – 2.3% per individual dose (based on an assumed six doses per year).

One finding of interest was the level of remedy reactions in children whose parents or grand-parents had been infected with the disease that the remedy corresponded to. An example is the child who reacted to the remedy Diphtherinum, and whose father had had Diphtheria as a child (Golden 1998, p. 144). This may be viewed as a typical healing response experienced in normal homoeopathic treatment.

Another significant finding relating to long-term safety was that the parents who used HP for their children frequently reported how healthy their children were over the term of the study, suggesting that HP in no way lessened the general health of their children (Golden 1997, p. 15).

Part of the new research reported in Chapters 4 and 5 also examined the level of reactions to Golden's HP program. The second part of this new research analysed the link between the use of HP and the incidence of certain chronic diseases.

2.5.3 Criticisms of the Research Methods of Quantitative Studies of HP

The following criticisms of the quantitative HP studies will be used to test the methodological quality of the research reported in Chapters 4 and 5.

Jonas stated that 'a critical assessment of nosode and SAD [serially agitated dilutions] prophylaxis literature reveals a variety of major methodological flaws.' (Jonas 1999, p. 37).

1. low statistical power
2. uncertain methods of data collection
3. inadequate description of the preparation being tested
4. lack of proper control groups
5. use of improper statistical methods
6. delivery of the SAD through routes that bypass normal immunosurveillance pathways of the organism.

The sixth criticism relating to the route of delivery of SAD does not relate to the human trials reported above as it is appropriate to administer HP remedies orally, and this was the method used in all of the human trials as well as in the research reported in Chapters 4 and 5.

Neustaedter (1990, p. 31) found:

1. lack of proper controls in most studies
2. incomplete, tentative or poorly reported results.

Vickers and Smith (2000, pp. 5,7) reported:

1. incomplete information to allow full data extraction
2. inadequate details of exclusions and withdrawals
3. reporting bias for patient assessment
4. some methodological bias in reporting and data analysis
5. lack of statistical significance due to insufficient power.

The authors suggested that two groups of 1,457 would be required to give a minimal, clinically significant difference of 5% and a power of 90%.

Finally, in a private communication with Golden concerning his 10 year study (Golden 1997), Kune identified ‘some major problems with interpretation of the data’, including:

1. cohort far too small due to the risk of the disease or adverse reactions being very low. He recommended a case-control design but acknowledged that it would be extremely difficult to obtain.

2. possibly inadequate length of follow-up to ascertain effectiveness
3. responses by parents may be unreliable
4. no controls to compare data with (Kune 2002, p. 1).

Most of the above procedural and reporting limitations are addressed in the research reported in Chapters 4 and 5. An effective control group for assessing effectiveness is found. However, the size of data collection is limited due to available resources, and the effect of this will be studied carefully to determine the impact on relevance of the data.

2.6 Concluding Comments on the Historical Use of Homoeoprophylaxis

HP was first used by the founder of homoeopathy, and in the 200 years following by many of homoeopathy's most esteemed practitioners. HP enjoys a high level of use and support among professional homoeopaths in Australia. Its support among practitioners in other countries has yet to be quantified.

HP appears from the literature to offer a level of protection around 90%, and appears to be an extremely safe method of prevention against infectious diseases, with a reaction rate of less than 2% per dose and no evidence of long-term adverse health consequences.

In Chapter 3 the conceptual basis of HP will be reviewed, and in Chapters 4, 5 and 6, new research examining the effectiveness and safety of HP will be reported and discussed.

3 The Conceptual Basis of Homoeoprophylaxis

Chapter 2 reported the significant support for and use of HP over the last 200 years. It also showed that not all homoeopaths do support HP.

In this chapter HP will be fully defined and its methodology examined. Seven aspects of HP that have been questioned by some practitioners will be outlined and discussed. Finally, possible mechanisms of actions of HP will be reviewed.

3.1 The Concepts Supporting HP

3.1.1 The Definition of Homoeoprophylaxis

Homoeoprophylaxis (HP) is the use of potentised substances in a systematic manner to prevent the development of the characteristic symptoms of infectious diseases.

The key words in this definition are:

(i) potentised – the method of preparing substances that is specific to homoeopathic medicine was described in Chapter 2 above. If the substances are not potentised it is expected that the length of protection being offered by HP will be very brief, or zero. Clinical experience in treatment with homoeopathically potentised remedies finds that the higher the potency the longer the duration of action of the dose. As may be expected, the same is apparently true for prevention (Eizayaga 1991, p. 284).

(ii) systematic – the schedule of medicines given in an HP program is not random. The medicines are chosen using the Law of Similars. The medicines are administered in a potency and frequency, designed by the homoeopath based on their own and historical experience with HP, to give a maximum protective effect with a minimum of doses.

(iii) characteristic – the remedies used in a HP program are chosen because of their similarity to the common or characteristic symptoms of the disease

being targeted. If the patient does not experience these symptoms following disease exposure then the method has been successful. It is possible that the patient actually contracts the disease, but that the defence mechanism is so well prepared that the resulting symptoms are sub-clinical. This occurs in the real world every day as people are exposed to cold and flu viruses, glandular fever, and so forth, but develop no symptoms of the disease.

As stated above, medicines used in an HP program must be selected according to the Law of Similars. This Law can be re-written in terms of disease prevention in two ways [note that some material in this chapter is based on an earlier presentation by the author (Golden 2001, p. 3)]:

A. A substance that is capable of producing in many healthy persons a group of symptoms similar to the characteristic symptoms of an infectious disease, is capable of preventing those characteristic symptoms in most previously unprotected persons.

For example, (1) Hahnemann's proving of Cinchona described in Chapter 2 above, which is a prophylactic for malaria; (2) Nosodes (homoeopathic potencies of diseased products) are further examples of this application of the Law of Similars. For example, the remedy Morbillinum is made from measles virus. Obviously, the measles virus can cause the characteristic symptoms of measles. Thus, potencies of the virus (Morbillinum) can be used to prevent the characteristic symptoms of measles.

The Law of Similars for prevention may also be re-written as:

B. A substance that is capable of removing the characteristic symptoms of an infectious disease in many infected patients is capable of preventing similar symptoms in most previously unprotected persons.

For example, (1) Hahnemann's uses of Belladonna to both treat and prevent scarlet fever that was described in Chapter 2 above; (2) the remedy Lathyrus

> Sativus that was used in potency in the 1950 polio epidemics by many homoeopaths to treat polio, can also be used for polio prevention. It has the advantage of covering the three main strains (Eisfelder, 1957a, page 147; 1957b, page 10; 1957c, page 167).

Thus, the use of HP is entirely consistent with the fundamental principle or Law underlying homoeopathy - the Law of Similars.

Some homoeopaths have never been taught that HP is consistent with the Law of Similars in terms of disease prevention. In the study of Australian practitioners described in Chapter 2 above it was shown that only 34.3% had read Hahnemann's original essay on HP, and less than 60% believed that HP is based on the Law of Similars. This is one reason why the use of HP is questioned by some homoeopaths today.

3.1.2 Methodology of Prophylaxis

Homoeopaths have developed the three methods of homoeoprophylaxis shown below. These methods have been thoroughly reviewed by Little (2000, pp. 1-12):

(i) the constitutional remedy.
(ii) the genus epidemicus.
(iii) the similar Nosode.

(i) The first method of homoeoprophylaxis is the use of the **constitutional remedy** – a remedy chosen from those mental, emotional and physical symptoms that are unusual or peculiar to the individual patient. This remedy strengthens the vital force in a general manner by removing predispositions, increasing vitality and raising general immunity to stress and disease. This remedy offers some level of prevention against all diseases. Some homoeopaths believe that it forms the first line of defence against all forms of infectious disease, but clinical experience shows that even very healthy people contract infectious diseases. The patient will always benefit from the constitutional remedy, but

it alone will not always guarantee the highest level of immunity against a specified disease.

(ii) The second method of homoeoprophylaxis is the use of the **genus epidemicus** remedy that is especially useful in offering protection against acute epidemic diseases. This remedy is chosen by analysing the symptom patterns of a number of patients with the prevailing disease, and finding the remedy that best fits the majority of cases. For example, every "flu season" a different genus epidemicus appears, and is useful treatment for most patients during that particular season, as well as being an effective preventative. It of course should be combined with sensible infection avoidance procedures.

(iii) The third method of homoeoprophylaxis is the use of the **similar Nosode.** In this method a Nosode of the targeted disease is given as a preventative to that disease. Homoeopathic Nosodes have a wider band of action than orthodox vaccines since they only need to be able to produce similar symptoms, which differing strains of an infectious disease often do. For example, the remedy Meningococcinum has a protective effect against meningococcal disease because the symptom picture of the remedy is similar to the symptom picture of the disease (Mroninski et al., 1998, p. 234). Mroninski et al., 1998, p. 234).

HP may be used both for short-term prevention and long-term prevention. These two possible uses, together with the three methods described above, make six possible types of use:

1. Short-term prevention using the constitutional remedy.
2. Long-term prevention using the constitutional remedy.
3. Short-term prevention using the genus epidemicus.
4. Long-term prevention using the genus epidemicus.
5. Short-term prevention using the similar Nosode.
6. Long-term prevention using the similar Nosode.

The research into a specific HP program reported in Chapters 4 and 5 examines uses 4 and 6 above. The General Health Survey also reported in Chapters 4 and 5 examines all six possible uses, with particular emphasis being on uses 2, 4 and 6.

Thus long-term prevention is the focus of the research undertaken in this Thesis. This is a necessary result of the need to examine the possible relevance of HP to public health policy where vaccination is primarily used for long-term prevention. In acute outbreaks of, for example, Meningococcal disease, HP has established its value both historically and in recent large-scale experiences (Castro and Nogeira 1975, p. 219 ; Mroninski et al., 1998, p. 234).

3.2 Some Conceptual Questions Concerning HP

As stated above, not all homoeopaths agree with the use of potentised substances to prevent infectious diseases. It was shown in Chapter 2 above that in Australia these practitioners are in the minority. However, it is appropriate to address the questions and concerns they raise. If HP is a legitimate therapeutic option, then it should be able to withstand both conceptual and practical scrutiny. Seven different aspects of HP that are questioned by some homoeopaths are now examined.

3.2.1 Treatment, Not Prevention

Some opponents of HP argue on conceptual grounds that we should not use HP to prevent infectious diseases. They argue that patients should be treated constitutionally to build up general vitality, and this will also provide an increased level of immunity. Further, if the patient acquires an infectious disease then his or her symptoms should be treated according to the Law of Similars, thus ensuring that the patient's Vital Force is given the most appropriate help to both remove the disease and develop a strong and active immune system (Neustaedter 1995, p. 30).

There is some agreement that acquiring some infectious diseases may be beneficial to the normal maturation of a child's immune system. The so called *"hygiene hypothesis"* states that a lower level of exposure to bacteria and fewer infectious diseases in childhood results in an increase in asthma, eczema and allergic diseases in later years. The hypothesis is controversial, with support from orthodox medicine (Matricardi et al, 2002; Braun-Fahrlander et al, 2002), yet with questionable validity (Dahl et al, 2004).

However there is little if any evidence that demonstrates that every child needs to acquire **every** disease in order to be healthy. In fact, there is ample evidence that infectious diseases may create "layers" of distress in otherwise apparently healthy persons, for example those patients "never well since" measles, glandular fever, pertussis, etc., who are commonly encountered in homoeopathic practice.

Further, it can be argued that if the stimulation caused by an infectious disease is beneficial, then the similar stimulation on the subtle level provided by the remedies will be similarly beneficial but without the risks sometimes associated with the natural disease.

Vaccines are manufactured to attempt a stimulation of antibodies without the risk of the natural disease. HP does not work on the antibody level, and therefore the two methods should not be thought of as comparable. They are two distinctly different methods of disease prevention.

Hahnemann spoke of his desire to prevent the suffering arising from scarlet fever. Anyone who has treated a tiny infant with pertussis would be aware of the potential for suffering there. And so on. So while we should not fear every disease, many would agree that some disease prevention is called for. In practice, many parents would insist on this.

Because the correct use of HP also accords with the Law of Similars, it is not inferior conceptually to the "treat-don't-prevent" position. There is no evidence that HP

adversely affects the patient, and in fact evidence is presented in Chapter 5 following that HP may be beneficial to the recipient's general health.

In practice, not all patients have immediate access to an experienced homoeopath who can confidently treat pertussis, polio, etc. This opportunity will vary both between and within countries. It is a further and major reason why the "treat-don't-prevent" position is impractical at times.

Further, in practice many parents (and practitioners) simply do not accept that their children should be allowed to develop all infectious diseases. Whilst it is appropriate for a practitioner to suggest alternatives, the final choice of treatment or prevention should belong to the parents, **not** to the practitioner. A parent can do no more for his or her own children than carefully research available options and then do what he or she believes is best for their child. Many parents would place pertussis in a tiny infant, polio, tetanus and Hib meningitis in the category of diseases worth preventing.

Some practitioners believe that parents should not have the final say in the treatment of their children. They believe that practitioners should not accommodate the wishes of parents when they differ with the practitioner's own views. These practitioners exist both in orthodox and traditional medicine.

There are situations where complying with patients' requests could be irresponsible or illegal, but in the present context it is more likely that differences are due to opinion. Thus some practitioners may cause parents to be left with no acceptable option, or to accept with great misgivings the practitioner's opinion. Neither result is satisfactory, and the practitioner's preparedness to refer to a colleague who can accommodate the patient's needs is essential at such times.

In conclusion, if **both** practitioner and patient feel most comfortable with the "treat-don't-prevent" approach, it certainly is a legitimate one. However, it in no way invalidates the appropriate use of HP.

3.2.2 Epidemics Only

Some practitioners acknowledge the use of HP by Hahnemann and others, and point out that this use occurred mainly at times of epidemics. They conclude that the use of a preventative remedy during an outbreak of a disease is the only legitimate form of HP. They usually endorse the use of the *genus epidemicus* remedy, but that issue will be considered in the following section.

Practitioners' use of HP in epidemic situations demonstrates agreement that some disease prevention is appropriate. However, in many communities measles and pertussis are constantly present. Hib is becoming increasingly common. In countries where oral polio vaccine is used, exposure to this disease is constant due to the virus being excreted by recipients.

In such situations, when should HP be used?

The difficulty with the "epidemics only" position is that we can never know in advance when some patients will be exposed to diseases that are constantly circulating in the community, thus the level of protection offered will be significantly lower than if there is routine coverage.

If the "epidemics only" position is adopted, some children will have to fall ill before protection can be offered to others. This will not be acceptable to many parents.

There is a logical inconsistency in the "epidemics only" approach. On the one hand, proponents believe that a disease should be prevented, but on the other hand, they must allow some children to be infected to remain true to this approach.

Thus, the "epidemics only" position does not prove that long-term HP prevention is either impossible or inappropriate.

3.2.3 The Genus Epidemicus Only

A variant of the "epidemic only" approach is the argument that the *genus epidemicus* of a current outbreak is the only suitable remedy according to the Law of Similars. Its use certainly is consistent with position **B** noted in 3.1.1 above.

However, position **A** noted in 3.1.1 above shows that the *genus epidemicus* is **not** the only remedy suitable to use for HP purposes. The use of the relevant Nosode as well as other "similar" remedies is also acceptable in terms of the Law of Similars

The advantage of the using the Nosode is that it does not rely on waiting until a number of patients have succumbed to the outbreak, which is what is required to allow the *genus epidemicus* remedy to be worked out. The Nosode may be given in advance of an outbreak, thus providing year-round protection. All that is needed to defend the long-term use of Nosodes is to show that they are safe and effective, and this will be demonstrated in Chapter 5.

Further, a *genus epidemicus* from previous outbreaks of the disease may be used for long-term prevention **if** the characteristic symptoms of the current disease are similar to those of the previous outbreak.

For example, the remedy Lathyrus Sativus was used successfully for both treatment and prevention in the polio epidemics in the 1950's (Eisfelder 1957a, p. 147; 1957b, p. 10; 1958, p. 167). The remedy appears to cover the characteristic symptoms of the current strains of polio, and therefore may be used as a long-term HP preventative against polio.

Thus there is no reason either conceptually or practically why the *genus epidemicus* of a current outbreak is the only legitimate HP remedy.

3.2.4 Nosodes and Isodes

Some authors have – incorrectly, I believe - labelled HP as "Isode therapy".

An **Isode** may be defined as a remedy prepared from the patient's OWN diseased material, e.g., a remedy prepared from a whooping-cough patient's own sputum. This definition is not uniformly accepted in the literature (Gaier 1991, pp. 290-309), but it the most useful definition for the purposes of this discussion. HP is clearly not Isode therapy as the patients' own diseased tissue is not used in any of the three types of HP outlined in 3.1.2 above.

Some label HP as "Nosode therapy". It is only necessary to refer back to Hahnemann's use of Belladonna to prevent scarlet fever to see that the use of Nosodes is not an essential part of the use of HP. However, Nosodes are the remedies of choice in many situations for one simple reason - they most obviously satisfy the requirement of position **A** of the Law of Similars stated in 3.1.1.

Some object that Nosodes are "the same" rather than "the most similar" remedy, and thus breach the Law of Similars. This objection would hold true only if Isodes were used, and they are not.

Some practitioners fear using Nosodes, possibly because they are derived from material that is not benign (unlike most herbs and minerals from which many homoeopathic remedies are derived). Yet the original antigenic material used to prepare Nosodes is no more toxic than some venom, acids, or other materials that are frequently used in potency by all practitioners.

Nosodes prepared in homoeopathic potencies above 12c contain no molecules of the original diseased material, and are non toxic. If they are administered correctly, Nosodes are no more "dangerous" energetically than any other homoeopathically potentised remedy.

Finally, it must be remembered that the use of Nosodes is not essential in an HP program, which may be designed using non-Nosode remedies selected according to the Law of Similars.

3.2.5 The Risks of Homoeoprophylaxis

Some homoeopaths suggest that the long-term, non-epidemic use of HP exposes patients to unknown risks of disturbing their energetic health. They oppose the use of remedies when there may be no current exposure to the related disease, and when the patient is not unwell and thus not calling for the remedy based on presenting symptoms (Neustaedter 1990, pp. 31,32).

The concern of such practitioners relates to potential damage to the subtle energy bodies (sometimes referred to the "mental" and "emotional" bodies) of patients taking HP remedies. They acknowledge that any potential risks that may exist do not relate to possible toxicological damage from antigenic material, adjuvants or preservatives, all of which are used in orthodox vaccines

When we examine current homoeopathic practice, we find that one situation where healthy people are given remedies when they are not indicated for treatment purposes is during homoeopathic provings. It is generally agreed that provided remedy administration is stopped once proving symptoms develop, no harm is done to the provers. In his footnote to Aphorism 141, Hahnemann stated that one way to improve general health is to undertake regular provings (Hahnemann 1843, p. 210).

It may be argued that more remedies are given during the course of an HP program than would be taken in a series of provings over a year. However if HP doses are not given past the point of symptoms being developed, there appears to be no reason conceptually or practically why such dosing should cause problems.

Further, the design of the HP program can address risk concerns, for example different remedies are given over a 12 month period in Golden's HP program, not

repeated doses of the same remedy as in provings. HP doses are taken no more frequently than monthly. Individual remedies are given no more frequently than every 10 months, and are given either as a single dose or as a triple dose over 24 hours. Parents are instructed to stop administration of remedies if reactions occur. Thus the chance of dynamic damage due to over-prescription is remote.

It is shown in Chapter 5 that fewer than 9.2% of children using Golden's HP program develop some reactions to the remedies. This translates to less than 1.6% of reactions per dose. Most immediate reactions are mild and temporary, and the long-term health of children is in no way weakened, according to the clinical evidence. This suggests that long-term energetic damage is not caused by Golden's HP program.

Some opponents of HP argue that there may be very deep "constitutional" changes that are neither immediately obvious, nor apparent after a decade. However, objective evidence of systematic long-term damage arising from a properly administered HP program is yet to be presented. The practical evidence presented in Chapter 5 suggests that HP poses no risk to constitutional health.

Some practitioners offer anecdotal evidence from their own personal experience with one or a few patients who have used long-term HP, where the patient was generally unwell. Such isolated experience must be compared to the systematic collection of evidence from thousands of patients over 15 years that is analysed in Chapter 5. No such comparable evidence exists to show any long-term adverse health effects of an appropriate HP program.

3.2.6 Prevention or Palliation

Some practitioners have suggested that HP does not prevent infectious disease, but rather reduces the severity of any infection often to the point where clinical symptoms are not obvious.

Thus, children may not develop any obvious symptoms when exposed to a disease. Or they may, for example, develop those primary-stage disease symptoms common to many infectious diseases (e.g., sore throat, mucus discharges, elevated temperatures, headaches, etc.,), but not the characteristic symptoms of the disease. This idea raises a number of interesting possibilities.

If infection does occur but symptoms are rendered mild, then those who oppose HP on the basis that it stops the normal maturation of the immune system by preventing individuals acquiring natural diseases presumably will be appeased.

Some may try to argue that fewer symptoms following exposure/infection means that the immune system is not working efficiently, and conclude that HP suppresses the immune response. However the practical examples we have of the type of suppression that causes a feeble response to infectious challenges, typically occur in heavily medicated or deeply unwell people. There is no evidence that HP leads to a lower state of health; in fact, the reverse appears to be true.

In practice we observe that many people who use an appropriate HP program do not develop any characteristic symptoms of a disease after a definite exposure to it. The question becomes - can a person who develops no characteristic symptoms after definite exposure be said to have been infected by the disease?

An examination of antibody levels in apparently uninfected patients both before and after definite exposure to a disease would help to answer this question. It appears likely that there would be an increase in antibody levels in at least some cases.

An attempt to make such an examination was considered when planning this thesis. It did not proceed due to the perceived difficulty in obtaining subjects because of the possible trauma to infants from the blood tests required to determine antibody levels, and the understandable reluctance of parents to put their infants through such trauma.

3.2.7 The Length of Prevention

One criticism that applies to HP, as it does to all types of immunisation, is that the level of and duration of protection is not known with complete certainty. With vaccination and with HP it is possible that protection may extend over some decades, but the recipient will be unprotected in adult years when some diseases may be more virulent than in the pre-teen years. It is also true that the exclusive use of constitutional remedies does not guarantee protection against specific infectious diseases at any age.

Even the most certain form of protection – acquiring the disease itself – is not 100% effective over a long term as very occasionally some people acquire measles or whooping cough twice. However this factor does remain the most compelling argument supporting the 'treat don't prevent' position.

However, if protection against a particular disease is required in infancy, then parents are faced with a dilemma. Doing nothing now will leave their infant with a reduced level of protection against the disease, yet because there is no option, whether disease-specific or constitutional, that can guarantee that the recipient will not lose some level of immunity later in life, then protection now may render their infant less protected when they become an adult, compared to a person who acquired the disease as a child.

If the long-term HP program allows an infant, if exposed to a disease, to acquire a sub-clinical case of disease, as discussed in 3.2.6 above, then the perfect solution is obtained. Antibodies will be formed to give additional long-term protection, yet short-term distress will be minimised.

If this is not the mechanism involved, then the only other option for those parents desiring protection for their children in infancy and beyond is to ensure that HP boosters are given regularly. For example, Chauvanon's experience with the Schick test suggests that a booster every ten years should be sufficient to provide ongoing protection for most people (Eizeyaga 1991, p. 284).

3.3 The Mechanism of Action of Homoeoprophylaxis

In practice, many people decide to use homoeopathy to treat disease firstly because they believe it is safe and relatively effective when administered correctly and secondly because it is conceptually consistent with unchanging Laws of Nature. The precise mechanism of action cannot be explained in terms consistent with current scientific knowledge (although this will almost certainly change in the future).

Experience also shows that HP is safe and relatively effective when administered correctly, and is conceptually consistent with unchanging Laws of Nature. At present it cannot be explained using orthodox scientific terminology, and in fact works quite differently to the antibody-stimulation model used by allopaths.

Some homoeopaths object to the use of HP because its mechanism of action cannot be explained in orthodox terms, but this can be seen to be illogical given that their use of homoeopathic treatment that is also "scientifically" unproven (Neustaedter 1995, p. 30; Golden and Neustaedter 1996, p. 28).

Previous attempts to suggest a model for the action of HP have been made (Golden 1987, pp. 3-10; Golden 1989a, pp. 69-76; Traub 1994, pp. 50-61).

Two models of the mechanism of action of HP are discussed below – the idiosyncrasy model and the proving model. Both are speculative, but both provide further insight into why the results observed in practice do occur.

3.3.1 The Idiosyncrasy Model of Protection

The idiosyncrasy model proposes that the mechanism of action of HP can be explained in terms of it ability to change the level of idiosyncrasy or sensitivity of recipients to the energetic stimulus of various infectious diseases.

To give a specific example, we find in practice that if a patient is sensitive to the physical and dynamic stimulus of the Rhus tree, then by taking appropriate potencies of Rhus Tox the patient will be rendered less sensitive to this stimulus.

More generally, the idiosyncrasy model argues that a patient may be rendered less idiosyncratic, or sensitive, to the physical and dynamic stimulus of any other substance - including viral and bacterial material – by taking either a potency of the material (the Nosode) or of a substance that is similar in its symptom picture (the *genus epidemicus*).

It is important to consider the order in which contagion occurs. Simply put, the antibody response is the third line of defence. The immune mechanisms in the respiratory and GIT tracts are the second line. Homoeopaths believe that the first line of defence is an energetic one, and that if the person is not susceptible to the dynamic stimulus of the infecting agent then the physical symptoms that we call the disease will not appear.

We know that simple exposure to, for example, a measles virus does not guarantee infection in all “unprotected” people. For example, Europeans brought what were to them simple diseases to the South Sea Islands. Many islanders died, many caught the disease, but there also was a significant minority who escaped infection. There were no vaccines at the time, and the diseases had never appeared in their communities so there were no circulating antibodies. Because of their communal lifestyle we know there would have been widespread exposure. So what protected the minority?

Homoeopaths believe that the first effect of, for example, the measles virus is the action of the energy of the virus upon the energy body of the exposed patient. If the virus-specific dynamic defences are strong at that point, the effect of the physical viral material will be minimal (as with the influence of the Rhus Tox material on non-allergic people).

Every person is more or less susceptible to every substance on this planet. Most people are not highly susceptible to most things (otherwise we would be in a constant state of "allergic" stress). HP renders patients less susceptible to specific influences; however HP will never be completely effective because the idiosyncrasy of some people is so strong that they remain hypersensitive to certain stimuli for most of their lives (e.g., people who

are infected more than once by diseases where lifelong immunity usually results after the first infection).

In some other cases exposure will be so intense and constant that initially strong defences will weaken and fail. Repeated doses of the HP remedy at such times are definitely indicated.

Thus the appropriate use of HP does not appear to suppress diseases. Instead, the dynamic idiosyncrasy of the individual to specific substances (viral and bacterial antigens) is changed. If suppression did occur, then the general health of the recipient would be expected to deteriorate due to the weakening of the immune system. All the practical evidence we have, as well as the results reported in Chapter 5, suggest that general health may even improve using HP, making the likelihood of suppression remote.

In summary, according to the idiosyncratic model of HP, when a patient is exposed to an antigenic stimulus various reactions occur. The disease is effectively "prevented" when the antigen-specific part of the general vital force is stronger than the dynamic strength of the antigenic stimulus, i.e., the patient is not idiosyncratic (sensitive) to the antigenic stimulus.

HP changes the antigen-specific part of the vital force, rendering the recipient less idiosyncratic or sensitive to the antigen, thus effectively preventing the occurrence of the characteristic physical symptoms of the disease.

3.3.2 The Proving Model of Protection

The philosophical model supporting the "epidemics only" approach discussed earlier is based on the assertion that the genus epidemicus or the Nosode given during an epidemic creates a proving, i.e., an artificial disease state whose characteristic symptoms are very similar to the characteristic symptoms of the natural disease.

Hahnemann observed and demonstrated that two similar diseases cannot exist in the system at the same time (Hahnemann, 1843). The stronger will either repel or replace the weaker, depending upon which disease comes first and which second. So the "proving model" of protection argues that if we create a sufficiently strong proving state, the natural disease will be repelled when the patient is exposed to it.

Supporters of the "epidemics only" approach further argue that because it is not desirable to continue a proving state over a long period, the method should only be used when there is danger of exposure in an epidemic situation.

So the "proving model" does offer a possible alternative explanation of the mechanism of action of HP. However, it is unlikely that a patient would continue proving a remedy for many years, especially if under long-term homoeopathic treatment or exposed to antidoting forces.

Thus, the observed fact that the protective effect of HP can continue for many years makes it appear that the "proving model" is not sufficient to fully explain the mechanism of action of HP.

3.3.3 Concluding Comments on the Mechanism of Action of HP

At the present state of knowledge, it appears that the mechanism of action of HP cannot be – or at least has not been - explained in terms of orthodox science. It is likely that science will continue to expand its knowledge base, as it has over centuries, and eventually will provide an explanation for the mechanism of action of HP in terms of its own paradigm,

It must also be remembered that in orthodox medical science, methods of treatment have been used without a complete mechanism of action being understood. The case of Asprin is a relevant example. It was used for decades before its mechanism of action was understood. Orthodox practitioners accepted its effectiveness based on clinical observation, and thus its use continued.

The mechanism of action of HP can only be discussed in conceptual terms which may seem inadequate to those who do not accept the concepts associated with the human energy field, from which homoeopathic science derives.

However, as with Asprin, the safety and effectiveness of HP has been observed in the clinical setting over centuries of use. If those in orthodox science who supported the use of Asprin and other such "unproven" medicines are to be consistent they would accept the continued use of HP based on the evidence supporting its safety and effectiveness.

3.4 Concluding Comments on the Conceptual Basis of Homoeoprophylaxis

Based on the review of the literature as well as Golden's own experience and research, it appears that a properly constructed HP program is conceptually consistent with the fundamental Laws underpinning homoeopathy, in particular the Law of Similars and the Law of Minimum Dose.

The concerns and criticisms voiced in the homoeopathic literature about HP can all be answered, with one exception. The length of protection of HP is unknown and this limitation of HP may lead to an individual becoming susceptible to an infectious disease later in life.

This criticism, though, applies to every method of disease prevention. Some people even contract the same infectious disease twice.

Thus, no approach to disease prevention is either conceptually or practically perfect in terms of effectiveness and safety.

The conceptual basis of HP, however, is consistent with homoeopathic principles, and appears from the homoeopathic literature to offer a reasonably effective and non-toxic method of protection against infectious diseases.

In Chapters 4 and 5 research into the effectiveness and safety of HP will be presented, and the findings will be discussed in Chapter 6.

PART 3: RESEARCH METHODS, RESULTS AND DISCUSSION

Introduction to Part 3

Part 3 of the thesis is divided into the following three parts:

Chapter 4 Research Methods

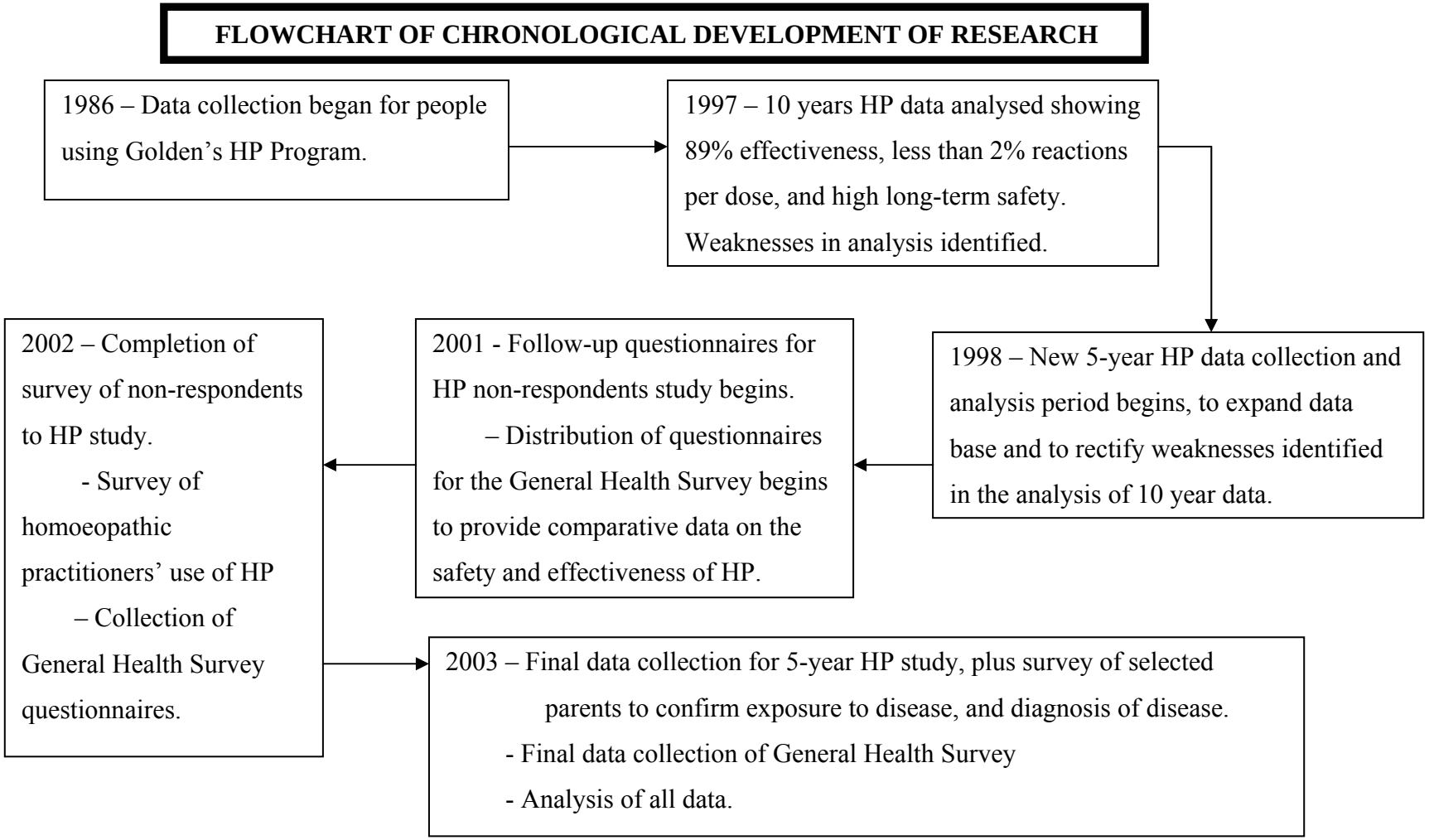
Chapter 5 Results

Chapter 6 Discussion of Results

The following flow chart shows the chronological progression of data collection and analysis from 1986 when distribution of questionnaires to parents using Golden's HP program began, to 2003 when final data collections for both the HP program and the General Health Survey were made, and analysis of data undertaken.

Whilst the collection of data was undertaken to establish figures for the effectiveness and safety of HP, and was continuous from 1986 to 2003, the description of research methods and results will be made in three parts:

1. The Initial HP Data Collection
2. The Second HP Data Collection
3. The General Health Survey.


FLOWCHART OF CHRONOLOGICAL DEVELOPMENT OF RESEARCH
1986 – Data collection began for people using Golden's HP Program.
1997 – 10 years HP data analysed showing 89% effectiveness, less than 2% reactions per dose, and high long-term safety. Weaknesses in analysis identified.
1998 – New 5-year HP data collection and analysis period begins, to expand data base and to rectify weaknesses identified in the analysis of 10 year data.
2001 - Follow-up questionnaires for HP non-respondents study begins.
– Distribution of questionnaires for the General Health Survey begins to provide comparative data on the safety and effectiveness of HP.
2002 – Completion of survey of non-respondents to HP study.
- Survey of homoeopathic practitioners' use of HP
– Collection of General Health Survey questionnaires.
2003 – Final data collection for 5-year HP study, plus survey of selected parents to confirm exposure to disease, and diagnosis of disease.
- Final data collection of General Health Survey
- Analysis of all data.

4 Research Methods

4.1 Initial Research of a Specific Homoeoprophylaxis Program

Golden first prepared a five-year HP program in 1986 after researching the topic in the homoeopathic literature. The original program was changed in 1991 due to clinical experience suggesting that “triple doses” (three doses in 24 hours), usually using ascending potencies (200; 1,000; 10,000) would lessen the possibility of accidental antidoting of the remedies given (due to errors in the administration of a dose), and offer longer and more effective protection (Golden 1990).

The program currently is delivered to patients in the form of a program of 20 different medicines with comprehensive instructions. The program recommends 28 doses (a “triple dose” being regarded as a one dose) of various medicines to be taken over 5 years, each dose being spaced at least one month apart.

HP remedies are provided to offer protection against Whooping Cough, Diphtheria, Tetanus, Polio, Measles, Mumps and Hib Meningitis. The suggested dates of remedy administration begin at one month of age, but instructions guide parents of children who are older than one month.

The current program and the original program, both consisting of remedy schedules called a “Main Program” and a “Supplementary Program”, are described in detail in Appendix 1 in the Tables 1.1-1 to 1.1-6.

4.1.1 Research Design of Initial Research

The specific HP programs described above were researched using a prospective longitudinal trial of children using the programs.

4.1.1.1 The Study Population

Given that Epidemiology may be viewed as based on two fundamental assumptions, namely that human disease does not occur at random and that it has causal and preventive factors that can be identified through the systematic investigation of different populations or subgroups of individuals within a population in different places or at different times, this survey was a population-based study where all children whose parents received Golden's HP program from 1st March 1986 to 28th February 1996 were eligible for inclusion.

The total number of eligible children is unknown due to incomplete records of HP programs supplied. It is estimated that approximately 2,000 programs were directly distributed to parents by Golden with others being supplied to practitioners for use with their own patients.

4.1.1.2 The Study Design

Use of questionnaires is an essential epidemiological tool. The study was a self administered, annually requested, questionnaire based study completed by parents of the participating children and returned by post.

Each questionnaire covered the preceding year of the child's life and asked questions relating to the child's experience with the program, including any reactions to the medicines in the program, the child's exposure to infectious diseases, and his or her infectious disease history. A general question inviting any other comments was also included (see Appendix 1, Tables 1.2-1 and 1.2-2).

Only infectious diseases covered by the remedies in the HP program were studied.

The first questionnaire was given to parents when they purchased a program, and is shown in Table 1.2-1 of Appendix 1. They were asked to complete and return a questionnaire for each child in the February that fell at least 12 months following the

acquisition of the program. These questionnaires were allocated into 10 groups (Series 1-10). The first annual questionnaires were collected for ten years on 28th February 1988 through to 28th February 1997.

A similar follow-up questionnaire was sent every subsequent February to those parents who returned a prior year's questionnaire, and is shown in Table 1.2-2 of Appendix 1. Subsequent annual questionnaires were collected on 28th February 1989 through to 28th February 1997.

An analysis of the 10-year data collection to 28th February 1997 comprising 1,305 responses was published (Golden 1997). 220 further returns were accepted as part of this study from 1st March 1997 to 31st May 2003.

Epidemiological findings are often based partly or completely on responses to questionnaires which are used extensively for collecting information on exposures, outcomes, modifiers and confounders. The adequate preparation of the questionnaires in the study of this thesis was thus essential for the quality of the data expected. The attention given to the development of the questionnaire and its validation was paramount for its eventual implementation, noting specifically design, population selection and sampling biases.

The research upon which this thesis is based represents primarily and observational design with some prospective elements, but without a concomitant comparison group recruited similarly from the community. Good observational data is often needed to provide the foundation for the design of randomized controlled trials.

Among the major aims of epidemiology has been to describe the health status of populations, to explain the aetiology of disease, to predict disease occurrence and hence to control the distribution of disease (Rothman and Greenland, 1998). Associations between the causes and the occurrence of disease can be discovered from investigations into case studies, by experimental laboratory studies and by field studies that add a distinct descriptive profile to the data. These studies are based on direct personal investigator observations that may relate an outcome of interest to an anatomical part or

physiological process which even though it can be systematically quantified remains at best qualitative in nature. Although these observations can be extremely intensive and of great detail, the inherent disadvantage is that they are subjective in their very nature and therefore subject to some degree of variation between cases studies (Susser 1973). Studies in which validity is less secure have been often referred to as hypothesis generating studies to distinguish them from the so called analytic studies in which validity may be better.

Approaches for connecting observations and theories have been studied by philosophers since the beginning of the last century (Kuhn, 1970; Pearson 1937; Popper 1960). In recent years, it has become increasingly evident that the science of epidemiology has inherent limits. Although epidemiology is very effective in identifying strong links between an environmental factor and a disease (for example, the link between smoking and lung cancer), it is less effective in discerning weaker associations.

Observational studies have several important roles in medical research. They are often the first foray into a new disease or area of inquiry—the first scientific step toward understanding a relationship between a factor an outcome of interest (Hulley SB, et al , 2001). They document the health of populations and often prompt more rigorous studies.

Since observational studies are often reported, clinicians need to know their uses, strengths, and weaknesses. An observational study is very much concerned with and designed only to describe the existing distribution of variables, without regard to causal or other hypotheses (Fletcher and Fletcher, 1979). Further, observational studies are often the first, tentative approach to a new event or condition. These studies generally emphasise features of a new disease or assess the health status of communities. Health administrators use descriptive studies to monitor trends and plan for resources. By contrast, epidemiologists and clinicians generally use observational reports to search for clues of cause of disease—i.e., generation of hypotheses. In this role, observational studies are often a springboard into more rigorous studies with comparison groups.

Common pitfalls of observational reports include an absence of a clear, specific, and reproducible case definition, and interpretations that overstep the data. Studies without a comparison group do not allow conclusions about cause of disease. However without them many hypotheses would never be generated or subsequently tested for validity.

This study allows for the generation of a hypothesis that the use of an appropriate long-term HP program can provide a level of protection against targeted infectious diseases without incurring long-term weakening of the recipients overall wellbeing.

4.1.1.3 Selection Bias

In epidemiological studies selection bias is a distortion in a measure of association (rate ratio, risk ratio, or odds ratio). Selection bias usually occurs as a result of either using improper procedure for obtaining persons from the target population to become members of the study population or as a result of factors that influence continued participation of subjects in a study. Selection bias occurs when the association between exposure and disease is different for those who complete a study compared with those who are in the target population, the overall population for which the measure of effect is being calculated and from which study members are selected.

There are different sources of bias and these include:

Selective health outcomes and losses to follow-up – After enrolment of subjects and collection of baseline data there is usually some loss to follow-up with some individuals dropping out of the study. This biases the study when the association between risk factor and disease differs in dropouts compared with study participants.

Volunteer and non-response bias – Individuals who volunteer for a study may possess different characteristics than the average individual in the target population. Individuals who do not respond to requests to be studied generally have different baseline characteristics than responders. Bias will be introduced if the association between exposure and disease differs between study volunteers and non-responders.

Further, selection bias will occur as a result of the procedure used to select study participants when the selection probabilities of exposed and unexposed cases and controls from the target population are differential and not proportional. This can occur when exposure status influences selection.

Recall bias may arise because individuals with a particular exposure or adverse health outcome are likely to remember their experiences from those who are not similarly affected.

Although it is very difficult to determine precisely the impact of a potential source of bias actually has on estimate of effect it remains crucial to attempt to identify the magnitude as the direction of the bias for any estimate.

In the study of this thesis bias may have been present due to all questionnaire returns being voluntary, and reflected each parent's interest in participating in the research, as well as their intellectual ability to understand and be able to complete a questionnaire. It also reflected each parent's ability to keep the questionnaire for at least a year, or ability to receive forwarded mail when they changed address during that period.

Bell and others have described the potential for bias due to participants in homoeopathic trials being also regular users of homoeopathy, and therefore more healthy in general (Bell et al, 2004, pp. 269-283). This bias appears not to be a significant factor in this study as it has been observed anecdotally that the clear majority of children using the HP program being studied in this thesis had never used homoeopathic treatment previously (Golden, 2002a, p. 27).

There is potential bias in figures for both diseases and exposure to diseases due to the information being based on parent's opinions. The follow up questionnaires sent to parents in the Second HP Study were designed to minimise this bias (see Appendix 1, Tables 1.4-1 and 1.4-2).

The potential bias due to non-responses was addressed through the survey of non-respondents in the Second HP Study (see Appendix 1, Table 1.3-1).

Epidemiological findings are often based partly or completely on responses to questionnaires, which are used extensively for collecting information on exposures, outcomes, modifiers and confounders. Obviously, the use of an invalid instrument is a waste of resources. The adequate preparation of questionnaires was thus essential for the quality of data. Detailed attention was given to questionnaire development and validation in the study of this thesis.

Most of the developmental work of relevance to epidemiology has been carried out in the area of outcome measures, usually of non-observable outcomes such as depression, headache and intelligence. Relatively little work has been undertaken to develop questionnaires related to exposures, with certain exceptions. Certainly the study of this thesis may be viewed as such an exception.

Indeed, questionnaire development involved understanding the concerns of willingness to respond, discriminatory power, comparability, responsiveness/reliability and validity of data from previous experiences reported by Golden.

No pilot study was undertaken in 1986 to validate the original questionnaire. The basic questionnaire was fine tuned over the fifteen years of the study to improve the layout of questions. There was no change over that time to the questions asked, as the resulting data was providing the information needed by the researcher.

Further, well constructed questionnaires exist, however they are not always used by other researchers and opportunities for improvement are thus missed. Frequently, questionnaires are designed with little if any consultation of past research experience with similar measurement tools. In the study of thesis improvement of the original questionnaire was undertaken with the new health survey.

4.1.1.4 Sample Size

Statistical studies (surveys, experiments, observational studies, etc.) are always better when they are carefully planned.

A hypothesis test gives the probability of the desired outcome result occurring, if the null hypothesis is false. If the probability is lower than a pre-specified value (alpha, usually 0.05), it is rejected. This can be likened to a search process where one searches for evidence to reject the null hypothesis, in the same way that one may search for the presence of a chemical in an environment.

The ability to reject the null hypothesis depends upon:

Alpha (a): Usually set to be 0.05, although this is somewhat arbitrary. This is the probability of a type I error, that is the probability of rejecting the null hypothesis given that that the null hypothesis is true. To use the search analogy, it is the probability of thinking we have found something when it is not really there.

Sample size: A larger sample size leads to more accurate parameter estimates, which leads to a greater ability to find what we were looking for. The harder we look, the more likely we are to find it.

Effect Size: The size of the effect in the population. The bigger it is, the easier it will be to find.

Power analysis allows us to make sure that we have looked hard enough to find it. The size of the parameter we are looking for is known as the *effect size*. Several methods exist for deciding what effect size we would be of interest. Different statistical tests have different effect sizes developed for them however the general principle is the same.

The total sample comprised 637 children whose parents received Golden's HP program and who returned at least one questionnaire. Of the 1,525 completed questionnaires received by 31st May 2003, 637 were received after the first year of using the program, and a further 888 questionnaires were received during following years. These returns are shown in Table 4.1-1 following.

Table 4.1-1 Respondents to Series 1-10

15 Year Clinical Study - 1988 to 2002 - Responses Received															
	Sur.1	Sur.2a	Sur.2b	Sur.3	Sur.4	Sur.5	Sur.6	Sur.7	Sur.8a	Sur.8b	Sur.9	Sur.9	Sur.9	Sur.9	Sur.9
Series	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
1	50	40	23	19	11	11	9	6	0	0	0	0	0	0	0
2		39	13	8	11	10	4	6	0	0	0	0	0	0	0
3			48	25	18	15	7	10	1	1	0	0	0	0	0
4			2	60	47	33	26	18	0	1	3	3	0	0	0
5					55	30	24	20	1	0	0	0	0	0	0
6						135	77	65	34	32	1	0	0	0	0
7						3	64	25	13	13	0	0	0	0	0
8								48	20	22	14	12	10	6	4
9								3	43	14	11	12	10	7	5
10										42	19	18	17	16	2
Total	**50**	**79**	**86**	**112**	**142**	**237**	**211**	**201**	**112**	**125**	**48**	**45**	**37**	**29**	**11**
					Total Responses Series 1-5					708		Group A			
					Total Responses Series 6-10					817		Group B			
					TOTAL RESPONSES					**1525**		**Total Groups**			

4.1.1.5 Compliance

Data to allow calculation of the response rates showing the proportion of questionnaire returns from eligible parents was not kept. One aim of the Second HP data collection over 5 years was to calculate precise response rates for the return of the first year's questionnaire.

4.1.1.6 Analyses

Responses to the questionnaires were checked and coded by one person. Another person entered data into a computer, and a data check was carried out. All responses indicating either exposure to disease or acquisition of a disease were re-checked and inconsistencies corrected, e.g., responses that stated the child contracted a disease but did not report exposure to the disease were adjusted to show that exposure did occur.

A ratio analysis was performed to show the proportion of reactions to the program, the proportion of exposure to targeted diseases, the proportion of diseases to the total population of the study, and the proportion of diseases to the group that reported exposure to the targeted diseases.

Results were tabulated progressively, with a major analysis of the first 10 years data being undertaken and published in 1997 (Golden 1997). A full analysis of an additional 5 years of data collection was undertaken as part of this thesis. This included data checking and inclusion of 220 late responses up to 1st March 2003.

The **effectiveness** of the program was examined by finding the proportion of

The number of children who did **not** acquire an infectious disease covered by the program, whose parents reported exposure to the disease, and who received the preventative remedies associated with the particular disease, **to**

The number of children whose parents reported exposure to the particular disease covered by the program, and who received preventative remedies associated with the disease.

Even though the parental assessments of exposure are subjective, the elimination of cases of non-exposure is designed to improve the validity of the reported figure for effectiveness.

There are two potential errors (titled E1 and E2) in this figure for effectiveness that have opposite effects on the data:

(E1) some parents would have reported exposure to a disease when in fact exposure did not occur. For example, they may have assumed exposure occurred because the disease appeared among other children in their child's school, playgroup, family, etc., but in fact their child was not exposed.

(E2) some parents would not have reported exposure when in fact exposure did occur. For example, their child was exposed to a disease at their school, playgroup, etc., but because the child did not contract the disease the parents did not know that their child had been exposed. It should be noted that over the entire length of the study only one possible exposure to polio was reported; yet it is known that if a child plays with a recently (orally) vaccinated child then exposure is possible.

A third potential error (E3) related to the reliability of the parents report of a disease.

Two further potential weaknesses of the study were that (1) no control group was available against which to compare the results of the research, and (2) no precise data on parental response rates were available.

An attempt to evaluate the extent of these three potential errors and two weaknesses was made in the Second HP study

The **safety** of the program was assessed in two ways.

The first method examined the number of reactions to doses of remedies experienced by children using the program. The proportion of reactions per respondent child was initially calculated, and then adjusted to estimate the proportion of reactions per individual dose.

This latter figure was calculated assuming that each child would have 6 doses of medicine per year. This is less than the number of suggested doses in the first year of the program (10) but takes into account that many parents miss doses due to illness of the child when doses are suspended, or due to simple forgetfulness. It also takes into account the reduced number of doses suggested in the second and subsequent years of the program.

Parents' comments on the intensity and duration of reactions were also collected.

A second method to assess safety was employed where the general comments made by those respondents who chose to answer the question "any other comments" were examined. The comments were analysed to reveal positive and negative comments concerning the general health of children using the program.

Safety and effectiveness figures were reported in Chapter 5 for each individual disease covered by the program, as well as total figures for all diseases (Golden, 1997).

4.1.1.7 Composition of HP Remedies

All remedies were purchased from Brauer Biotherapies in liquid form. Unmedicated pilules made from maize starch were then medicated using the drops.

4.1.1.8 The Choice of Remedies used in the HP Program

The remedies used in the current HP program are described in detail in Appendix 1 in the Tables 1.1-1 to 1.1-6.

The choice of remedies used was based on previous experience in homoeoprophylaxis as described in Section 2.3 above. The choice of potencies and doses were originally determined on this previous experience, and later modified on the basis of the researcher's own experiences. The conceptual and practical reasons supporting the remedies used in the HP program are discussed in detail elsewhere (Golden, 2001, pp. 7-32).

4.2 Second Study of a Specific Homoeoprophylaxis Program

The purpose of the Second HP Study (titled Research Project A1) was to test the validity of the figures for safety and effectiveness reported in Table 5.1-1, and to deal with the potential errors and weakness in the Initial HP Study described in section 4.1.1.6 above. This was done in four ways:

- collect new figures for the safety and effectiveness of the program for 5 years from 1998 to 2002 (Series 11-15), and ensure that the first-year responses account for over 70% of parents who purchased programs during that period (to provide a representative sample).
- survey non-respondents to see if their experience with the program is similar to or different from the experience of respondents. This will verify whether the responses received accurately depict the experience of the entire group.
- make a comparative analysis of the new data and the existing data. This includes a comparison of the results using HP with national attack rates for the diseases being studied, thus providing a limited but available control group against which to compare results.
- survey respondents who said their children were either exposed to targeted diseases, and/or contracted targeted diseases to verify the resulting figures for effectiveness. This will also provide some indication of the extent of the biases E1, E2 and E3 mentioned in 4.1.1.6 above.

4.2.1 Research Design of Second HP Research

The methodology of the basic questionnaire survey of the additional research population is identical to the prospective longitudinal method reported in 4.1.1 above.

In addition, non-respondents were sent a special questionnaire in order to provide confirmation that the original responses were representative of the total group. This questionnaire is shown in Table 1.3-1 in Appendix 1.

As well, a special questionnaire was sent to those respondents who said that their child had contracted an infectious disease covered by the main program, and another to those who said their child had been exposed to a disease covered by the main program. The questionnaires are shown in Appendix 1 in Table 1.4-2 and Table 1.4-3 respectively.

4.2.1.1 The Study Population

This survey was a population-based study where all children whose parents received Golden's HP program from 1st March 1996 to 28th February 2001 were eligible for inclusion. 622 children were entered into the study on the basis of questionnaires given to their parents.

4.2.1.2 The Study Design

The study was identical to the study design reported in section 4.1. It was a self administered, annual, questionnaire based, postal study completed by parents of the participating children.

As with the previous study, each questionnaire covered the preceding year of the child's life and asked questions relating to the child's experience with the program including any reactions to the kit, their exposure to infectious diseases, and their infectious disease history.

The first questionnaire was given to parents when they received Golden's HP program, and is shown in Table 1.2-1 of Appendix 1. They were asked to complete and return the questionnaire in the February that fell at least 12 months following the acquisition of the program. These parents were allocated into 5 groups (Series 11-15). First annual questionnaires were collected on 1st February 1998, 1999, 2000, 2001, and 2002.

A similar follow-up questionnaire was sent every subsequent February to those parents who returned a prior year's questionnaire, and is shown in Table A1.2-2 of Appendix 1. Subsequent annual questionnaires were collected on 28th February 1999, 2000, 2001, and 2002.

Thus questionnaires were progressively collected from 28th February 1998 to 2002, with late returns being accepted up to 31st May 2003.

4.2.1.3 Selection Bias

As with the previous ten year study, bias is present due to all questionnaire returns being voluntary, and reflected each parent's interest in participating in the research, as well as their intellectual ability to understand and be able to complete a questionnaire. It also reflected each parent's ability to keep the questionnaire for at least a year, or ability to receive forwarded mail when they changed address during that period.

There is potential bias in figures for both diseases and exposure to diseases due to the uncertainty of the information, based as it is on parents' opinions. The follow up questionnaires sent to parents were designed to minimise this bias.

The potential bias due to non-responses was addressed through the survey on non-respondents.

4.2.1.4 Sample Size

The total sample comprised 424 children whose parents received Golden's HP program and who returned at least one questionnaire. Of the 817 completed questionnaires received by 31st May 2003, 424 were received after the first year of using the program, and a further 393 questionnaires were received during following years.

The responses are shown in Table 4.2-1 below.

Table 4.2-1 Respondents to Series 11-15

5 Year Clinical Study - 1998 to 2002 - Responses Received					
	Sur.9	**Sur.9**	**Sur.9**	**Sur.9**	**Sur.9**
	1998	**1999**	**2000**	**2001**	**2002**
11	72	41	21	17	29
12		78	47	36	30
13			97	61	57
14				90	54
15					87
Total	**120**	**164**	**202**	**233**	**268**
Total Responses Series 11-15			817		

4.2.1.5 Compliance

The initial first year response rate from Series 11-15 participants of 68.2% is shown in Table 4.2-2 below. The follow up of non-respondents (discussed in 5.2.9 below), excluding accounting for returned mail, caused the accountability rate to increase to 74.9%.

Table 4.2-2 Percentage of Responses after One Year to Questionnaires Given with Program or Sent Out Later

Series 11-15					Including Initial Non-Respondents		
Series	**Received**	**Sent**	**Response Rate**		**Extra Received**	**Total Questionnaires Accounted For**	**Adjusted Response Rate**
15	87	142	61.3%		12	99	69.7%
14	90	155	58.1%		16	106	68.4%
13	97	122	79.5%		5	102	83.6%
12	78	106	76.3%		5	83	78.3%
11	72	97	74.2%		4	76	78.4%
	424	**622**	**68.2%**		**42**	**466**	**74.9%**

Note: 53 (25%) responses were received from the follow-up questionnaires sent to the original 209 non-respondents. 11 of these also returned completed questionnaires with their response, which are included in the total received of 424. Thus, 42 responded without sending in questionnaires. The 14 responses for Series 11, 12 and 13 were collected at the same time and thus could not be allocated to each series with certainty due to the confidentiality of the follow-up questionnaire that had no identifying numbering. These 14 have been randomly allocated over the three series.

4.2.1.6 Analyses

The data from the questionnaires responses were checked and coded by one person. Another person entered data into a computer twice, and a data check was carried out. All responses indicating either exposure to disease or acquisition of a disease were re-checked and inconsistencies corrected, e.g., responses that stated the child contracted a disease but did not report exposure to the disease were adjusted to show that exposure did occur.

A ratio analysis was performed to show the proportion of reactions to doses during the program, the proportion of exposure to targeted diseases, the proportion of diseases contracted to the total population, and the proportion of diseases to the group that reported exposure.

The **effectiveness** of the program was examined by finding the proportion of

The number of children who did **not** acquire an infectious disease covered by the program, whose parents reported exposure to the disease, and who received the preventative remedies associated with the particular disease, **to**

The number of children whose parents reported exposure to the particular disease covered by the program and who received preventative remedies associated with the disease.

The elimination of cases of non-exposure is designed to improve the statistical value of the reported figure for effectiveness.

95% confidence limits were calculated for the figure for effectiveness.

The analysis of follow-up questionnaires that were sent to selected respondents reporting exposure and disease were designed to account for the three potential errors (described in 4.1.1.6 above as E1, E2 and E3) in the figure for effectiveness.

A further analysis involving calculation of the odds ratio and Chi Squared probability for different national disease attack rates was also completed to provide an effective control group against which to compare the figure for effectiveness.

The **safety** of the program was assessed in two ways.

The first method examined the number of reactions to doses of remedies in the kit experienced by children using the kit. The proportion of reactions per respondent child was initially calculated, and then adjusted to estimate the proportion of reactions per individual dose.

This latter figure was calculated assuming that each child would have 6 doses of medicine per year. This is less than the number of suggested doses in the first year of the program (10) but takes into account that many parents miss doses due to illness of the child when doses are suspended, or due to simple forgetfulness. It also takes into account the reduced number of doses suggested in the second and subsequent years of the program.

Parent's comments on the intensity and duration of reactions were also collected and analysed to further assess the short-term safety of HP.

A second method to assess long-term safety was employed where the general comments made by those respondents who chose to answer the question "any other comments" were examined. The comments were analysed to reveal positive and negative comments concerning the general health of children using the program.

Safety and effectiveness figures are reported for each individual disease covered by the program, as well as total figures for all diseases.

4.3 General Health Survey

A retrospective health survey of children aged between four and twelve years of age was undertaken to further examine the safety and effectiveness of HP.

Children aged between 4 and 12 years of age were targeted for two reasons: (1) if children were too young (i.e., <4) there would not be sufficient health history to reasonably assess their level of health, and (2) if they were too old (i.e., > 12) then too many other factors other than the ones under study could have influenced their health.

A number of early childhood factors were examined in the questionnaire. The one that is relevant for the purposes of this study was the immunisation history of the child. Four different types of immunisation history were questioned. They were:

Homoeoprophylactically protected.

Vaccine protected.

"Constitutionally" protected, (i.e., any general health measures intended to improve overall health, and thus improve overall immunity against all infectious diseases).

No specific protection against infectious diseases.

Because of the possible combinations of alternatives, eight different categories were examined. They were:

Homoeoprophylaxis only.

Vaccination only.

General/constitutional protection only.

Homoeoprophylaxis and vaccination.

Homoeoprophylaxis and general protection.

Vaccination and general protection.

Homoeoprophylaxis, vaccination and general protection.

No method of protection.

The earlier work of Dr M. Odent and colleagues is acknowledged. Although they were investigating the long-term health advantages of breastfeeding, they discovered a link between immunisation status and conditions such as asthma and eczema through a questionnaire based study somewhat similar to that used in the General Health Survey (Odent et al., 1994a, p.140; Odent et.al, 1994b, pp.592-3).

4.3.1 Research Design of the General Health Survey

A retrospective questionnaire-based survey was used. The questionnaire is shown in Table 1.5-1 in Appendix 1.

4.3.1.1 The Study Population

This survey was a population-based study where all persons who expressed an interest in participating in the General Health Survey were sent a questionnaire for each of their eligible children.

Practitioners who expressed an interest in distributing questionnaires to their patients were sent quantities of questionnaires. Questionnaires were also handed out in public lectures offered by Golden in Western Australia, Queensland and Victoria. Quantities of questionnaires were also sent to primary schools that expressed an interest in distributing them.

The total number of parents receiving questionnaires is unknown. The total number of questionnaires distributed was approximately 5,000.

4.3.1.2 The Study Design

The study was a self-administered, questionnaire based, postal study completed by parents of eligible children.

Each questionnaire asked general questions about the child such as their age and sex (see Appendix 1, Table 1.5-1, for the General Health Survey questionnaire).

Questions were asked examining early childhood factors such as birth weight, gestation, APGAR scores, length of breastfeeding and method of disease prevention.

The child's health experience with asthma, eczema, ear and hearing problems, allergies and behavioural problems was examined, as was the parents' evaluation of their child's general health.

Cases of whooping cough, measles and mumps were recorded, as was each child's hospitalisation experience.

With both health conditions and infectious diseases, respondents were asked whether a diagnosis by a medical practitioner was made.

The variables noted above were not used as screening data to either accept or reject participants in the study, with the exception of the variable for age. It was decided to accept into the study only children aged between 4 and 12 years of age in order to ensure that a child had sufficient health experience to make the results meaningful (was at least four years of age) but was not so old as to introduce too many other possibly confounding variables. The selection of these age limits was subjective, and based on what the researcher felt was reasonable.

The choice of the other early childhood factors was subjective, but was intended to include factors that were commonly seen as possibly influencing later childhood development. The choice of the three infectious diseases was based on the fact that they were covered in the orthodox vaccination schedule and the HP program, and that there was a positive incidence of the diseases in the Australian community (Australian Bureau of Statistics, 2003d). The choice of the health conditions being studied was subjective, but was intended to include common health problems of childhood.

A small pilot study was undertaken to determine whether prospective respondents could understand the meaning of the questions and respond appropriately. The study was also used to test the value and relevance of questions. The pilot study revealed that asking questions regarding a child's APGAR scores and receipt of Vitamin K injection would add to the potential value of the questionnaire in terms of relevant information being provided that may confound the final results.

4.3.1.3 Selection Bias

Bias is likely due to all questionnaire returns being voluntary, and reflected each parent's interest in participating in the research, as well as their intellectual ability to understand and be able to complete a questionnaire.

Bias also existed due to the Education Departments in N.S.W. and the Northern Territory refusing to allow the questionnaire to be distributed in their State Primary Schools. Also, parents who did not use the natural health media, or attend lectures offered by Golden, would have been unlikely to know of the survey.

4.3.1.4 Sample Size

All children, whose parents answered a questionnaire from 1st March 2002 to 31st October, 2003 were included.

850 questionnaires were received by 31st October 2003. Following data entry, 69 questionnaires were separated from the central analysis as the ages of the children were either below 4 years of age or above 12 years of age. Thus 781 questionnaires were accepted into the main GHS study.

4.3.1.5 Compliance

Two types of approaches were made to parents to attract participants.

The first involved advertising the research in a variety of health journals, on the Internet, and at public lectures conducted by Golden.

The second involved sending questionnaires to a number of schools around Australia and requesting parents to participate in the survey.

There were 495 responses obtained through general advertising, and 286 responses via the school system. The exact rate of responses, through each system is unknown.

2,401 questionnaires were sent to primary schools. It is not known how many were actually given to parents, as some schools said they would advertise the survey in their school newsletter and leave it up to interested parents to collect questionnaires if they wished.

However an estimate of compliance (the rate of response) through the participating primary schools is 15%.

Questionnaires were posted to parents who contacted Golden. The rate of response from this source is estimated at greater than 90%.

The number of questionnaires handed out at public lectures and by practitioners is unknown. However a response rate of less than 20% is probable.

It is reasonable to assume that the overall response rate of parents of eligible children who received questionnaires is below 50%.

4.3.1.6 Analyses

Data and respondent details were checked and coded by one person. Responses were entered into a computer by a second person. Another person then checked the data output, and any required corrections were made.

The **effectiveness** of HP used by participants in the General Health Survey was measured in the following ways.

The following proportion measured the absolute effectiveness of HP for each of the three diseases studied:

Effectiveness (GHS) = children in the study who used HP but who did not contract the disease

all children in the study who used HP

Figures were calculated for all respondents, as well as for those where the disease was diagnosed by a GP.

The relative effectiveness of HP was determined by calculating the proportion shown above for each method of disease prevention, together with 95% confidence limits.

Also the Odds Ratio and Chi Squared probabilities were calculated for the four non-combined methods of disease prevention.

Once again, figures were also calculated for GP-diagnosed diseases.

The **safety** of the HP programs used by participants in the General Health Survey was calculated using the following two ratios for the five conditions (asthma, eczema, ear/hearing, allergies and behavioural problems) and the three diseases (whooping cough, measles, mumps) studied as part of the GHS.

1. Proportion (SHP1) = $\frac{\text{Condition (using HP only)}}{\text{All Persons (HP only)}}$

2. Odds Ratio (SHP2) = $\frac{\text{Condition (using HP only)}}{\text{No Condition (HP only)}} / \frac{\text{Condition (not using HP)}}{\text{No Condition (not using HP)}}$

The Chi Squared probability for each Odds Ratio was calculated.

The same figures were also calculated for GP-diagnosed conditions and diseases.

The relative safety of HP was also assessed by comparing Odds Ratios and Chi Squared probabilities for the four non-combined preventative options and the five health conditions studied.

Measures that were statistically significant were compared to determine the relative safety of HP only, vaccination only, general protection only and no preventative method.

A participant profile of respondents to the General Health Survey was undertaken in Chapter 5.3 to determine if the participants were typical of the Australian population.

A comparison between responses collected in the general community and responses collected through schools was made in Chapter 5.4 using simple proportions.

Finally, a comparison of responses using a HP program that either was or was not supplied by Golden was undertaken in Chapter 5.5 using simple proportions, Odds Ratios with Chi Squared probabilities as well as cumulative rankings of general wellbeing. No information was available on the different types of programs used by respondents, but variations from Golden's long-term program in remedies used, potencies and doses would all be expected.

Results Assessing the Safety and Effectiveness of Homoeoprophylaxis

Introduction

The results of the three stages of investigation into the effectiveness and the safety of HP are reported below. Effectiveness and safety are examined separately showing the progressive development of results from the three groups of research data:

1. The Initial HP Data Collection (Golden's data Series 1-10)
2. The Second HP Data Collection (Golden's data Series 11-15)
3. The General Health Survey.

The following flow chart shows the manner in which the measures of effectiveness progressed from the publication of the Series 1-10 effectiveness of 88.8% in 1997, through to the collection of additional data and surveys designed to address weaknesses identified in the original data.

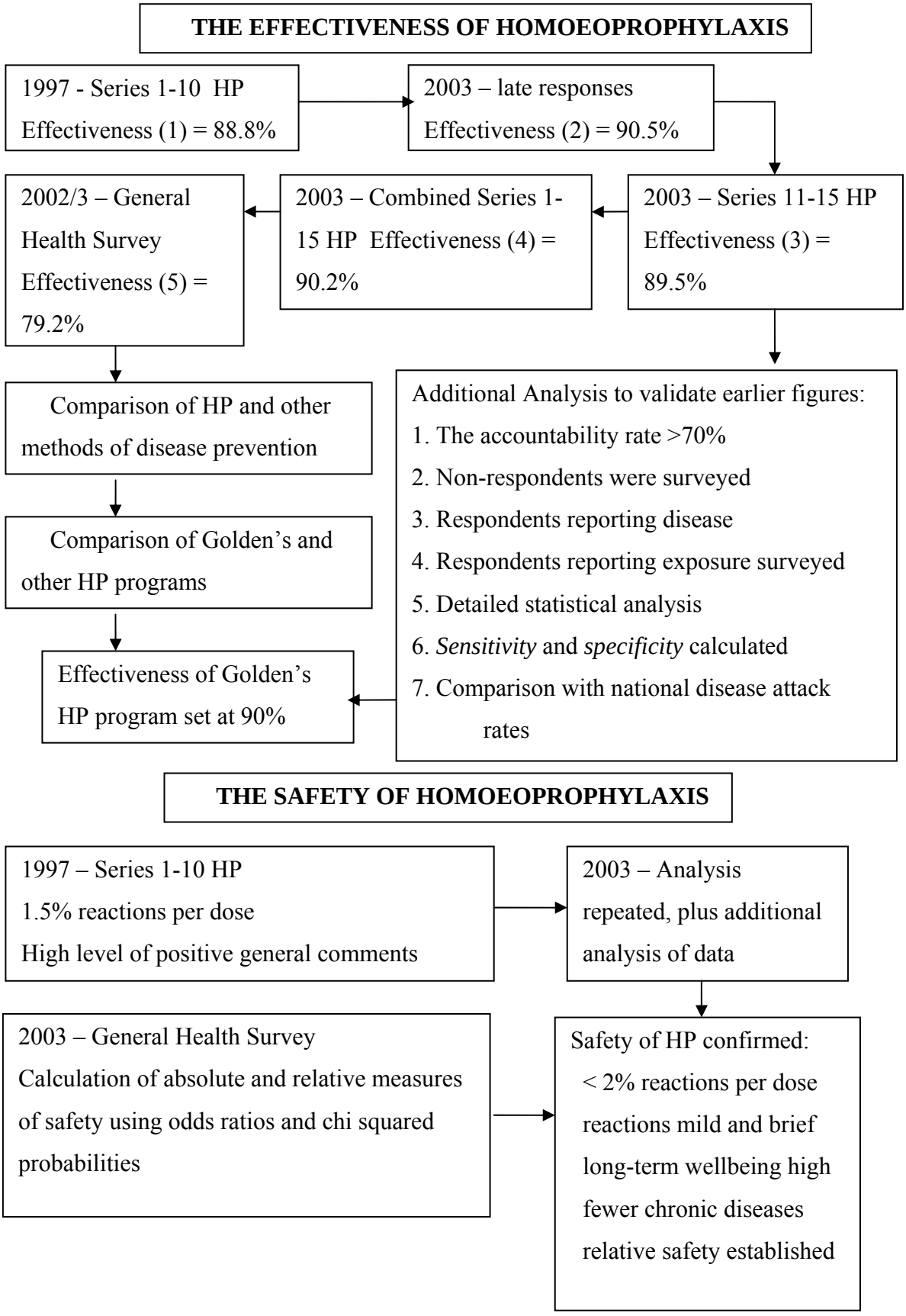
The chart further shows how the measures of safety progressed from a simple proportion of the reactions to the remedies in the program and the analysis of general comments, to a detailed statistical analysis of the relationships between the use of HP and the incidence of chronic conditions such as asthma and eczema, as well as a comparative analysis involving other methods of disease prevention.

Three additional analyses are reported.

The first presents a descriptive profile of respondents to the General Health Study in order to determine whether the respondents to the study are representative of the general community.

The second presents an analysis of the effectiveness and safety of general HP programs used by participants recruited through the school system, and other participants.

The third presents an analysis of the effectiveness and safety of HP programs supplied by Golden, compared to HP programs not supplied by Golden.


THE EFFECTIVENESS OF HOMOEOPROPHYLAXIS
1997 - Series 1-10 HP
Effectiveness (1) = 88.8%
2003 – late responses
Effectiveness (2) = 90.5%
2003 – Series 11-15 HP
Effectiveness (3) = 89.5%
2003 – Combined Series 1-15 HP Effectiveness (4) = 90.2%
2002/3 – General Health Survey
Effectiveness (5) = 79.2%
Comparison of HP and other methods of disease prevention
Comparison of Golden's and other HP programs
Effectiveness of Golden's HP program set at 90%
Additional Analysis to validate earlier figures:
1. The accountability rate >70%
2. Non-respondents were surveyed
3. Respondents reporting disease
4. Respondents reporting exposure surveyed
5. Detailed statistical analysis
6. Sensitivity and specificity calculated
7. Comparison with national disease attack rates
THE SAFETY OF HOMOEOPROPHYLAXIS
1997 – Series 1-10 HP
1.5% reactions per dose
High level of positive general comments
2003 – Analysis repeated, plus additional analysis of data
2003 – General Health Survey
Calculation of absolute and relative measures of safety using odds ratios and chi squared probabilities
Safety of HP confirmed:
< 2% reactions per dose
reactions mild and brief
long-term wellbeing high
fewer chronic diseases
relative safety established

To facilitate reading this chapter, material has been broken into the following four sections:

1. The Effectiveness of HP (section 5.1)
   - The effectiveness of Golden's HP program
   - Additional tests to verify effectiveness
   - The effectiveness of HP programs in general

2. The Safety of HP (section 5.2)
   - Short-term safety of Golden's HP program
   - Long-term safety of Golden's HP program
   - The absolute safety of HP programs in general
   - The relative safety of HP programs in general

3. Participant Profiles from the General Health Survey (section 5.3)

4. Additional Analyses (sections 5.4 and 5.5)
   - A comparison of "school" and "non-school" respondents
   - A comparison of HP programs supplied by Golden, and programs not supplied by Golden

4.4 The Effectiveness of HP

The effectiveness of a HP program is defined as the simple proportion of children who were definitely exposed to a disease but who did not contract the disease, in relation to all children exposed to the disease.

$$\text{Effectiveness (HP)} = \frac{\text{exposed children who did not contract the disease}}{\text{all definite reports of exposure}}$$

The first full report describing the effectiveness of Golden's HP program, based on 1,305 responses from participants in data Series 1-10, showed the following effectiveness (Golden 1997, p. 7):

Effectiveness (1) = 88.8%

A further 220 questionnaires from Series 1-10 respondents were collected to 31st May 2003, making a total of 1,525 questionnaires to be analysed. The result was:

Effectiveness (2) = 90.5%

Note that this result is the average of the first five-year measure of effectiveness (Series 1-5) of 89.8% and the second five-year measure of effectiveness (Series 6-10) of 91.3%.

Finally, the third 5-year data collection of 817 responses (Series 11-15) was made to further test the consistency and therefore reliability of these earlier measures of effectiveness. The result was:

Effectiveness (3) = 89.5%

These three measures are summarised in Table 5.1-1, demonstrating an average effectiveness of Golden's HP program over the 15-year data collection period of 90.2%:

Effectiveness (4) = 90.2%

Table 4.4-1 Effectiveness of Golden's HP Program Over All Data Collection Periods

	Series 1-5		Series 6-10		Series 11-15		Series 1 - 15	
	No.	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
Responses	708		817		817		2,342	
Diseases	18		11		12		41	
Exposure to Diseases	177		127		114		418	
Effectiveness of the Program	159/177	**89.8**	116/127	**91.3**	102/114	**89.5**	377/418	**90.2**

A description of the limitations and potential errors in the first two measures of effectiveness was outlined in Chapter 4. The following seven additional tests were performed on Series 11-15 data in order to address the identified limitations of the earlier analysis (points 1-7 below), and two new measures of effectiveness were derived from the General Health Survey (points 8 and 9 below):

1. The accountability rate of the final 5-years' data was calculated to ensure a significant level of accountability (>70%) and thus greater reliability of results.
2. Non-respondents were surveyed to ensure that the questionnaires received gave responses that were reflective of the entire population.
3. Respondents who reported a disease were surveyed to verify the accuracy of their initial report.
4. Respondents who reported exposure to a disease were surveyed to verify the accuracy of their initial report.
5. A more detailed statistical analysis of the data was undertaken to determine the 95% confidence limits for the figure for the effectiveness of HP.
6. The accuracy of the measurements of effectiveness based on notifications of and exposure to diseases was tested by calculating the *sensitivity* and *specificity* of the data.
7. A comparison with national disease attack rates was undertaken to provide an effective control group against which to compare results.
8. Data collected during the General Health Survey were analysed to determine if a stand-alone effectiveness measure could be found.
9. Data collected during the General Health Survey were analysed to make a comparison between the effectiveness of HP and the effectiveness of the other methods of disease prevention examined in that Survey (vaccination and a general health approach), and also with no method of disease prevention.

4.4.1 Additional Research to Verify the Effectiveness of HP

4.4.1.1 Accountability Rate of Additional Data Collection

Data collected for a further 5 years from Series 11-15 participants resulted in the collection of 817 new questionnaires.

The accountability rate for the first responses to each of the five new annual data series was 74.9%, including replies by initial non-respondents. These figures are reported above in Table 4.2-1 (page 74 above). This is sufficient to suggest that the responses received were likely to reliably portray the experience of the entire study population. Surveying non-respondents further tested this possibility.

4.4.1.2 Follow-up of Non-Respondents

A survey of non-respondents was undertaken to determine whether the survey population was representative of all persons using the HP program. Replies were received from 53 (31.2%) of 170 non-respondents surveyed.

The survey questionnaire is shown in Appendix 1, Table 1.3-1. The full results are shown in the Tables of Results at the end of this chapter in Table 5.6-1.

In summary, those non-respondents who replied reported the following:

1. 43 (81.1%) of non-respondents had partially or fully used the kit.
2. 31 (58.5%) of non-respondents said the kit was successful in preventing disease, and none said it was unsuccessful. 15 (28.3%) either did not know, or did not use the kit.
3. When asked to rank their level of satisfaction with the kit, 14 (26.4%) did not respond to that question. 32 (60.4%) ranked their satisfaction between 8 and 10. Only 4 (7.6%) ranked their satisfaction between 1 and 5.
4. 35 (66.0%) of non-respondents stated that they would be prepared to participate in a general health survey of Australian children.

A clear majority of the non-respondents were satisfied with the HP program, and most felt it was successful in preventing disease. These views are consistent with the strong support for the HP program by those who responded to the annual questionnaires.

This demonstrates that the replies received from participants in the 5-year study, and therefore by implication the full 15-year study, were representative of the entire population of children using the HP program.

4.4.1.3 Follow-up of Respondents Reporting a Disease

In order to validate the accuracy of the actual responses made by parents who reported that their child contracted a disease covered by the HP program, after the relevant HP remedy had been administered, each of these parents were sent the questionnaire shown in Table 1.4-1 in Appendix 1.

The responses were recorded in four columns:

- The entry showed if a new classification was required, and what it was.
- If the initial classification was valid, the level of certainty was recorded as either – 1 = high certainty; 2 = medium certainty.
- The entry showed if the survey envelope was returned to sender.
- The entry showed if there was no response to the questionnaire (excluding returned mail).

These data are summarised below in Table 5.1-2, which shows the accountability and response rates to the survey of parents reporting a disease, and in Table 5.1-3, which shows the level of reclassification of results that was necessary.

Table 5.1-2 reports an accountability rate of 84.2%, with an actual response rate of 68.4%. This level is sufficient to suggest that the additional survey will give a reliable indication of the validity of all responses.

After reclassification, it was reported in Table 5.1-3 that the number of cases of definite diseases needed to be reduced from 12 to 11.

Whilst the level of accountability of responses was reasonable, the actual number of diseases was small. This makes an automatic extension of the result for Series 11-15 to the earlier data series problematic. However, what data are available suggests that the measures of effectiveness reported above are conservative.

4.4.1.4 Follow-up of Respondents Reporting Exposure to a Disease

In order to validate the accuracy of the actual responses made by parents who reported that their child was exposed to a disease covered by the HP program, after the relevant HP remedy had been administered, each of these parents were sent the questionnaire shown in Table 1.4-2 in Appendix 1. When a parent reported that their child had contracted a disease they were not contacted to verify exposure.

In order to validate the accuracy of their reports, each of these parents were sent the questionnaire shown in Table 1.4-5 in Appendix 1. When a parent reported that their child had contracted a disease they were not contacted to verify exposure.

The classification of responses is shown in Table 1.4-6 in Appendix 1. The responses were recorded in four columns:

- The entry showed if a new classification was required, and what it was.
- If the initial classification was valid, the level of certainty was recorded as either – 1 = high certainty; 2 = medium certainty.
- The entry showed if the survey envelope was returned to sender.
- The entry showed if there was no response to the questionnaire (excluding returned mail).

These data are summarised below in Table 5.1-2, which shows the accountability and response rates to the survey of parents reporting exposure to a disease, and in Table 5.1-3, which shows the level of reclassification of results that was necessary.

Table 5.1-2 reports an accountability rate of 59.5%, with an actual response rate of 51.4%. This level is not high enough to give a reliable indication of the validity of all responses.

After reclassification, it was reported in Table 5.1-3 that there were six cases where the classification was downgraded to “uncertain” and five cases where the classification was upgraded to “definite”. The net result was that the number of cases of definite exposure to diseases needed to be reduced from 114 to 113.

The level of accountability of responses was not adequate to make an automatic extension of the result for Series 11-15 to the earlier data series. However, what data are available once again suggests that the measures of effectiveness reported above are conservative.

After adjusting the figures for disease and exposure, a recalculation of the measure for effectiveness for Series 11-15 (Effectiveness (3)) shows an increase from 102/114 or 89.5% to 102/113 or **90.3%.**

Table 4.4-2 Accountability Rates to the Survey of Selected Respondents to Series 11-15 Questionnaires

	Reported a Disease	**Reported Exposure to a Disease ***
Total Reports	19	114
Questionnaires sent	19	111
Letters sent	19	84
Mail returned	3	6
Questionnaires returned	3	9
Responses	13	57
Response Rate	**68.4%**	**51.4%**
Questionnaires unaccounted for	3	45
Accountability Rate	**84.2%**	**59.5%**

* Note: There were 114 reports of exposure. 11 respondents reported exposure to 2 diseases, and 1 respondent reported 3 diseases. 10 different respondents reported exposure in 2 years, and 2 in three years. Thus, 87 envelopes, 24 of which would include multiple follow-up questionnaires could have been sent. In fact, 2 envelopes each containing 1 questionnaire were not sent due to the respondents moving overseas. Another envelope containing 1 questionnaire was not sent due to the address being unclear.

Table 4.4-3 Verification of Exposure and Disease Classifications

	Series 11-15	
	Original Classification	**Amended Classification**
Total Responses	817	
Parents Reporting Definite Exposure to the Disease	114	113
% to Total Responses	14.0%	
Parents Reporting Possible Exposure to the Disease	37	38
% to Total Responses	4.5%	
Parents Reporting Definite Disease	12	11
% to Total Responses	1.5%	
Parents Reporting Possible Disease	7	8
% to Total Responses	0.9%	

4.4.1.5 Additional Statistical Analysis of Data

To further assess the effectiveness of Golden's HP program, a comparative analysis of results from the three series of data was made. The findings are shown in Table 5.1-4 below. These findings show the corrected figures for Series 11-15 data, following the corrections made as a result of the follow-up surveys of respondents who reported a disease, or an exposure to a disease, reported in sections 5.1.1.3 and 5.1.1.4 above.

The effectiveness of the HP program for the three series combined was 90.4%. The confidence limit for a 0.05 significance level was 2.83%.

Thus we can say with 95% confidence, based on the data provided, that the effectiveness of Golden's long-term HP program ranges between 87.6% and 93.2%.

Table 4.4-4 95% Confidence Limits for the Effectiveness of Series 1 – 15 Data

	Series 1-5	**Series 6-11**	**Series 11-15**	**Series 1-15**
Effectiveness = Not Infe / Exposed	159/177	116/127	102/113	377/417
Proportion	0.898	0.913	0.903	0.904
Std Dev	0.303	0.282	0.298	0.295
Significance	0.05	0.05	0.05	0.05
Confidence	0.045	0.049	0.055	0.028
Range	0.943	0.963	0.957	0.932
	0.854	0.864	0.848	0.876

NOTE: These findings show the corrected figures for Series 11-15 data, following the corrections made as a result of the follow-up surveys of respondents who reported a disease, or an exposure to a disease.

4.4.1.6 Indices of the Accuracy of the Measurements of Exposure and Notifications

The follow-up of parents reporting either exposure to a disease or notification of the disease enables the calculation of two indices of the accuracy of the measurements made as part of Golden's long-term HP study.

Kelsey, et al., (1986, p. 286) stated, 'For a discrete variable that is binary, there are two separate aspects of the accuracy of measurement. One is *sensitivity*, which is defined as the proportion of those who truly have the characteristic that are correctly classified as having it by the measurement technique. The other is *specificity*, which is defined as the proportion of those who truly do not have the characteristic that are correctly classified as not having it by the measurement technique.'

They further stated that the indices are used to assess accuracy in the following way – 'Measurement of a binary characteristic is perfect only when both sensitivity and specificity are 100%. When sensitivity is equal to one minus specificity, then the measurement method is no better than an entirely random means for classifying individuals.' (p. 287)

Table 5.1-5 shows the calculation for sensitivity and specificity based on corrected figures for exposure to a disease, and Table 5.1-6 shows these figures for notifications of the disease, after the corrections for exposure rates shown in Table 5.1-5.

The four indices are between 90.9% and 99.0%. This indicates an extremely high level of accuracy of the measurements for exposure and a high level of accuracy for notifications based on the amended results obtained.

The value of the results is limited due to a follow-up response rate below 100%. However, it is clear that the results that were returned were very supportive of the accuracy of the study.

Table 4.4-5 Data Defining Sensitivity and Specificity for Exposure

		Corrected Data		
		Exposure	No Exposure	Total
Original Data	Exposure	108	6	114
	No Exposure	5	708	713
	Total	113	714	817

Sensitivity (exposure) = 108/113 = 95.6%

Specificity (exposure) = 708/714 = 99.2%

Table 4.4-6 Data Defining Sensitivity and Specificity for Disease

		Corrected Data		
		Disease	No Disease	Total
Original Data	Disease	10	2	12
	No Disease	1	101	102
	Total	11	103	114

Sensitivity (disease) = 10/11 = 90.9%

Specificity (disease) = 101/103 = 98.1%

4.4.1.7 Comparison of Data with National Disease Attack Rates

One weakness of the 1997 analysis of the Golden's HP program was that no control group existed against which to compare the figures for effectiveness. However, an effective control group does exist in the form of national disease attack rates, i.e., the proportion of unimmunised people who are expected to contract a disease if exposed to it. Such a figure is exactly equivalent to the proportion of people using HP who contract a disease if exposed to it – i.e., 9.8% over the 15-year study.

An analysis of the Odds Ratios and Chi Squared probabilities for a range of disease attack rates was undertaken to provide an effective "control" figure against which the effectiveness of HP could be compared. The results are summarised in Table 5.1-7 below.

The Odds Ratio = Disease:No Disease / HP:No HP

The actual average attack rates for the four diseases that were reported in the research varied. Some citations in the literature are:

Whooping Cough: 70-100% in unvaccinated household members (NH&MRC, 2000)

Measles: 90% of unvaccinated household members (Nemours Foundation, 2001)

Mumps: 70% in unvaccinated household members (estimate) (Schleqel et al, 1999)

Hib: not available.

The breakdown of the 41 diseases reported in the 15-year survey was Whooping Cough 15/41; Measles 22/41; Mumps 3/41; Hib 1/41. This yields a weighted average attack rate of 73.9% as shown in Table 5.1-8.

Thus we are able to say with 99% confidence that the use of HP is associated with a reduction in the incidence of disease, and that an effectiveness of around 90% is supported by the analysis. The claim is of course subject to the limitations and the potential biases in the data noted earlier.

Table 4.4-7 Odds Ratios and Chi Squared Probabilities for Various Disease Attack Rates Compared to the Attack Rate Associated With HP

Attack Rates of Wild Disease	Odds Ratio	Chi Squared Probability
90%	0.012	8.1E-30
80%	0.03	1.9E-23
79.0%	**0.03**	**7.0E-23**
70%	0.05	3.5E-18
60%	0.07	9.5E-14
50%	0.11	5.3E-10
40%	0.16	7.9E-7
30%	0.25	3.5E-4
20%	0.44	0.43
10%	0.98	0.96

Assumptions: Average Attack Rate with HP = 9.8%
Number of respondents to HP survey = 2,304
Persons assumed to use HP, or no HP = 100/group
(note – this assumption reduces the value for X^2)

Table 4.4-8 Weighted Average National Attack Rates of Relevant Diseases

Diseases	**Attack Rate (%)**	**Proportion of Reported Diseases (%)**	**Weighted Average Attach Rates (%)**
Whooping Cough	70 – 100	15/41 = 36.6	25.6*
Measles	90	22/41 = 53.7	48.3
Mumps	70	3/41 = 7.3	5.1
Hib	N/A	1/41 = 2.4	0.0
Total			**79.0**

* The lowest attack rate figure was used – 70% x 36.6% = 25.6%

4.4.1.8 The Absolute Effectiveness of HP Found in the General Health Survey

The effectiveness of the various HP programs used in the General Health Survey is defined as the proportion of children who used an HP program, but who did not get the disease.

Note that this figure differs from the figure used to measure the effectiveness of Golden's HP program, where the proportion was taken against children who were exposed to a disease. Probable exposure was not available from the General Health Survey figures, and thus the absolute measure of effectiveness is less accurate than the earlier measures.

$$\text{Effectiveness (GHS)} = \frac{\text{children who used HP but who did not contract the disease}}{\text{all children using HP}}$$

The figure for the effectiveness of HP for all participants in the General Health Survey who used HP either alone or with other forms of disease prevention, is calculated based on the data in Table 5.1-9 below. Figures are shown for total diseases as well as for only those diseases that were diagnosed by a GP:

Effectiveness (5) = 75.0% (96/128); OR 87.5% (112/128) for GP diagnosed diseases.

The figure for effectiveness for participants using HP as their only method of disease prevention is:

Effectiveness (6) = 79.2% (57/72); OR 87.5% (63/72) for GP diagnosed diseases.

As stated above, these figures are not directly comparable with the HP figures for effectiveness (Effectiveness (1) – (4)) as no data on exposure rates were obtained in the General Health Survey. Further, only three individual diseases were examined –

whooping cough, measles and mumps – although these were also the most common diseases found in the 15-year study. Also, no checks were possible on the accuracy of the statements made by participants in the Survey.

On the other hand, comparative data between HP and other preventative methods is available from the General Health Survey, and these are studied below.

4.4.1.9 The Relative Effectiveness of HP Found in the General Health Survey

Three types of analysis are made on the General Health Survey data to test the earlier measures of effectiveness.

(1) The incidence of the three diseases targeted in the General Health Survey questionnaire, calculated for each of the different preventative methods, is shown in Tables 5.1-9 and 5.1-10. Diagnosis of each disease by a GP is also shown in both tables to give some indication of the possible reliability of the figures.

(2) The effectiveness of each method, shown as the proportion of no disease to group total for each method, together with 95% confidence limits, is shown in Tables 5.1-11 and 5.1-12.

(3) An Odds Ratio and Chi Squared probability analysis is undertaken on the four different non-combined methods, and the results shown in Tables 5.1-13 and 5.1-14.

Note: In Table 5.1-9, "N.R." = no response

Table 4.4-9 Diseases and Method of Immunisation

			Measles					Whooping Cough					Mumps					Total Diseases			
			Saw GP?					Saw GP?					Saw GP?					Saw GP?			
Description	No.		Yes	No	N.R.	Sum		Yes	No	N.R.	Sum		Yes	No	N.R.	Sum		Yes	No	N.R.	Sum
Vaccination	332		19	2	1	22		8	2	0	10		1	0	0	1		28	4	1	33
Only		%	5.7	0.6	0.3	6.6	%	2.4	0.6	0.0	3.0	%	0.3	0.0	0.0	0.3	%	8.4	1.2	0.3	9.9
HP only	72		6	0	0	6		3	6	0	9		0	0	0	0		9	6	0	15
		%	8.3	0.0	0.0	8.3	%	4.2	8.3	0.0	12.5	%	0.0	0.0	0.0	0.0	%	12.5	8.3	0.0	20.8
General	51		1	9	0	10		1	8	0	9		0	0	0	0		2	17	0	19
Only		%	2.0	17.6	0.0	19.6	%	2.0	15.7	0.0	17.6	%	0.0	0.0	0.0	0.0	%	3.9	33.3	0.0	37.3
Vaccination	20		1	0	0	1		1	1	0	2		0	1	0	1		2	2	0	4
and HP		%	5.0	0.0	0.0	5.0	%	5.0	5.0	0.0	10.0	%	0.0	5.0	0.0	5.0	%	10.0	10.0	0.0	20.0
Vaccination	71		4	0	1	5		1	1	0	2		0	1	0	1		5	2	1	8
and General		%	5.6	0.0	1.4	7.0	%	1.4	1.4	0.0	2.8	%	0.0	1.4	0.0	1.4	%	7.0	2.8	1.4	11.3

			Measles					Whooping Cough					Mumps					Total Diseases			
			Saw GP?					Saw GP?					Saw GP?					Saw GP?			
Description	**No.**		**Yes**	**No**	**N.R.**	**Sum**		**Yes**	**No**	**N.R.**	**Sum**		**Yes**	**No**	**N.R.**	**Sum**		**Yes**	**No**	**N.R.**	**Sum**
HP &	36		2	4	1	7		3	2	1	6		0	0	0	0		5	6	2	13
General			5.6	11.1	2.8	19.4	%	8.3	5.6	2.8	16.7	%	0.0	0.0	0.0	0.0	%	13.9	16.7	5.6	36.1
All 3	31		4	4	0	8		0	6	0	6		0	1	0	1		4	11	0	15
		%	12.9	12.9	0.0	25.8	%	0.0	19.4	0.0	19.4	%	0.0	3.2	0.0	3.2	%	12.9	35.5	0.0	48.4
Nothing	150		10	5	1	16		13	6	1	20		1	1	1	3		24	12	3	39
(exc NR)		%	6.7	3.3	0.67	10.7	%	8.7	4.0	0.7	13.3	%	0.7	0.7	0.7	2.0	%	16.0	8.0	2.0	26.0
No Response	18		4	0	1	5		1	0	0	1		0	0	0	0		5	0	1	6
		%	22.2	0.0	5.6	27.8	%	5.6	0.0	0.0	5.6	%	0.0	0.0	0.0	0.0	%	27.8	0.0	5.6	33.3
Total	**781**		**47**	**20**	**5**	**72**		**31**	**26**	**2**	**59**		**2**	**3**	**1**	**6**		**80**	**49**	**8**	**137**
		%	6.0	2.6	0.6	9.2	%	4.0	3.3	0.3	7.6	%	0.3	0.4	0.1	0.8	%	10.2	6.3	1.0	17.5

The figures in Table 5.1-9 are summarised in Table 5.1-10 where the totals for each disease and for the four non-combined methods of prevention are shown. The figures for total diseases diagnosed by a GP are also shown, as are simple rankings for each method.

A simple ranking of methods shows that vaccination appears to give the highest level of protection, followed by HP, no method of protection, and finally general protection. This order is changed when examining total figures for diseases diagnosed by a GP, where general protection moves to the first place, the other three remaining in the previous order.

It is possible that parents who use constitutional and specific general health measures to protect their child against infectious diseases have made themselves more informed than other parents, are more self reliant in times of illness on their own ability to treat the illness, and thus are less likely to consult a GP than are other parents who rely more on advice from professionals.

This is probably the cause of the latter result, where GP diagnosed diseases were proportionally lowest within this group of parents.

The effectiveness for HP of 79.2%-87.5% is subject to errors such as incorrect diagnosis, and the likelihood of non-exposure in a number of cases where the disease was not reported. This is also true for the other methods of disease prevention examined.

Table 4.4-10 Total Diseases by Immunisation Method

Disease			Measles		Whooping Cough		Mumps		Total Diseases			Ranking	
Method of Protection	Total Using Each Method		All		All		All		All	GP Diagnosed		All	GP Diagnosed
Vaccination only	332		22		10		1		33	(28)			
			6.6	%	3.0	%	0.3	%	9.9	(8.4)	%	1	2
HP only	72		6		9		0		15	(9)			
			8.3	%	12.5	%	0.0	%	20.8	(12.5)	%	2	3
General Only	51		10		9		0		19	(2)			
			19.6	%	17.6	%	0.0	%	37.3	(3.9)	%	4	1
Nothing	150		16		20		3		39	(24)			
(excluding No Response)			10.7	%	13.3	%	2.0	%	26.0	(16.0)	%	3	4

The 95% confidence limits for Vaccination only, HP only, General Protection only, and no method of protection are shown in Tables 5.1-11 and 5.1-12. The figures for the effectiveness of HP for the 15-year study are also shown for comparative purposes.

The 15-year HP figures are the most reliable of the five groups because they take into account exposure to the disease, which makes the effectiveness of HP of 90.2% significant, as the highest reading.

One reason for the difference between this figure and the effectiveness of HP from the General Health Survey of 79.2% is because the survey examines children who use Golden's program as well as children who use other HP programs.

An analysis is made in Chapter 5.5 following of the differences between programs supplied by Golden and other programs. This analysis clearly shows that differences do exist between different HP programs, and that the inclusion of programs other than those supplied by Golden is likely to reduce the total effectiveness recorded.

Table 4.4-11 95 % Confidence Limits for the Effectiveness of Different Methods of Disease Prevention

	Vaccination Only	**HP Only**	**General Prevention Only**	**No Disease Prevention**	**15 Year Study**
	299/332	57/72	32/51	111/150	377/418
Effectiveness (Proportion)	0.901	0.792	0.628	0.740	0.902
Std Dev	0.300	0.409	0.488	0.440	0.298
Significance	0.05	0.05	0.05	0.05	0.05
Confidence	0.032	0.095	0.134	0.07	0.029
Range	0.933	0.885	0.762	0.810	0.931
	0.868	0.696	0.493	0.67	0.873

Table 4.4-12 95% Confidence Limits for the Effectiveness of Different Methods of Disease Prevention – GP Diagnosed Diseases

	Vaccination Only	**HP Only**	**General Prevention Only**	**No Disease Prevention**	**15 Year Study**
	304/332	63/72	49/51	126/150	377/418
Effectiveness (Proportion)	0.92	0.88	0.96	0.84	0.902
Std Dev	0.28	0.33	0.21	0.37	0.30
Significance	0.05	0.05	0.05	0.05	0.05
Confidence	0.03	0.08	0.06	0.06	0.03
Range	0.92	0.88	0.96	0.84	0.90
	0.89	0.80	0.90	0.78	0.87

The Odds Ratios and Chi Squared probability figures are shown in Tables 5.1-13 and 5.1-14 below.

The figures for HP are not statistically significant in either Table, and therefore no reliable conclusion can be drawn regarding the effectiveness of HP.

We are able to conclude with 99% confidence, based on the figures shown, that vaccination is 8.3 times more effective than general protection only, and 5.7 times more effective than no method of disease prevention.

The figures are suggestive of an effectiveness of around 80%, and suggestive that the effectiveness of HP lies between that of vaccination only and general prevention and no method of prevention.

However, the above analysis based on data obtained from the General Health Survey is unable to provide evidence at P≥95% of either the absolute effectiveness of HP or its effectiveness relative to other methods of disease prevention.

Table 4.4-13 The Relative Effectiveness of HP – All Diseases

		Method				
Condition	**Measurement**	**HP only**	**Vaccination only**	**General only**	**Nothing**	**HP supplied by Golden**
Whooping Cough	Odds Ratio	1.67	0.22	2.52	2.2	0
	Chi Test	0.18	3.8E-6	0.015	0.005	0.126
Measles	Odds Ratio	0.78	0.48	2.24	1.15	0
	Chi Test	0.58	0.004	0.027	0.62	0.086
Mumps	Odds Ratio	0.0	0.2	0.0	3.2	0
	Chi Test	0.4	0.13	0.28	0.11	0.629
Total Diseases	Odds Ratio	1.099	0.31	2.58	1.762	0
	Chi Test	0.76	7.5E-9	0.001	0.007	0.013

Table 4.4-14 The Relative Effectiveness of HP – All Diseases Diagnosed by a GP

		Method			
Condition	**Measurement**	**HP only**	**Vaccination only**	**General only**	**Nothing**
Whooping Cough	Odds Ratio	1.06	0.46	0.46	3.2
	Chi Test	0.93	0.055	0.43	0.001
Measles	Odds Ratio	1.34	0.79	0.27	1.03
	Chi Test	0.52	0.43	0.16	0.94
Mumps	Odds Ratio	0.0	1.4	0.0	4.2
	Chi Test	0.65	0.83	0.71	0.27
Total Diseases	Odds Ratio	1.21	0.65	0.32	1.8
	Chi Test	0.62	0.07	0.09	0.02

4.5 The Safety of HP

The results showing measures of safety are separated into short-term safety and long-term safety. Figures are presented for both Golden's long-term HP program, and for the other HP programs used by participants in the General Health Survey.

4.5.1 Short Term Safety of HP

The reactions experienced by children using Golden's Series 11-15 HP program were recorded, and were classified according to intensity of reaction and duration of reaction. The reaction rate to the medicines in Golden's HP program is shown for all Series (1-15) in Table 5.2-1 below.

Parents using Golden's HP program reported a reaction rate to medicines in the program of 9.2%, with a confidence limit of 1.2% for a 0.05 significance level. Thus, we can say with 95% confidence, based on the data provided and an assumption of six doses per year that the level of reactions per person to a HP program will range between 8.0% and 10.4%, or between 1.3% and 1.7% per dose.

Table 4.5-1 Reactions to Remedies in Golden's Long-Term HP Program

	Reactions to HP – per person		**Reactions to HP – per dose (estimated)**
Series 1-5	50/708	7.1	1.2
Series 6-10	83/817	10.2	1.7
Series 11-15	82/817	10.0	1.7
Series 1-15	215/2342	9.2	1.5

The classification of the intensity and duration of these reactions for Series 11-15 of Golden's HP program is summarised in Table 5.2-2 below. Not all responses by parents showed the intensity or duration of reactions, and so the Table shows the figures both for all responses, as well as the figures that exclude responses where no details were given.

Further, figures are shown for (a) all reactions that are classified as either "possible" or "definite", as well as (b) just for reactions classified as "definite". The "definite" figures are shown in brackets.

Note that the classification of reactions into "definite" and "possible" is subjective, but is a necessary attempt to weight the value of the information provided by parents according to certainty. The classifications have been published for review (Golden, 1997).

Note also that the count in Table 5.2-2 is by respondent. The reason for this is that not all parents who reported a reaction to more than one remedy made clear which reaction was associated with which remedy.

There were 82 definite reports of reactions to kit remedies. However, 14 parents reported definite reactions to two diseases. That means that there were 68 questionnaire responses covering the 82 definite remedy reactions.

Table 5.2-1 reports that definite reactions were reported in less than 1.5% of doses. The analysis of responses in Table 5.2-2 shows that most were mild (56.7%), and very few were strong (1.5%). The figures showed that 41.8% were classified as moderate in intensity.

The data shows that homoeopathic remedies containing only the "energy" of substances can produce definite and observable changes in infants and young children where the likelihood of a placebo effect is small.

The clear majority of respondents (85.7%) who described the reactions stated that they were brief, lasting between 1-5 days. In fact only 2 respondents who reported a reaction classified as moderate or strong also reported that the reaction was more than brief. Another 11 did not indicate the duration of the reaction.

The general comments of these 13 respondents were checked to see if there was any evidence of long-term health problems. One respondent (#11138) reported that her child had contracted whooping cough and was still unwell 6 months later. Two others (#14221 and #15110) repeated comments on the reactions that they had already reported. The others either made no comments, or positive comments about the health of their children.

Thus it seems reasonable to conclude that whilst reactions to the remedies in the HP program are possible, and whilst very few do last more than a few days, the overwhelming experience of most children using the program is that short-term reactions are very unlikely, and those that do occur are usually mild and brief.

Table 4.5-2 A Summary of the Intensity and Duration of Reactions to the Series 11-15 HP Program, by Respondent

		Intensity/Duration of Reactions				
		All Responses				
		Mild/ Brief	**Moderate**	**Strong/ Long**	**No Details Given**	**Total Respondents**
Intensity	#	65 (38)	33 (28)	1 (1)	3 (1)	102 (68)
	%	63.7 (56.7)	32.4 (41.8)	1.0 (1.5)	2.9 (1.5)	100.0
Duration	#	46 (36)	7 (5)	1 (1)	48 (26)	102 (68)
	%	45.1 (52.9)	6.9 (7.4)	1.0 (1.5)	47.1 (38.2)	100.0
		Excluding Responses With No Details				
		Mild/ Brief	**Moderate**	**Strong/ Long**	**Total Respondents**	
Intensity	#	65 (38)	33 (28)	1 (1)	99 (67)	
	%	63.7 (56.7)	32.4 (41.8)	1.0 (1.5)	100.0	
Duration	#	46 (36)	7 (5)	1 (1)	54 (42)	
	%	85.2 (85.7)	13.0 (11.9)	1.9 (2.4)	100.0	

Note: the figures in brackets are for reactions classified as “definite”. Other figures are for all reactions, classified as either “possible” or ”definite”.

Classification of Duration of Reaction: 1 - 5 days – “Brief”
6-13 days - “Moderate”
14 + days - “Long”

4.5.2 The Long Term Safety of HP

Long-term safety is assessed using (1) data from the 5-year, Series 11-15, study of parents using Golden's HP program, and (2) data from the General Health Survey that included different HP programs.

The analysis examines results from each body of data in turn.

4.5.2.1 The Long-Term Safety of Golden's HP Program

A classification of general comments made by Series 11-15 respondents to Golden's HP program was made to assess the long-term wellbeing of children using the program.

These comments are shown in Appendix 1 in Table 1.5-5. A summary of responses is shown in Tables 5.2-3 and 5.2-4 below.

Table 5.2-3 shows the breakdown of all comments into "positive", "neutral" and "negative" for three categories of response – "health related comments", "administration of the program" and "other comments".

However, the very large percentage of comments in the "neutral" categories means that a meaningful analysis of the figures is difficult. Therefore, "neutral" comments are removed in Table 5.2-4 and only positive and negative comments are recorded. They provide a more accurate indication of the relative strengths or weaknesses of the program.

Table 4.5-3 Classification of "Other" Comments

	Health Related Comments		Administration of the Program		Other Comments	
	#	%	#	%	#	%
Positive	72	62.1	11	13.7	52	37.4
Neutral	38	32.8	40	50.0	81	58.3
Negative	6	5.1	29	36.3	6	4.3
Total	116	100.0	80	100.0	139	100.0

Table 4.5-4 A Re-Classification of "Other" Comments

	Health Related Comments		Administration of the Program		Other Comments	
	#	%	#	%	#	%
Positive	72	92.3%	11	27.5%	52	89.7%
Negative	6	7.7%	29	72.5%	6	10.3%
Total	78	100.0%	40	100.0%	58	100.0%

Three conclusions may be drawn from the data in Table 5.2-4.

1. Parents of children using the program who commented on the health of their child reported significantly more positive health experiences (92.3%) than negative ones (7.7%). This longer-term figure, combined with earlier findings of a less than 2% reaction rate per dose, suggests that the program is safe both in the short and long terms.

2. Parents of children using the program who commented on the administration of the program reported a significant level of problems (72.5%). These problems mainly related to difficulties in administering the pilules, especially the need to dose between meals. There is little that can be done to change the method of administration since giving doses with meals would antidote most doses. Fortunately these administration difficulties were reported in only 3.55 % of total responses (29/817). They cease to be an issue when the child is older and does not require regular feeding.

3. Parents of children using the program who made general comments on their experience with the program were generally very happy (89.7%) with only a minority (10.3%) voicing discontent.

The comments by Series 11-15 parents whose children used Golden's long-term HP program strongly suggest that these children experience very few long-term problems with their health, and in fact many positive comments are made about how well the children are.

These data suggest that the long-term safety of the program is high.

A more exact analysis of long-term health, investigating actual diseases experienced by children aged between 4 and 12 years of age, was made using data from the General Health Survey for children using HP and/or other methods of disease prevention.

4.5.2.2 The Long-Term Safety of HP Programs Used in the General Health Survey

The safety of HP is now examined in absolute terms, as well as being compared to three other methods of infectious disease prevention used by parents who responded to the General Health Survey - vaccination, general prevention, and no prevention.

4.5.2.2.1 The Absolute Safety of HP

The first task of the analysis to define a useful measure of the safety of HP.

The data from the General Health Survey link five health conditions – asthma, eczema, ear/hearing problems, allergies, behavioural problems - with different methods of immunisation, including HP.

The incidence of each condition in children who used HP is used to provide a measure of the safety of HP.

Two statistical measures of this incidence may be calculated.

1. Proportion (SHP1) = $\frac{\text{Persons with the Condition (using HP only)}}{\text{All Persons (HP only)}}$

The lower the value of SHP1, the more safe the method (HP). This proportion is compared to the national average for each condition, where available.

The figure is also calculated for conditions where a diagnosis was made by a GP, and this was compared with the total figures for all conditions. Whilst a GP diagnosis may not always be correct, and other diagnoses may not always be incorrect, it does give another insight into the reliability of the total figure.

2. Odds Ratio (SHP2) = $\frac{\text{Condition (using HP only)}}{\text{No Condition (HP only)}} / \frac{\text{Condition (not using HP)}}{\text{No Condition (not using HP)}}$

If the Odds Ratio was greater than 1 the method would be associated with an increase in the incidence of the condition, and therefore classified as unsafe. For a method to be regarded as very safe we would expect the Odds Ratio to be significantly below 1.

For example, the following classification of the incidence of a condition, suggesting degrees of safety, is shown in Table 5.2-5. This classification provides a subjective guide only to the safety of a method. This then allows for some conclusions to be drawn as to whether HP is associated with a change in the incidence of a condition in a way that will allow the method to be classified a being safe or unsafe.

Table 4.5-5 Estimation of Degrees of Safety Using the Incidence of Health Conditions

$0.00 < \text{Odds Ratio} \leq 0.25$	– method estimated as being very safe
$0.25 < \text{Odds Ratio} \leq 0.50$	– method estimated as being safe
$0.50 < \text{Odds Ratio} \leq 0.75$	– method estimated as being moderately safe
$0.75 < \text{Odds Ratio} \leq 1.00$	– method estimated as being not safe
$\text{Odds Ratio} > 1.00$	– method estimated as being unsafe

In addition to the Odds Ratio, the Chi Squared probability of the association between "the use of HP" and "the observed condition" being a coincidence is calculated.

A measure will not be accepted unless its confidence limit is at least 95%. This requires a Chi Squared probability of 0.05 or less. The lower the figure the greater the likelihood that the association reflected in the Odds Ratio is not a co-incidence. These ratios and probability estimates are listed in Table 5.2-6 below.

Table 4.5-6 Ratio Analysis of the Estimates of the Safety of HP Only

Condition	Proportion (SHP1)			Odds Ratio (SHP2)	Chi Squared Probability	Results	
	No GP diagnosis	With GP diagnosis	National Average			Safety	Confidence
Asthma	0.03	0.03	0.16** - 0.19*	0.117	0.0004	Very safe	Very high
Eczema	0.10	0.04	N/A	0.382	0.015	Safe	High
Ear/hearing	0.17	0.11	N/A	0.917	0.79	Not safe	Nil
Allergies	0.15	0.04	0.09 – 0.16**	0.550	0.07	Moderately safe	Medium
Behaviour	0.04	0.01	N/A	0.446	0.17	Safe	Low

References:

* (Australian Bureau of Statistics, 1999).

** (Australian Bureau of Statistics, 2001b).

The figure for SHP1 shows that the incidence of asthma among children who use only HP as a method of disease prevention (3%) is well below the national average of 19%. It further shows that the incidence of behavioural problems is extremely low, with very modest levels for the remaining conditions.

However, the Odds Ratio is the more reliable of the two figures. It is less than unity for every condition studied, which shows that HP is not linked with an increase in the incidence of any of the conditions examined.

Further, we can say with a high probability (P>98%) that HP is associated with a lower than average chance of acquiring asthma and eczema, with a moderate probability (P=93%) of developing fewer allergies, and with a low probability of having fewer behavioural problems (P=83%) than children not using only HP. The result linking HP only with ear and hearing problems indicated that HP only was unsafe; however, the result was not statistically significant.

Thus, in absolute terms HP is shown to be a safe method of disease prevention.

4.5.2.2.2 The Safety of HP Compared to Vaccination, General Protection and a Do-Nothing Option

We shall now assess safety by comparing HP to the other methods of disease prevention being studied.

One general measure of the relative safety of HP can be gauged by parent's assessments of the long-term general health of their child. The accumulated parental rankings of wellbeing are shown in Figure 5.2-1 below.

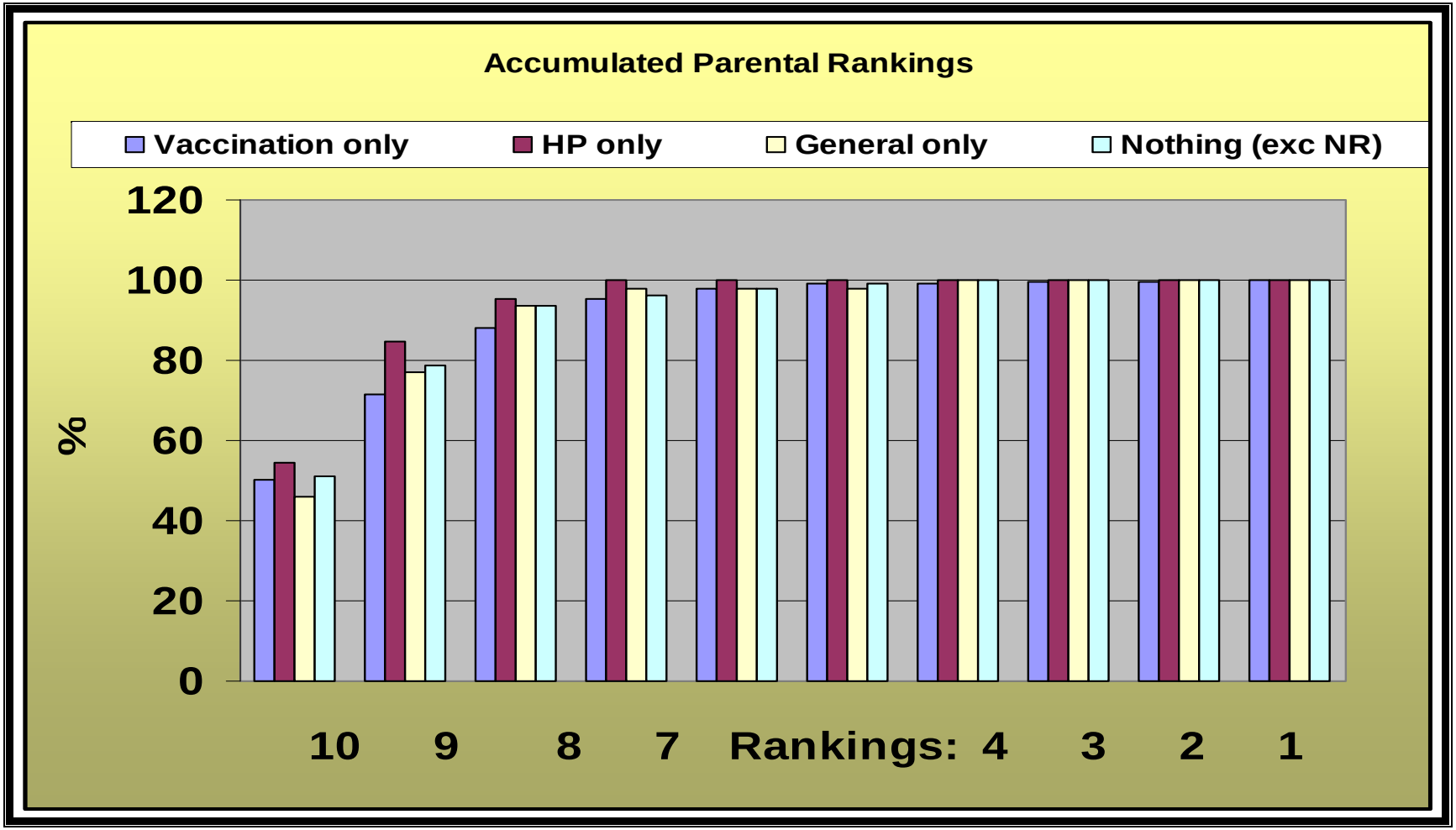
The graphs show that HP consistently ranks higher than other methods of immunisation when ranking the long-term health of children.

For example, 54.5% of parents whose children used HP only ranked the health of their children at '10' (excellent health), whereas the percentage was 50.2% among vaccinated children, 45.8% for children using general protection, and 51.1% for children using no method of prevention.

The relevant figures for the combined health rakings of '9' and '10' were 84.8% for HP, 71.5% for vaccination, 77.1% for general protection and 78.8% for no method of protection.

At every point of measure HP was associated with the highest accumulated ranking of general health.

Figure 4.5-1 Accumulated Parental Rankings



A more precise measure of safety can be found by examining the relationship between HP and other methods of immunization, and the five different chronic health conditions covered by the General Health Survey questionnaire. This relationship is examined in Table 5.2-7 below.

The measures for each condition that are statistically significant are shown in bold print. The relationship between the five conditions and HP programs supplied by Golden is also shown. The difference between HP programs supplied by Golden and other HP programs is discussed fully in Chapter 5.5 below. A significant difference is found.

Table 4.5-7 The Relative Safety of HP – All Conditions

		Method				
Condition	**Measurement**	**HP only**	**Vaccination only**	**General only**	**Nothing**	**HP supplied by Golden**
Asthma	Odds Ratio	**0.117**	**1.75**	0.464	**0.74**	**0**
	Chi Test	**0.0004**	**0.0025**	0.102	**7.9E-40**	**0.017**
Eczema	Odds Ratio	**0.382**	1.315	0.781	**0.674**	**0.153**
	Chi Test	**0.0146**	0.121	0.513	**5.3E-40**	**0.035**
Ear/Hearing	Odds Ratio	0.917	1.149	0.585	**0.533**	0.393
	Chi Test	0.792	0.459	0.222	**2.3E-40**	0.193
Allergies	Odds Ratio	0.550	1.220	0.653	**0.520**	0.60
	Chi Test	0.074	0.239	0.254	**1.2E-40**	0.351
Behaviour	Odds Ratio	0.446	0.869	2.103	**0.397**	0
	Chi Test	0.170	0.593	0.063	**2.7E-40**	0.123

Note: Statistically significant figures are shown in bold type

We may summarize the statistically significant findings (P>= 95%) for each condition using the above data as follows:

Asthma - we can say with P>99% confidence that HP is 15 times safer than vaccination and 6 times safer than no method of protection.

Eczema - we can say with P>98% that HP is 1.8 times safer than no method of protection.

Ears/Hearing Problems, Allergies, Behavioral Problems - we are not able to draw conclusions about the safety of HP with a greater than 95% probability that the conclusion is correct.

Thus, for the two conditions where statistically significant results were found, HP was the safest option in both conditions when compared with vaccination and the do-nothing option. This result also applied to HP programs supplied by Golden.

The overall reliability of these measures can be tested by re-examining the above results, but only including those conditions that have been diagnosed by a medical practitioner. Of course not all such diagnoses may be correct. Further, diagnoses made by non-medical practitioners or by parents themselves may be quite valid. These new figures are shown in Table 5.2-8 below.

It seems reasonable to assume that if the overall rankings of safety in the Tables 5.2-7 and 5.2-8 are consistent, then the results are reliable.

We find that many more measures in Table 5.2-8 have P>95% than in Table 5.2-7.

Table 4.5-8 The Relative Safety of HP - All Conditions - GP Diagnoses Only

Condition	**Measurement**	**HP only**	**Vaccination only**	**General only**	**Nothing**	
Asthma	Odds Ratio	**0.124**	**1.89**	0.49	**0.69**	
	Chi Test	**0.0006**	**0.0007**	0.13	**6.5E-40**	
Eczema	Odds Ratio	**0.239**	**1.76**	**0.225**	**0.665**	
	Chi Test	**0.0097**	**0.006**	**0.025**	**6.5E-40**	
Ear/Hearing	Odds Ratio	0.703	**1.517**	0.599	**0.401**	
	Chi Test	0.364	**0.04**	0.282	**9.4E-41**	
Allergies	Odds Ratio	**0.307**	1.518	0.446	**0.608**	
	Chi Test	**0.038**	0.061	0.171	**5.8E-40**	
Behaviour	Odds Ratio	**0.541**	0.784	**1.675**	**0.784**	
	Chi Test	**0.055**	0.613	**0.049**	**1.2E-40**	

Note: Statistically significant figures are shown in bold type

We may summarise the findings using the above data as follows for each condition, including only those readings with P>95%:

Asthma - we can say with P>99% that HP is 15 times safer than vaccination and 5.6 times safer than no method of protection.

Note is made of the similarity of this result to the finding by Odent and others that asthma is 5.43 times more likely to occur in vaccinated compared to unvaccinated children (Odent, 1994, pp592-3).

Eczema - we can say with P>99% that HP is 7.4 times safer than vaccination, with P>97% that HP is 0.06 times less safe than general protection, and with P>99% that HP is 2.8 times safer than no method of protection.

Ear/Hearing Problems - we are not able to draw conclusions about the safety of HP with a greater than 95% probability that the conclusion is correct. However, we can say with P>95% that Vaccination is 3.9 less safe than doing nothing

Allergies - we can say with P>94% that HP is 5 times safer than vaccination, and with P>99% that HP is 2 times safer than no method of protection.

Behavioral Problems - we are not able to draw conclusions about the safety of HP with a greater than 95% probability that the conclusion is correct. However, we can say with P>95% confidence that doing nothing is twice as safe as general protection. We can say with P=94.5% confidence that HP is the safest option.

Examining the statistically significant results from both tables, we find that only once was HP shown to be less safe than another method, and that was only 0.06 times less safe in that instance.

Thus we may conclude that, with the exceptions of ear and hearing problems, we can say with a high level of probability (P>95%) that HP is relatively a very safe method of disease prevention.

The profile of participants in the General Health Survey will now be examined to determine whether the participants were a representative cross section of the Australian community.

4.6 Participant Profiles from the General Health Survey

The results are presented in descriptive form to show the general characteristics of the children participating in the survey, and to highlight any apparent anomalies in the data, or any significant differences between the survey population and the national population that may produce bias in the results.

4.6.1 Descriptive Profile of the Respondents the General Health Survey

The following respondent profile covers the three main areas of the survey questionnaire. Each area is examined separately in Chapters 5.3.1.1, 5.3.1.2 and 5.3.1.3 following.

4.6.1.1 Data relating to general information about the early childhood experiences of the participants

The general information about the early childhood experiences of the participants included birth weight, whether breast-fed, APGAR scores, gestation term, and immunisation status, as well as age and sex.

Where available, information from the 2001 Australian National Census Data is used to give an indication of how typical the survey population is compared to the national population. If not available, other information is used where available and relevant.

Reference Note: where references in this chapter to material provided by the Australian Bureau of Statistics (ABS) were obtained from the ABS internet site, no page numbers are given as the material was provided as a continuous report without clear page differentiation.

(i) Age

The age profile of respondents is shown in Figure 5.3-1 below, which reveals a reasonably even spread of ages over most targeted years. This is compared to the national averages (Australian Bureau of Statistics 2003a).

Although the initial target range was 5-12 year old children, it was decided to include the group of 4 year olds (i) because they were in their 5th year of life and were old enough to have experienced a range of heath issues and (ii) because the size of the response group at this age (42 children) was a valuable addition to the study. The relatively poor response rate from this group reflects the fact that many parents of 4 year old children would have believed that their child was not eligible for this study (early information called for 5-12 year old participants) and thus would not have offered to complete a questionnaire.

The two groups, 5<6 and 7<8, contained noticeably more respondents than the national average (14.7% compared to 10.8%, and 15.1% compared to 11.2% respectively), and the 12 year old group noticeably less (8.2% compared to 11.3%). No reason for this is known, but there is also no apparent reason why this may cause any bias in the results.

(ii) Sex

Respondents are fairly evenly distributed between males (52.0%) and females (48.0%), as shown in Figure 5.3-2, and this very closely matched the national averages (51.1% and 48.9% respectively) (Australian Bureau of Statistics 2003a).

(iii) Birthweight

The range of respondents' birth weights was evenly distributed either side of the 3-4 kg group, which is typical and expected (0.7%, 2.1%, 16.7%, 65.5%, 15.0%). The

distribution is shown in Figure 5.3-3. The distribution among the target group is similar to the national distribution found in 1996 (0.7%, 1.8%, 18.9%, 67.0%, 11.6%) ((Lancaster et al. 1996).

Figure 4.6-1 Age Profile of Respondents and the National Population

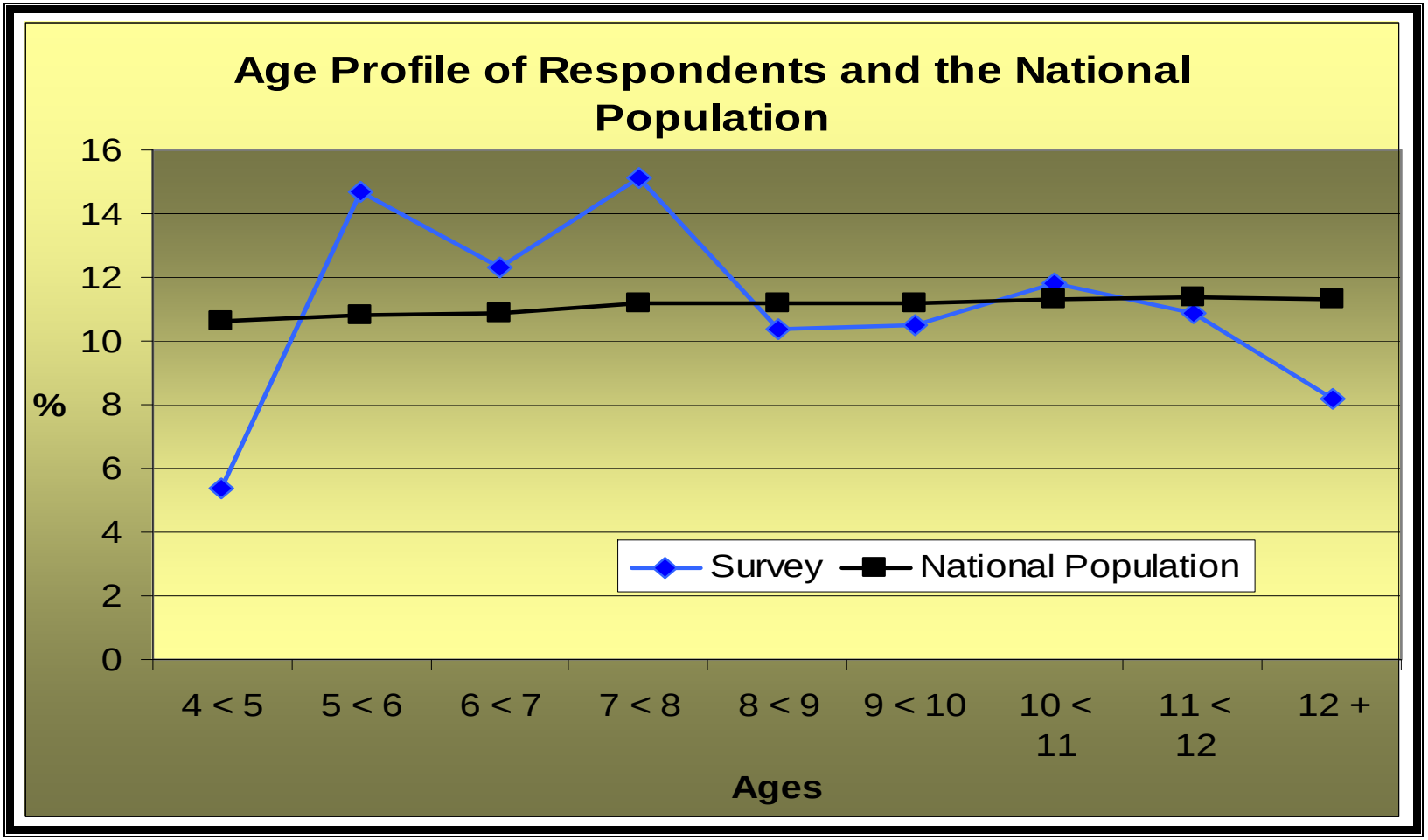


Figure 4.6-2 Sex of Respondents and National Average

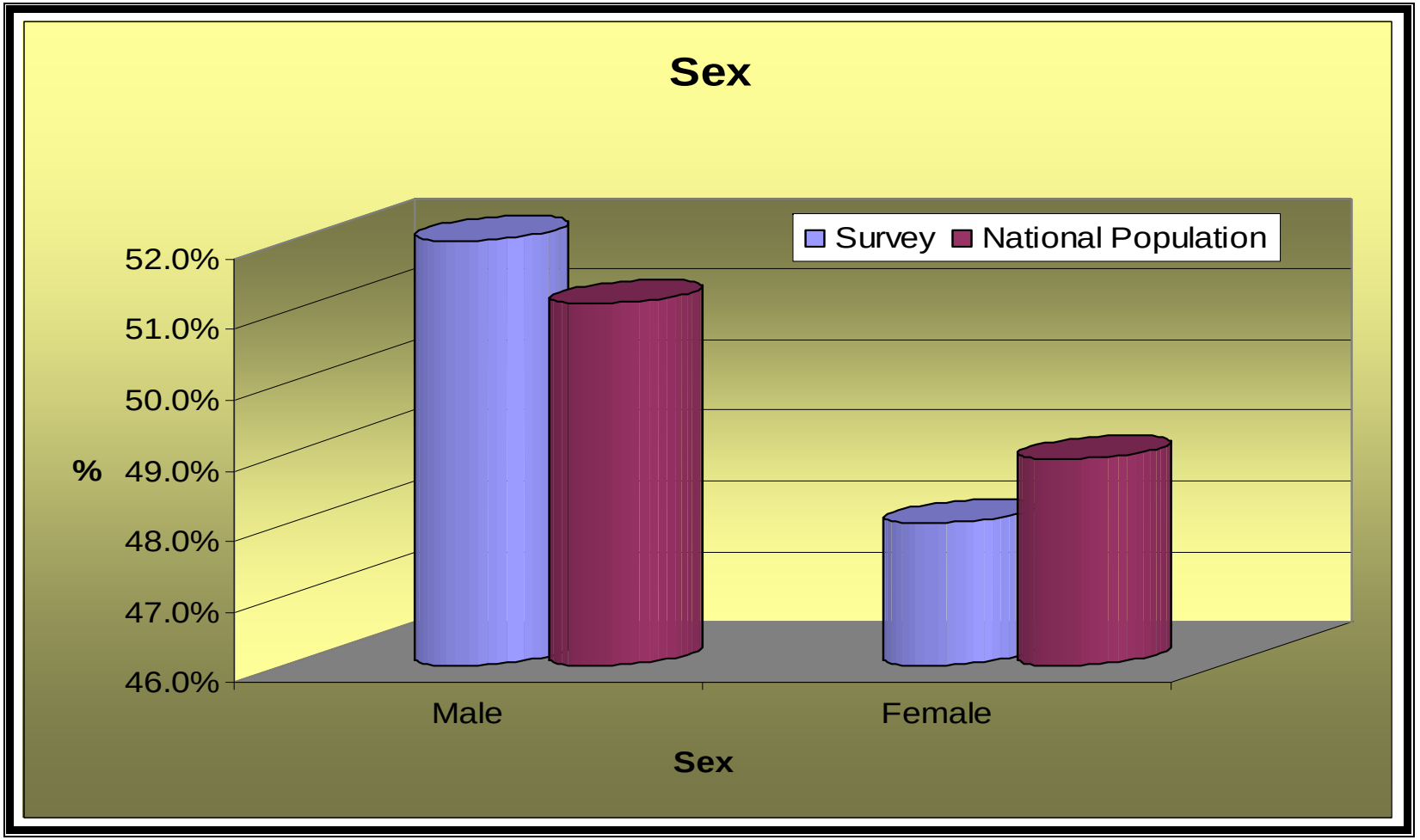
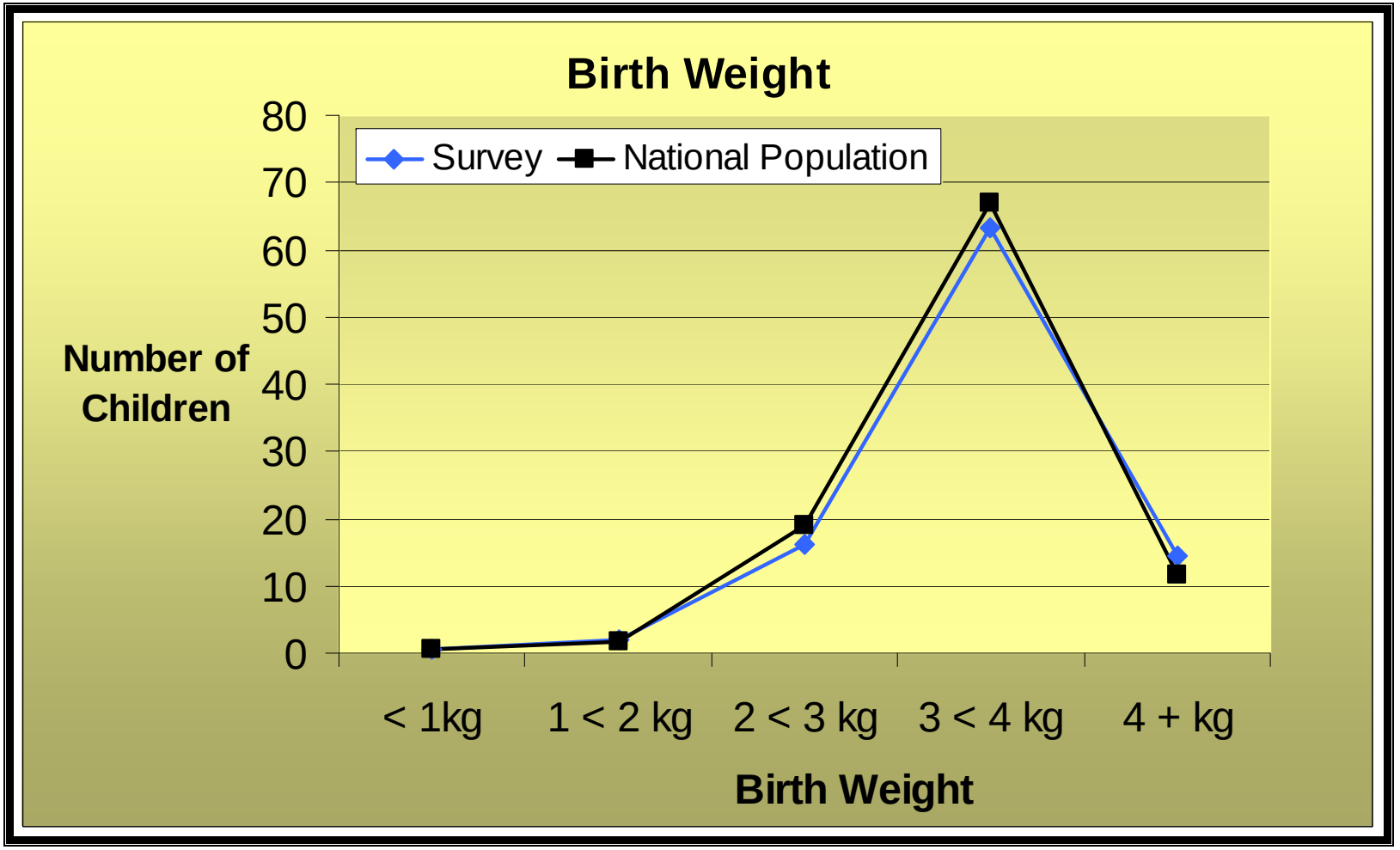


Figure 4.6-3 Birthweight of Respondents and National Average



(iv) Breastfeeding

The distribution of length of breastfeeding shown in Figure 5.2-4 is not quite so even, with a group of "long-term feeders" showing up. Nearly half of all respondents (49.3%) reported breastfeeding their children for between 6-18 months. 16% of children breast fed for less than 3 months or not at all, whilst nearly a quarter (23.5%) were breastfed for over 18 months.

When comparing these figures with the national trends in Figure 5.2-5 it is clear that breastfeeding rates are consistently higher in the survey group. The rate of decline in breastfeeding as the child ages, is similar to the national rate (Australian Bureau of Statistics, 2003c). For example, 74% of the survey group breastfed for at least 6 months compared to 48% in the national population, and 23.5% of the survey group breastfed for 18 months compared to 5% in the national population. The mean length of time being breastfed for children in the survey was 13 months. The comparable figure was not available from the Australian Bureau of Statistics.

(v) APGAR Scores

The collection of the APGAR scores proved difficult for many parents, as evidenced by the high non-response rate of over one third of respondents shown in Figure 5.2-6. In some cases records were not kept, and in fact the parents of some of the children in the survey may not have received the APGAR scores for their child.

Those who did respond reported a higher second score as is expected due to the nature of the test. For example, 256 reported a first APGAR score of 9 or 10, whilst the number rose to 413 for the 2nd APGAR test.

No national data was found showing APGAR scores.

Note that the actual data supporting Figure 5.3-6 to Figure 5.3-16 are shown in Table 5.6-2 following.

Figure 4.6-4 Length of Breastfeeding

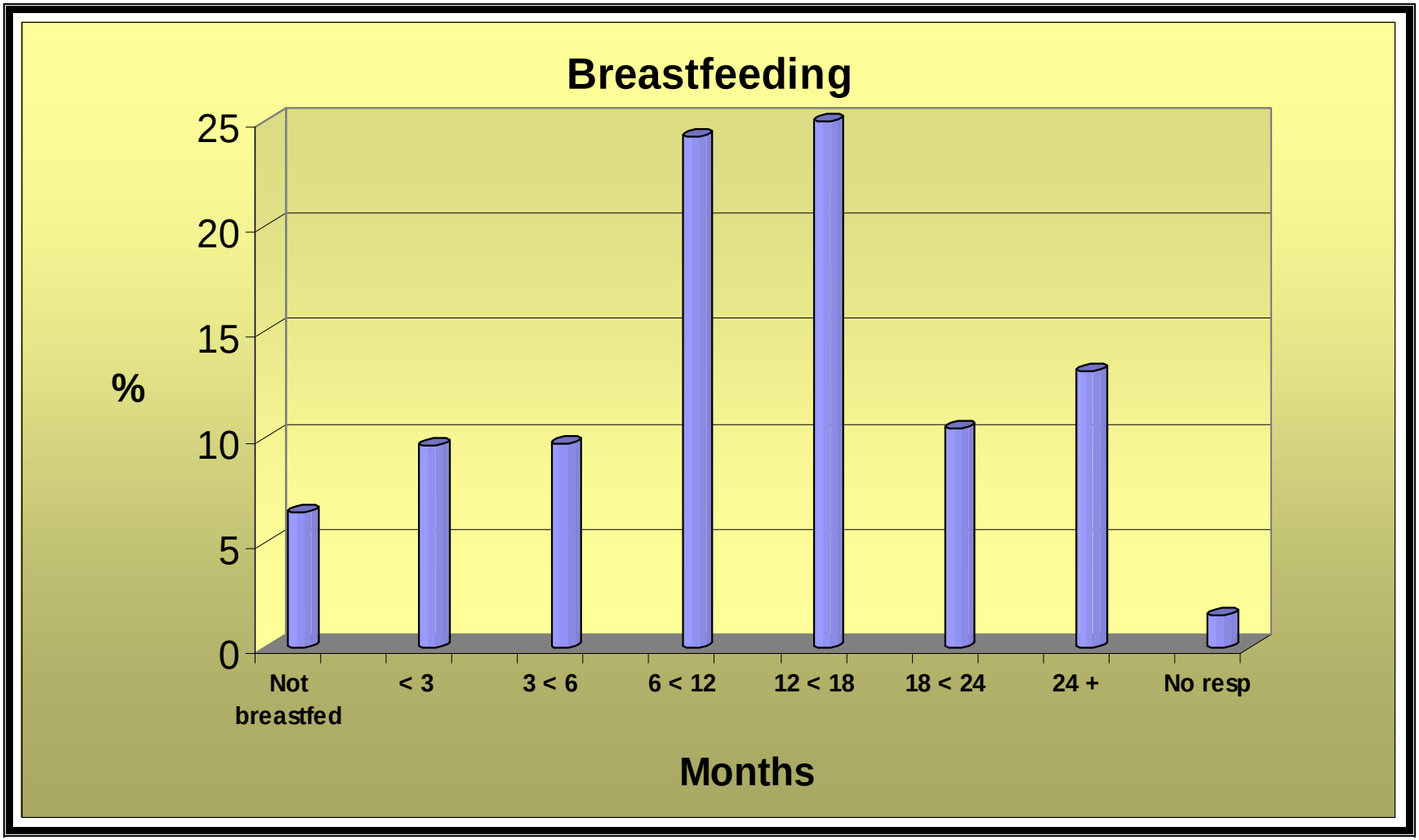


Figure 4.6-5 Proportion of Children Breastfed by Age

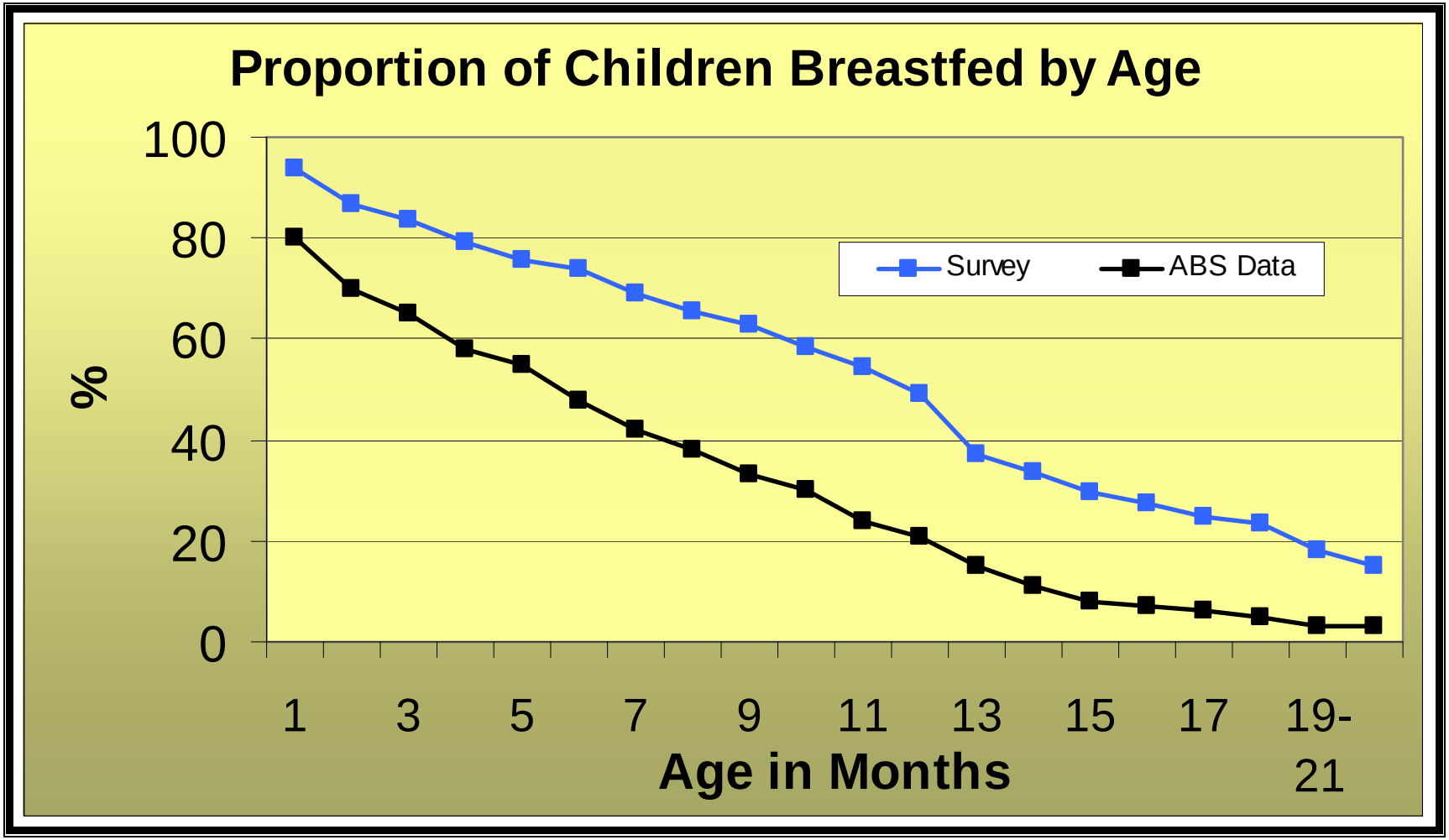
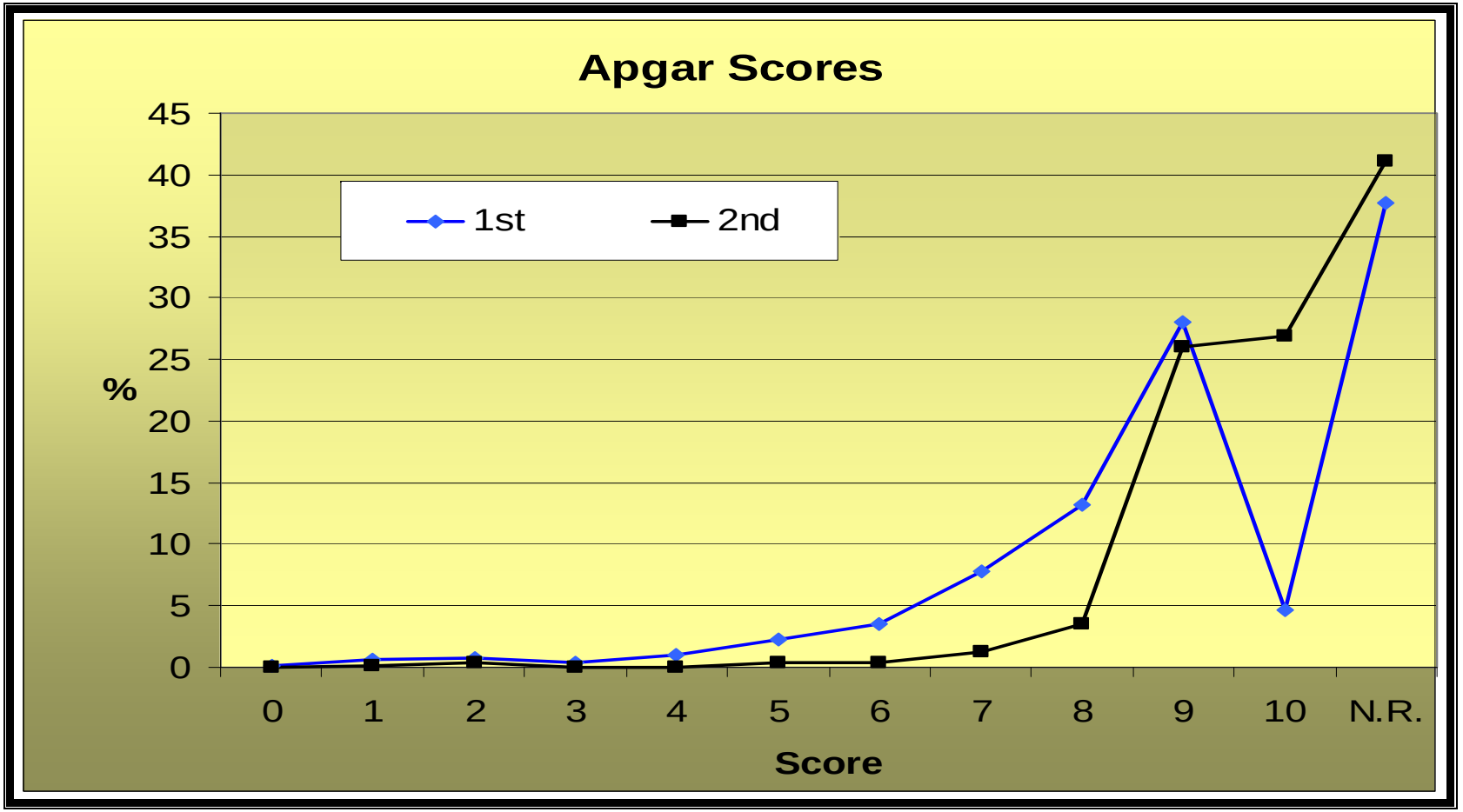


Figure 4.6-6 APGAR Scores



(vi) Gestation

The percentage of respondents did not report either an early or late delivery was 78.6%. Of the remaining 21.4%, Figure 5.2-7 shows the percentage of these respondents who reported that the birth of their child was either premature or late.

As can be seen, even though the percentages are small, some children were born very prematurely (4% over 6 weeks). The numbers of children going over term were small (1%) compared to the premature group, but national figures are not available to compare to a national average.

(vii) Vitamin K

Whilst a majority of respondents reported that their child had received a Vitamin K injection, 25.6% said they did not. This is shown in Figure 5.2-8. It is thus probable that the Vitamin K injection is refused more often by parents surveyed than by parents in the general community, and suggests that many respondents chose to make their own health decisions, independent of orthodox medical advice that recommends a Vitamin K injection following birth.

Figure 4.6-7 Term of Delivery

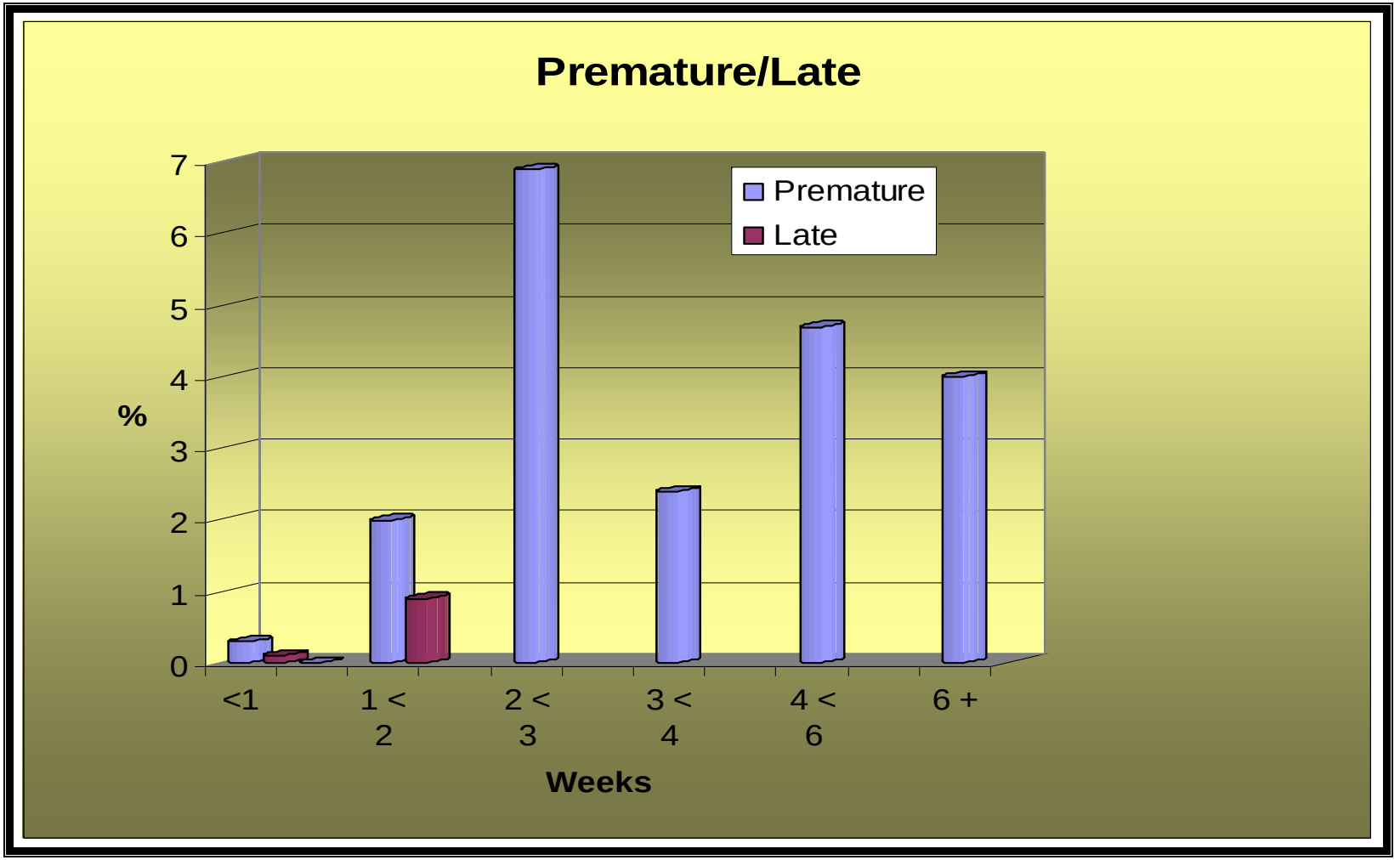
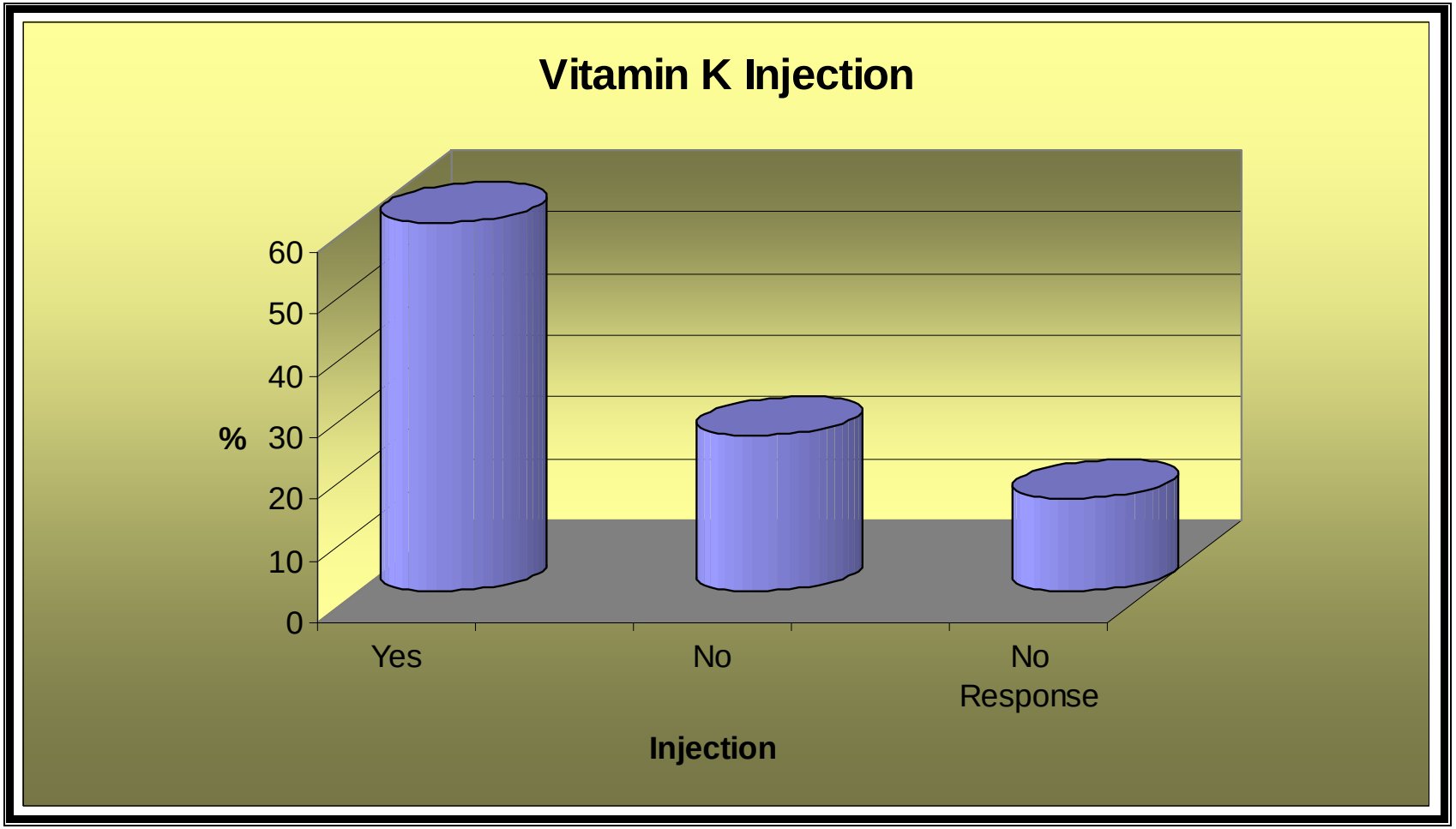


Figure 4.6-8 Incidence of Vitamin K Injections



(viii) Method of Disease Prevention

Three methods of disease prevention were considered in the survey – vaccination, HP, and general or constitutional prevention. The experience of those who used no method of disease prevention at all was also examined.

The method of disease prevention adopted by respondents is shown below. Actual numbers are shown in Figure 5.2-9 instead of percentages because there is a significant amount of multiple-use of methods, i.e. respondents whose children were vaccinated and used HP and/or general or constitutional prevention.

Whilst the majority of respondents vaccinated their children (58.0%), as would be expected, a significant number also used HP (20.4%) and/or general or constitutional prevention (24.3%).

18% of respondents reported that they used no method of disease prevention at all. This is a surprisingly high figure, the implications of which shall be considered later in the analysis.

National figures for vaccination are available from the Australian Bureau of Statistics, but figures are variable. Table 3 - *Immunised Children Aged 0 to 6 Years***,** gives a figure of 54% for fully vaccinated 0-6 year olds in 2001. However vaccination rates for individual vaccines was around 78%. In Table 4 - *ACIR estimates of vaccination coverage for Australian children 2002* – the figure for fully vaccinated children aged 72-74 months was 82.2% (Australian Bureau of Statistics, 2002).

Whilst no exact national figures are available for the other categories being examined, it is expected that the national average would show much lower rates for the use of HP and/or general or constitutional prevention.

Thus it is clear that the sample population contains relatively fewer vaccinated children and relatively more using HP and general protection than found in the general

community. This may create biases in the following analysis, and this factor will be carefully considered.

A positive aspect of the data from the perspective of this research is that sufficient numbers of respondents used all 3 methods of disease prevention considered to allow statistically significant comparative results to be produced

The use of more than one method of disease prevention has meant that eight different possibilities need to be examined. These are shown in Table 5.2-1 and Figure 5.2-10. The detailed statistical analysis above and following examined each of these options, with particular reference to the relative safety and effectiveness of HP to the other methods.

Figure 4.6-9 Method of Disease Prevention

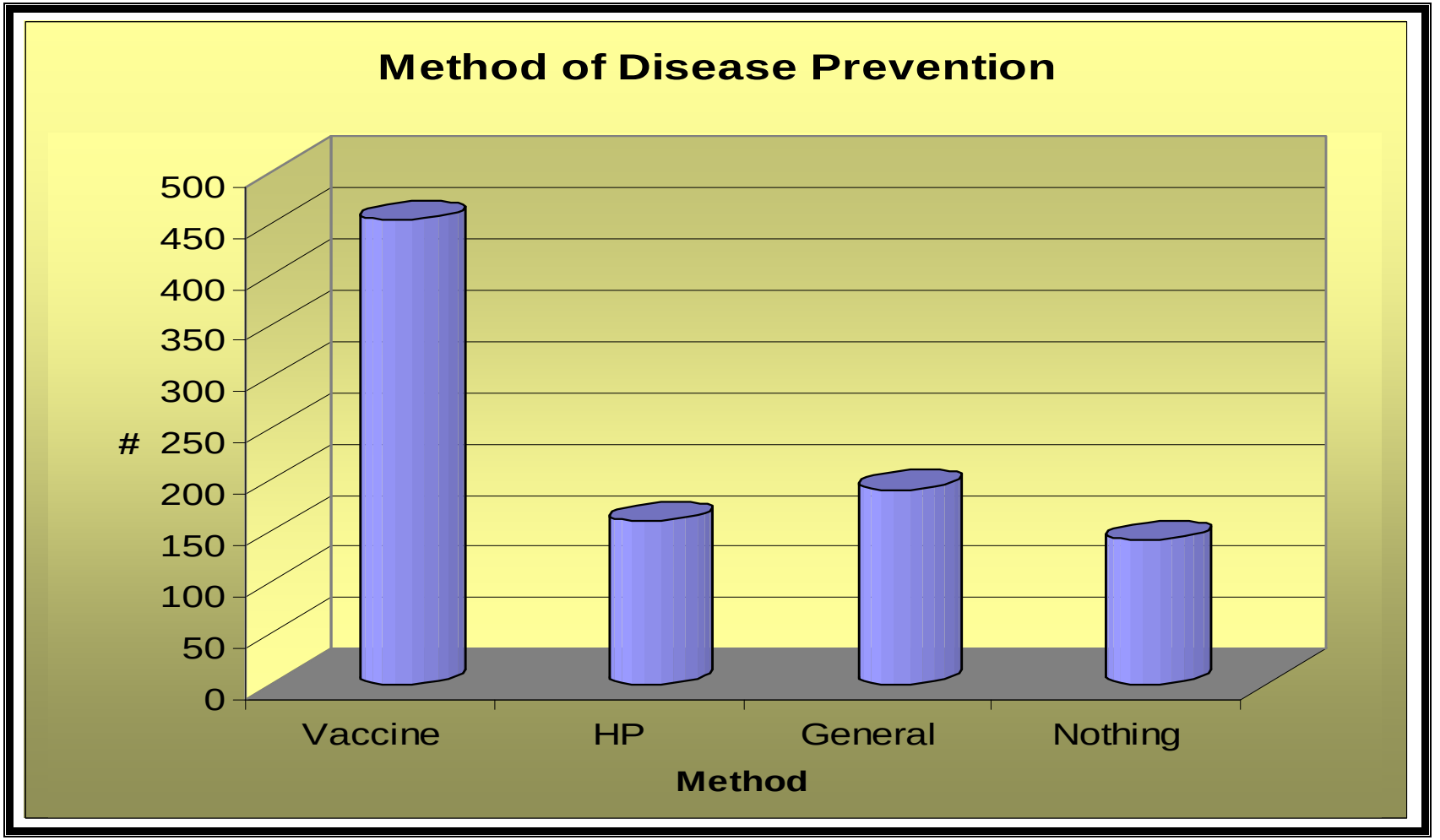
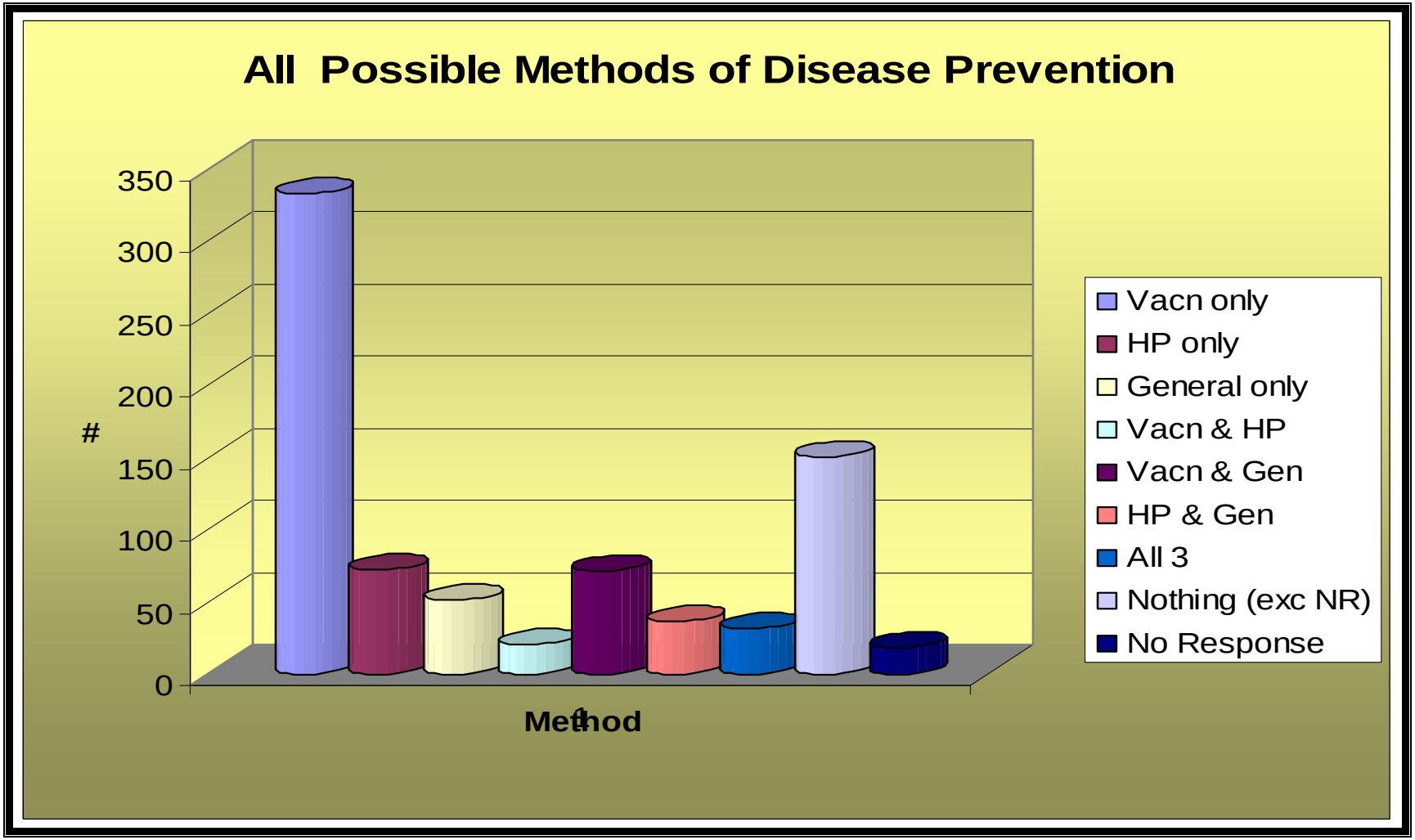


Table 4.6-1 All Possible Methods of Disease Prevention Reported in the General Health Survey

Method Used	#	%
Vaccination only	332	42.5%
HP only	72	9.2%
General/Constitutional only	51	6.5%
Vaccination & HP	20	2.6%
Vaccination & General/Constitutional	71	9.1%
HP & General/Constitutional	36	4.6%
All Three	31	4.0%
None (excluding No Response)	150	19.2%
No Response	18	2.3%
Totals	**781**	**100.0**

Figure 4.6-10 All Possible methods of Disease Prevention



4.6.1.2 Data relating to the safety of HP compared to other methods of disease prevention

The measurement of safety relied on two measures – (1) a general assessment of overall wellbeing by parents of their child's health, and (2) the incidence of specific conditions such as asthma and eczema which provide an indication of the child's overall wellbeing.

The parental ranking of the general health of their child is shown in Figure 5.3-11. This shows that over 79.5% of parents believed their child was healthy (ranking from 8-10). This belief was tested by two later questions which asked whether their child had ongoing health problems (19.8% said yes), and the numbers of children who had been hospitalised (38.9% had). In addition, most children (69.5%) had consulted a health professional and a bare majority (50.3%) received some form of special supplementation.

Examining the incidence of specific conditions further tested the general health of children, and the results are shown in Figure 5.3-12 below. An incidence rate of chronic illness of around 20% is noted.

This is in line with the National Health Survey by the Australian Bureau of Statistics that showed that 27% of Australian children less than 5 years of age have at least one chronic health condition (Australian Bureau of Statistics, 2001b), although the national figure is higher than the survey average.

Figure 4.6-11 Parental Ranking of General Health

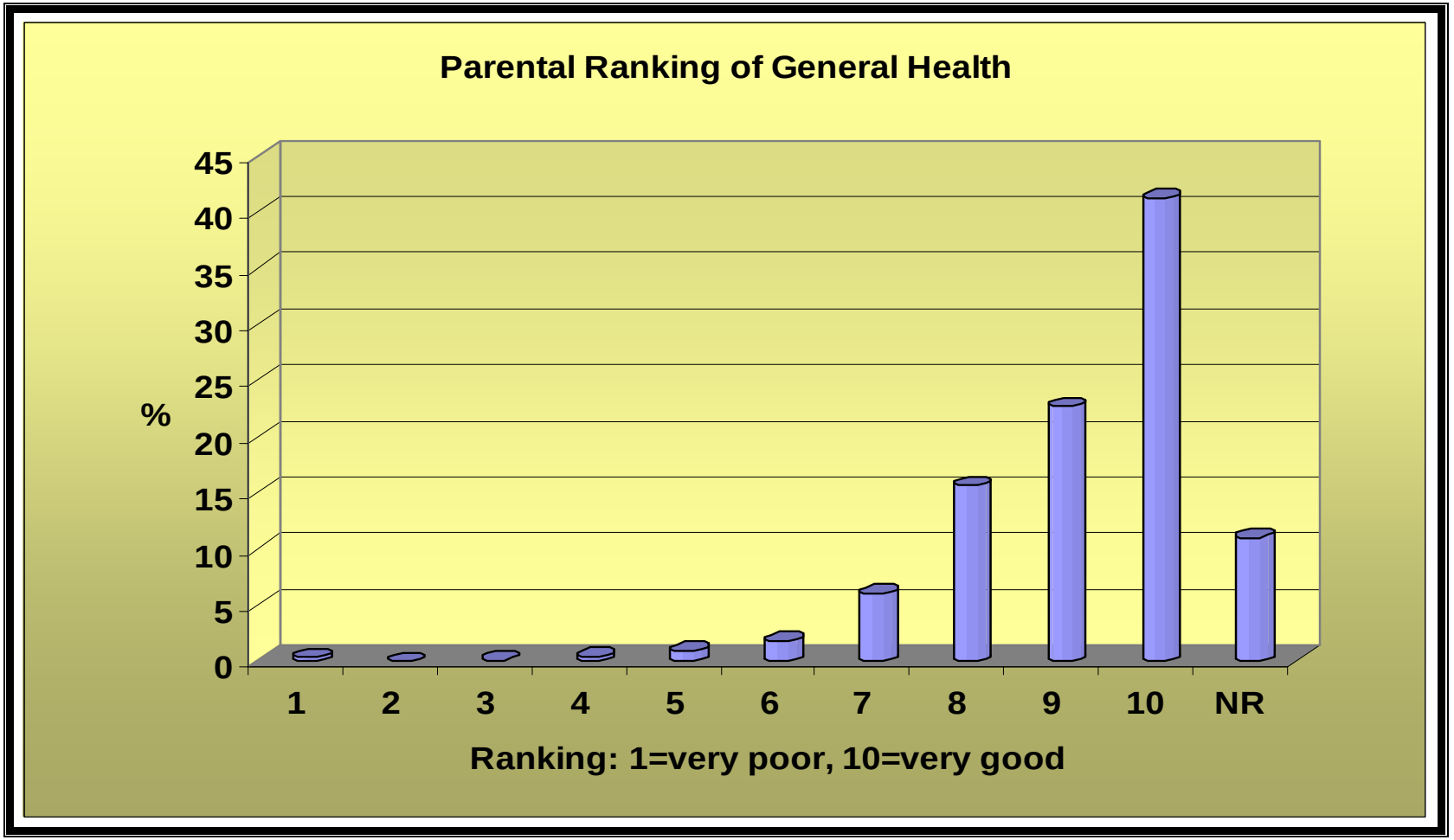
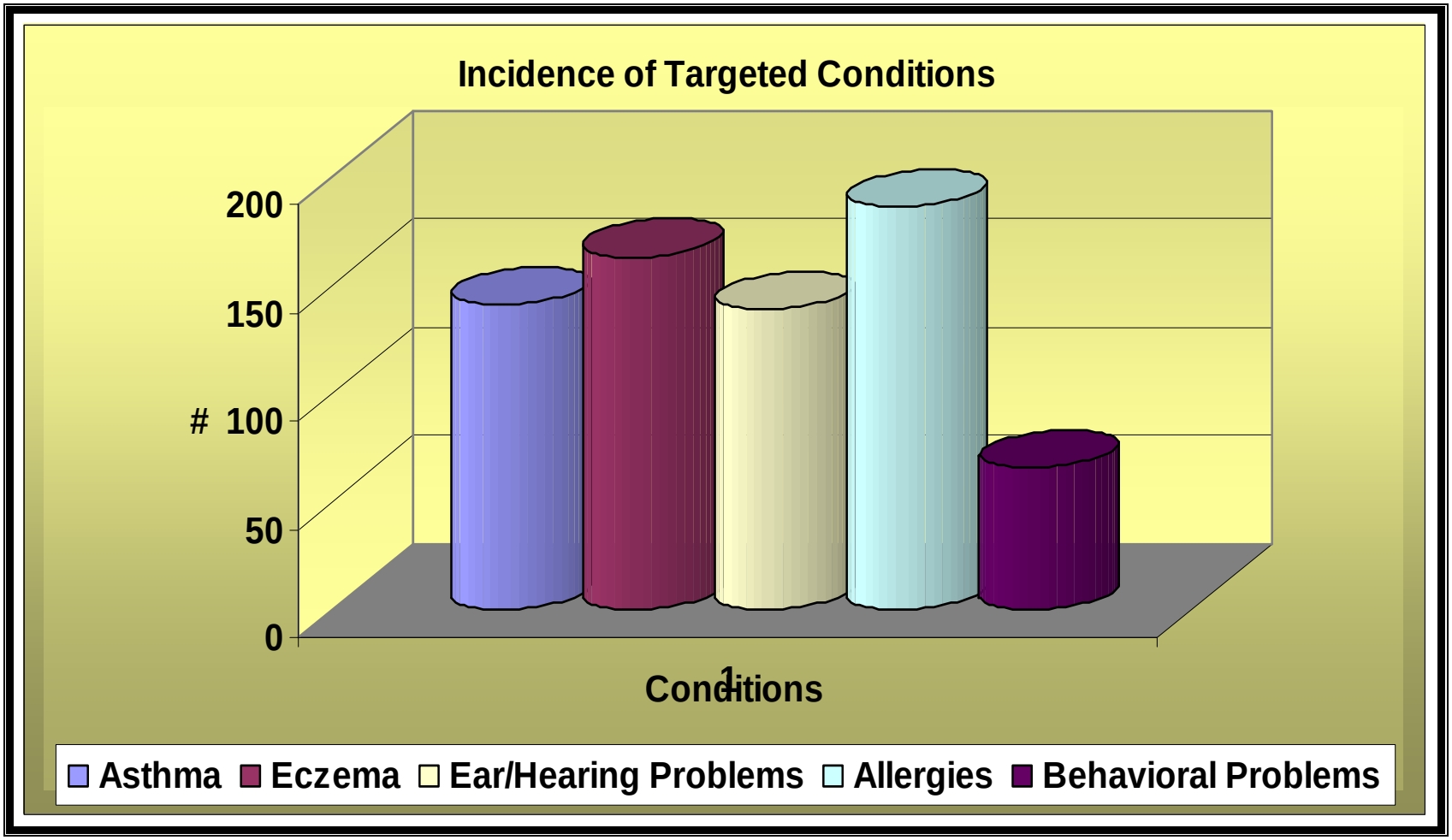
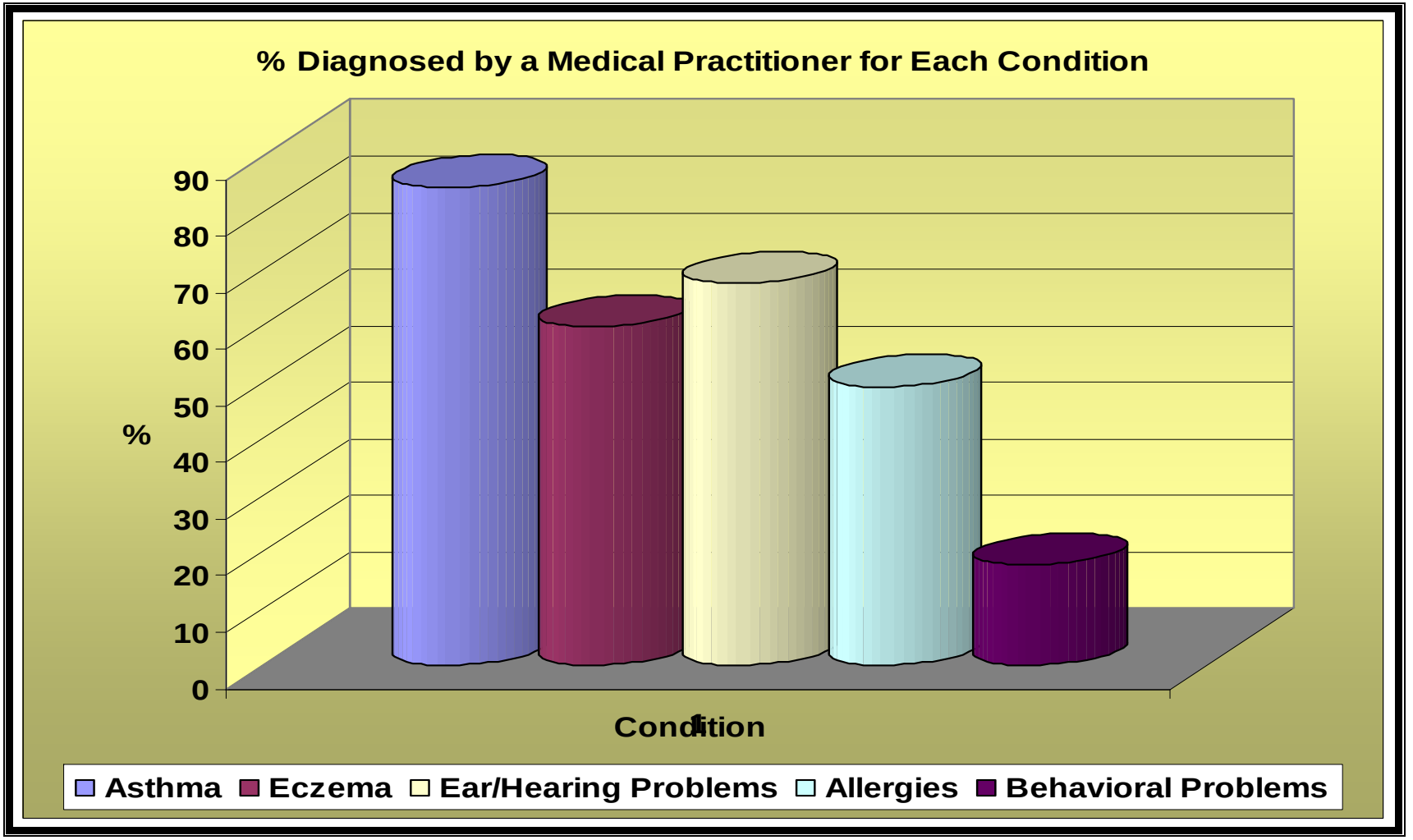


Figure 4.6-12 Incidence of Targeted Conditions



Another question asked was whether a medical practitioner diagnosed the condition. The results clearly demonstrated that most parents were prepared to consult a medical practitioner when they were concerned for the physical wellbeing of their children. This is shown in Figure 5.3-13 and is expected. The figures ranged from 84.5% diagnosed for asthma to 17.6% diagnosed for behavioural problems.

Figure 4.6-13 Percentage Diagnosed By a Medical Practitioner



4.6.1.3 Data Relating to the Effectiveness of HP

The third part of the research examined the incidence of specific diseases in order to gain some idea of the effectiveness of HP both in absolute terms and as compared to the other methods of disease prevention being studied.

Figure 5.3-14 shows the percentage of respondents who experienced Measles (10.2%), Mumps (0.9%) and Whooping Cough (8.3%). These diseases were targeted in the Questionnaire because they usually are covered by an HP program, and therefore are relevant when measuring the effectiveness of HP.

52.8% of respondents reported other infectious diseases. These would include diseases such as the common cold, chicken pox, and influenza, but as most HP programs do not cover them, they are not considered in the comparative analysis.

The percentage of children whose disease was diagnosed by a medical practitioner was also questioned. This is shown in Figure 5.3-15. When compared to Figure 5.3-13 it clearly shows that parents took the long-term conditions experienced by their children more seriously (in contacting medical practitioners) than the infectious diseases the children experienced.

It will surprise some to find that a doctor was consulted more often in cases of measles (44.3%) than in cases of whooping cough (31.0%), which is a potentially more life-threatening condition.

What is even more surprising is the very high level of diseases experienced by the children surveyed. Exact comparisons with national figures are not possible, however the data from the ABS *Health and communicable diseases* data gives some idea of the wide variance in the figures for Measles and Whooping Cough in particular (Australian Bureau of Statistics, 2003d).

The ABS report stated that in 2001, notifications for the targeted diseases were:

Measles	141
Whooping Cough	9,565
Mumps	114

Given that the notification figures are anecdotally based, it would appear likely that the ABS figures for the incidence of measles are understated. These figures show a 68 times greater chance of acquiring whooping cough than measles. Given that it is probable that some parents are still happy to treat measles in healthy children at home (as was widely done in previous decades), thus GP reports underestimate the true incidence of the disease.

If, for the purposes of this analysis, it is assumed that all notifications were in the 4-12 years age group (useful, even though clearly incorrect), then the expected figures for an "average" group of 781 children would become

Measles	0.05
Whooping Cough	3.1
Mumps	0.04

This compares to the survey figures for diseases diagnosed by a GP of

Measles	50
Whooping Cough	30
Mumps	1

This clearly shows that either the survey group were very different to the national population in terms of the incidence of the targeted infectious diseases, or that the national notifications significantly underestimate the true incidence of these diseases or, as is most likely, both are true.

Figure 4.6-14 Percentage of Targeted Infectious Diseases

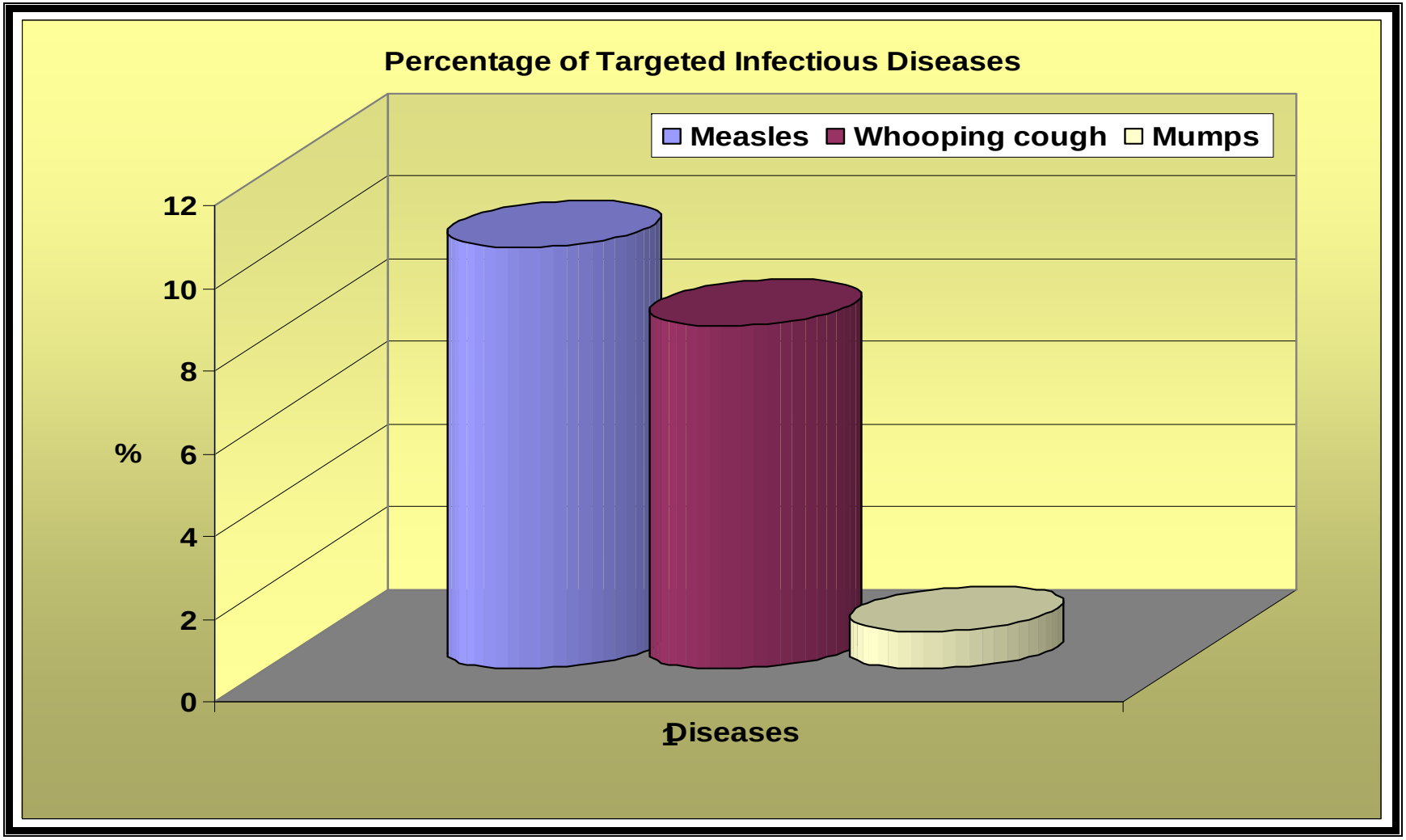
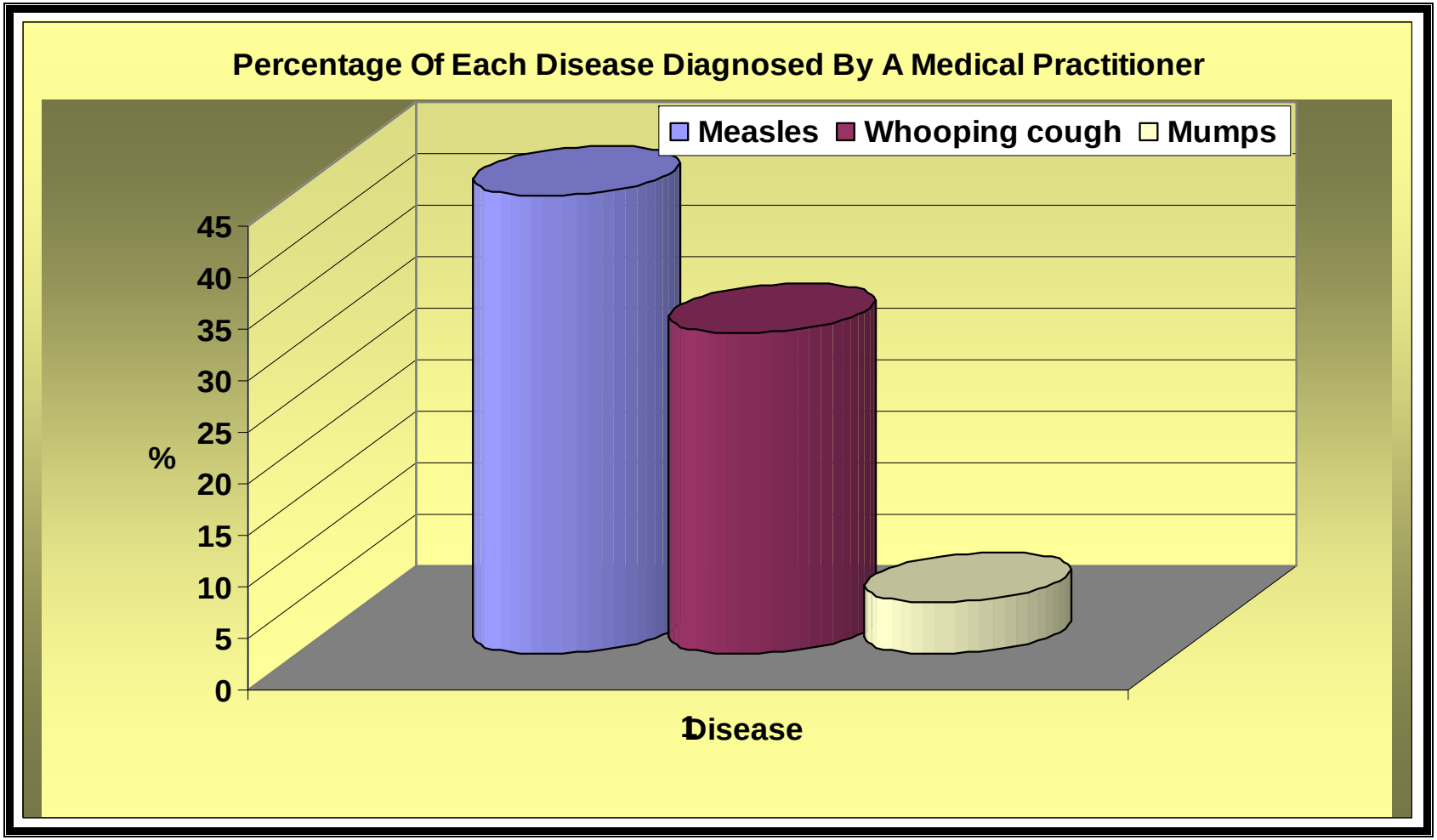


Figure 4.6-15 Percentage of Each Disease Diagnosed By a Medical Practitioner



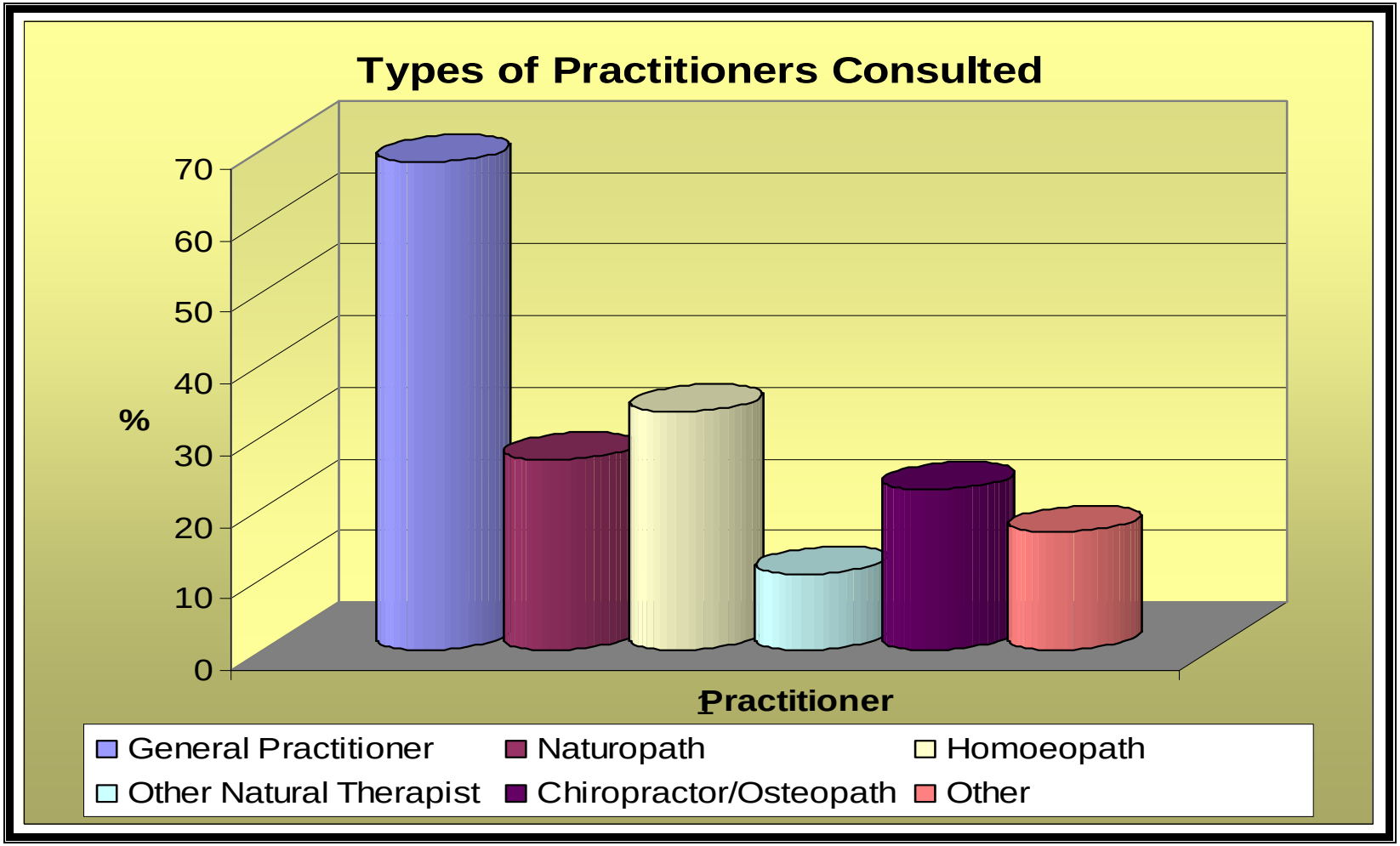
The use of different types of practitioners is shown in Figure 5.3-16. These results are typical in the sense that they reflect a high preparedness (68.1%) to consult orthodox medical practitioners. They also reveal a high preparedness to consult naturopaths (26.6%) and especially homoeopaths (33.3%).

This latter experience is expected, and reflects the fact that 20.4% of respondents used an HP program, as shown in Figure 5.3-9 above. However, it reveals a survey population that is not typical of the general community where consultations with naturopaths are much more common than consultations with homoeopaths.

An insight into national use of medical therapists was found in the ABS regional statistics for Tasmania which showed that in the 2 weeks prior to being interviewed for the 2001 National Health Survey, 23.5% of Tasmanians consulted a GP or a specialist and 12.3% consulted other health professionals which would have included natural therapists (Australian Bureau of Statistics, 2001).

No precise figures are available on consultations with naturopaths and homoeopaths, however, it is estimated that a figure of at least 5:1 is realistic.

Figure 4.6-16 Types of Practitioners Consulted



Finally a State distribution of responses was examined, and is shown in Figure 5.3-17.

The by-State distribution of respondents was very different to the actual population distribution in Australia as shown in the June 2001 National Census (Australian Bureau of Statistics 2003b). The exceptions were A.C.T., Western Australia and Victoria, where the survey and the census figures were similar.

Some reasons for these differences are:

New South Wales – 13.2% of respondents in the survey compared to 33.9% of national population.

One reason for the relative poor response from the most populated State was due to the refusal of the NSW Education Department to allow the questionnaire to be distributed through the NSW Primary School system. This refusal was a direct result of the NSW Health Department advising the Education Department not to allow the research to be conducted.

Queensland –13.2% of respondents in the survey compared to 18.7% of national population.

This difference may have in part been due to the geographical distance from the researcher's home state (Victoria) and Queensland, making awareness of the research more difficult.

South Australia – 18.7% of respondents in the survey compared to 7.8% of national population.

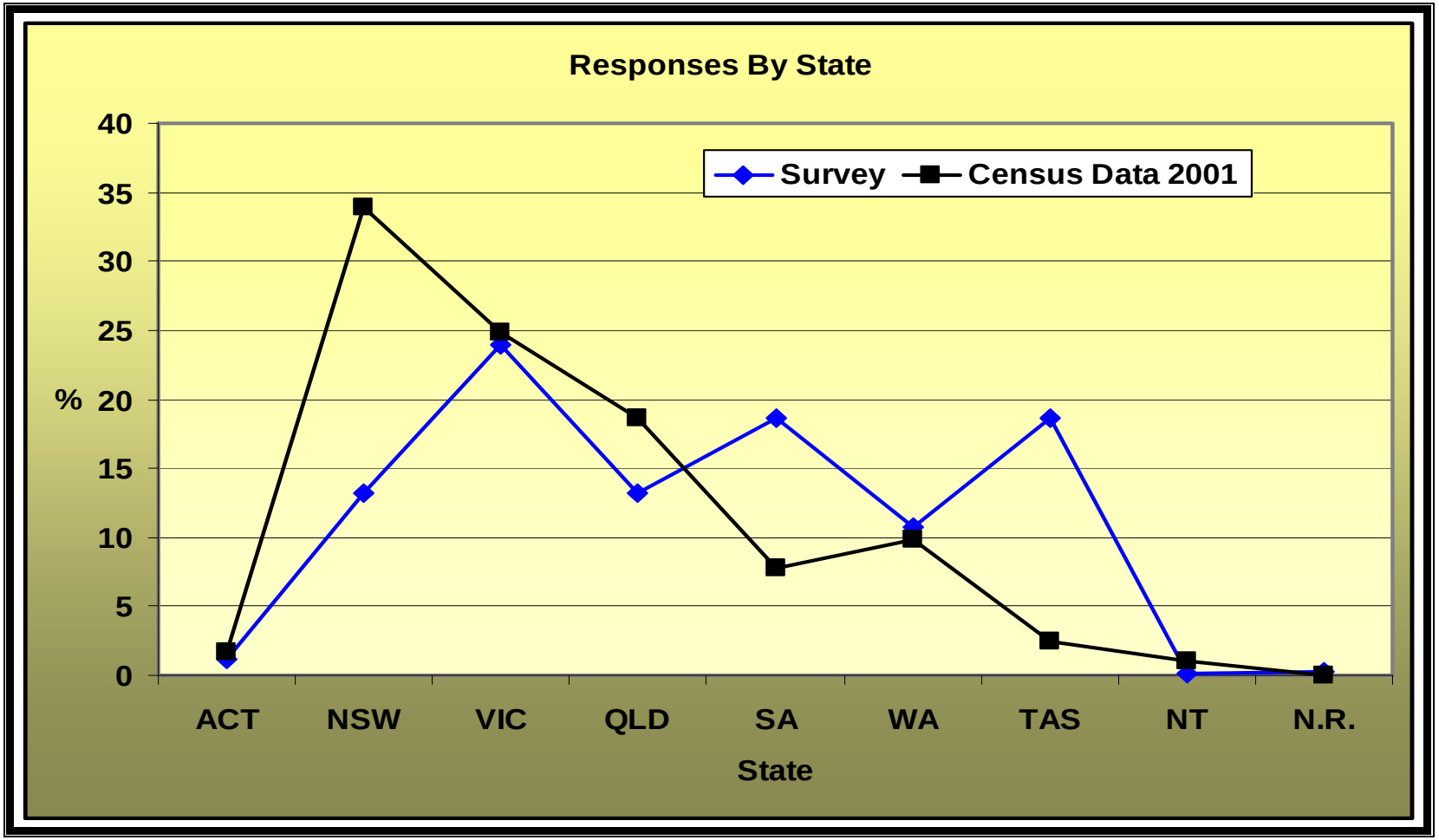
In this case the larger relative numbers achieved by the survey are directly attributable to the kind support offered by the S.A. Education Department, who allowed details of the research to be sent to primary schools in their State.

Tasmania – 18.7% of respondents in the survey compared to 2.4% of national population.

A similar reason is found for the relatively large numbers from Tasmania. In this case some individual primary school principals were very supportive of the survey and circulated details to the parents of children at their school.

Table 5.4-1 shows a brief comparison of responses to selected questions where the response was obtained from the general community and through primary schools.

Figure 4.6-17 Responses by State with National Average



4.6.2 Major Differences Between the Survey and National Populations

The following major differences exist between the survey and the national populations:

1. Children in the survey group were 15-25% more likely to be breastfed than children in the general population.
2. It is probable that Vitamin K injections were refused more in the survey group than in the general population.
3. Many more children in the survey group used HP and general/constitutional prevention than in the general population, and vaccination rates were lower.
4. A much higher than expected incidence of Measles, Whooping Cough and Mumps was found in the survey group, even when examining only diseases diagnosed by a GP. This may reflect a motivation for joining the survey group, or bring into question the accuracy of the national figures for notifications of infectious diseases. Whatever the reason(s) the survey population is definitely not typical of the national population in this regard. This suggests that the validity of the General Health Survey data in regard to the effectiveness of the different methods of disease prevention must be questioned.
5. A higher than expected number of children in the survey group consulted homoeopaths. This relates directly to point 3 above.
6. The by-State distribution of participants was different to the national distribution for the reasons shown above.

Thus the profile of the children surveyed in the General Health Survey was noticeably different to the profile of children in the general population. In some ways this difference is fortunate; otherwise, statistically significant figures relating to the use of HP would not have been available due to the relatively infrequent use of HP believed to occur in the general population.

However, this difference means that the validity of the figures for effectiveness of different disease prevention methods used by respondents to the General Health Survey must be examined with care to ensure that no biases are present to distort the figures.

4.7 A Comparison of School and Non-School Respondents

As stated in Chapter 4, participants in the General Health Survey were attracted by advertising in the general community and through some primary schools in Tasmania and South Australia, and a few schools in Victoria.

The general responses classified by source of data are shown in Table 5.6-2 at the end of this Chapter. The main results are summarised in Table 5.4-1 below.

Some of the major differences between the two groups of respondents (labelled **GC** for General Community and **PS** for Primary Schools) are:

1. The GC respondents are 15 months younger on average than PS respondents.
2. Disease Prevention methods differ significantly between the two groups. One third of GC respondents used HP, but only 2% in PS group. Half of the GC group vaccinated their children compared to over 70% of the PS group. One third of the GC group used general prevention compared to 14% of the PS group, although the numbers that used general prevention exclusively were very low (9% and 2% respectively). Thus the GC group used non-vaccination preventative methods much more actively than the PS group. In this way the PS group reflected the broader community, and the GC group reflected those parents who more actively investigate use natural health options. However 25% of the PS group reported that they used no form of prevention, suggesting most adopted a "vaccinate or nothing" approach
3. The PS group reported fewer problems with allergies and ears and hearing, but more asthma, eczema and behavioural problems. This is probably directly linked to their greater use of vaccination rather than HP.
4. The GC group reported more infectious diseases than the PS group, once again probably reflecting their disease prevention preferences.

The two groups are clearly different. If the General Health Survey is repeated in future research, a significant collection of respondents through the State Primary School Systems would produce a study group most closely resembling the national population.

The one disadvantage of relying on the primary school group is that it may not produce enough respondents who used HP and general/constitutional prevention to produce statistically significant comparative results. This would be remedied if a very large sample was collected. A sample of 5,000 responses should be sufficient.

Table 4.7-1 Summary of Some Attributes of School and Non-School Respondents

		General Community		Primary Schools		Combined	
Group Totals		495		286		781	
Average Age		96 months		111 months		102 months	
HP only	(total HP)*	14.3%	(30.9%)	0.4%	(2.1%)	9.2%	(20.4%)
Vaccination only	(total Vaccination)*	32.5%	(50.3%)	59.8%	(71.3%)	42.5%	(58.0%)
General Protection only	(total General Protection)*	8.9%	(30.3%)	2.1%	(14.0%)	6.7%	(24.3%)
No Protection		15.8%		25.2%		19.2%	
* (total figures include use of multiple methods)							
Proportion with Asthma		14.1%		24.8%		18.1%	
Proportion with Eczema		20.6%		21.3%		20.9%	
Proportion with Ear/Hearing Problems		19.4%		15.0%		17.8%	
Proportion with Allergies		26.3%		19.6%		23.8%	
Proportion with Behaviour Issues		0.2%		6.3%		2.4%	
Proportion with Measles		10.7%		9.5%		10.2%	
Proportion with Whooping Cough		4.7%		2.8%		4.0%	
Proportion with Mumps		1.0%		0.7%		0.9%	

4.8 Comparison of Respondents using a HP Program Supplied or Not Supplied by Golden

As noted in Chapter 4, respondents to the General Health Survey who said they used HP used a variety of programs. It was possible, through matching respondents' names and addresses, to identify which respondents to the General Health Survey purchased their program from Golden.

It is possible that some respondents who did not purchase an HP program from Golden still used a program purchased from another practitioner who copied Golden's program. However, it was not possible to identify these respondents from the data collected.

A comparison between respondents using programs purchased from Golden and programs not purchased from Golden revealed noticeable differences. The actual numbers of respondents is shown in Table 5.5-1, and proportions are reported in Tables 5.5-2 and 5.5-3.

The result in Table 5.5-2 shows that using HP alone gives a better result than using HP combined with other forms of disease prevention. This suggests that some users may have had a bad experience with other forms of prevention and then switched to HP, but this cannot be proved from the figures.

A comparison was reported in Table 5.5-3 between conditions and diseases for all HP users, and those who used HP only. All but one comparison (allergies – HP only) showed a better result for the programs supplied by Golden. However, the size of data collected does not allow the statistical significance of these comparisons to be calculated.

Chi Squared tests were performed to compare programs supplied by Golden and programs not supplied by Golden. An odds ratio >1 would show an unfavourable result

for programs supplied by Golden, and a result <1 would be favourable to Golden's program.

The following results were statistically significant, and all showed that Asthma and the three diseases studied are all less likely to occur if a program supplied by Golden is used compared to one not supplied by Golden.

Asthma: All HP: Odds Ratio = 0.28; P = 96%

Measles: All HP: Odds Ratio = 0.33; P = 95%;
HP Only: Odds Ratio = 0; P = 94%

Whooping Cough: HP Only: Odds Ratio = 0; P = 97%

Mumps: HP Only: Odds Ratio = 0; P = 100%

Finally, Figure 5.5-1 showing the accumulated parental rankings of their child's wellbeing indicates that HP programs supplied by Golden rank consistently with the other options, being top at the accumulated '9' and '10' rankings.

The results show that the type of HP program used does make a difference. They indicate, with some degree of significance, that children using HP programs supplied by Golden acquired fewer infectious diseases and reported fewer adverse long-term health conditions.

Table 4.8-1 Comparison of HP Use – Program Supplied/Not Supplied by Golden – Actual Numbers

	HP Supplied by Golden		HP Not Supplied By Golden		Combined	
	All HP	HP Only	All HP	HP Only	All HP	HP Only
Number of Respondents	59	25	100	47	159	72
HP only	25		47		72	
Vaccination also	20		31		51	
General Protection also	26		42		68	
(including all three methods)	12		20		32	
Number with Asthma	3	0	16	2	21	2
Number with Eczema	10	1	20	6	30	7
Number with Ear/Hearing	9	2	26	10	35	12
Number with Allergies	14	4	29	6	43	10
Number with Behaviour Issues	5	0	12	3	17	3
Number with Measles	4	0	18	6	22	6
Number with Whooping Cough	6	0	17	8	23	8
Number with Mumps	1	0	1	0	2	0

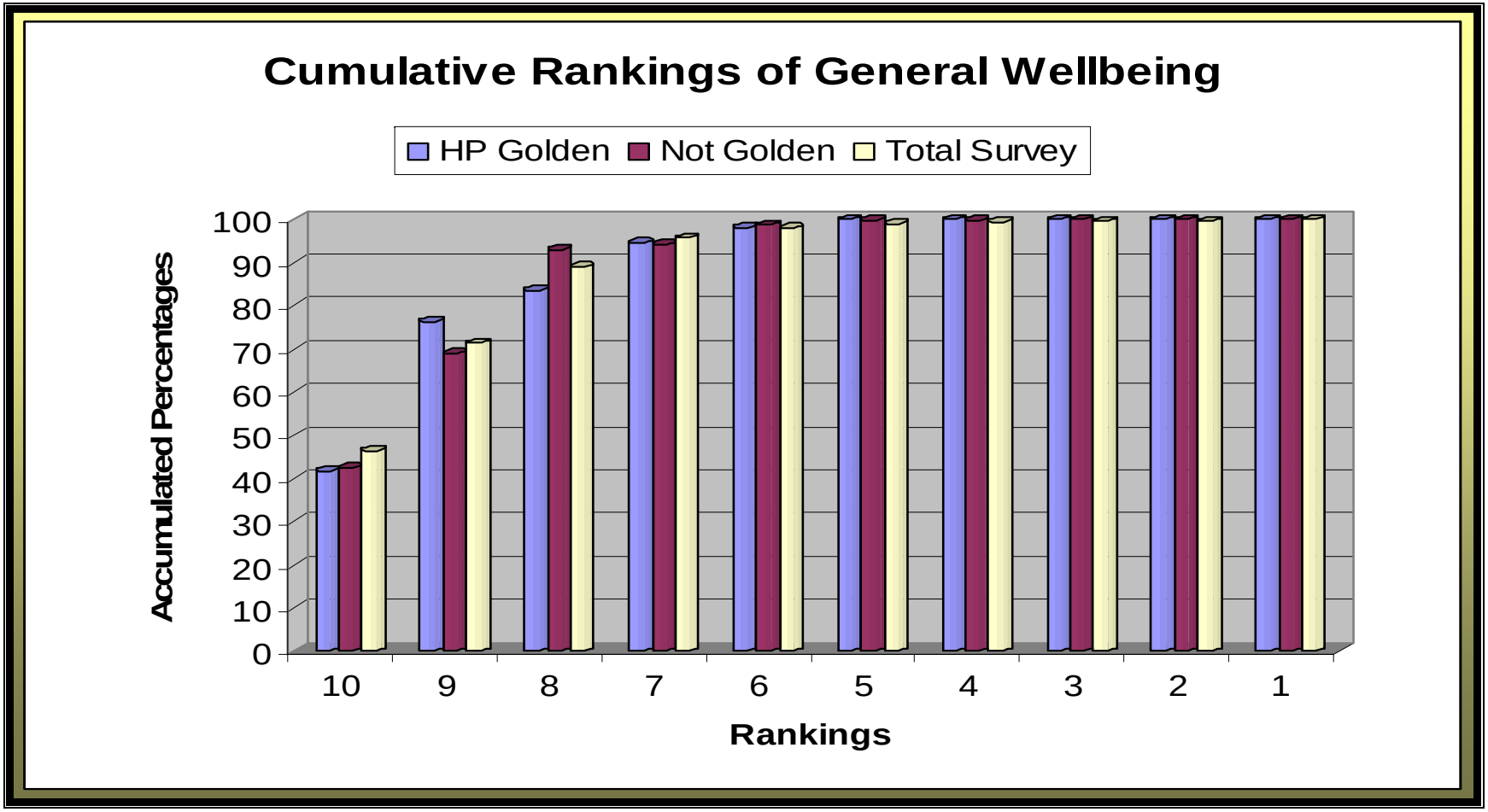
Table 4.8-2 Comparison of HP Use – Program Supplied/Not Supplied by Golden – Proportions (1)

	HP Supplied by Golden		HP Not Supplied By Golden		Combined	
	All HP	HP Only	All HP	HP Only	All HP	HP Only
Number of Respondents	59	25	100	47	159	72
HP only	42.4%		47.0%		45.3%	
Vaccination also	33.9%		31.0%		32.1%	
General Protection also	44.1%		42.0%		42.8%	
Proportion with Asthma	5.1%	0.0%	16.0%	4.3%	13.2%	2.8%
Proportion with Eczema	17.0%	4.0%	20.0%	12.8%	18.9%	9.7%
Proportion with Ear/Hearing	15.3%	8.0%	26.0%	21.3%	22.0%	16.7%
Proportion with Allergies	23.7%	16.0%	29.0%	12.8%	27.0%	13.9%
Proportion with Behaviour Issues	8.5%	0.0%	12.0%	6.4%	10.7%	4.2%
Proportion with Measles	6.8%	0.0%	18.0%	12.8%	13.8%	8.3%
Proportion with Whooping Cough	10.2%	0.0%	17.0%	17.0%	14.5%	11.1%
Proportion with Mumps	1.7%	0.0%	1.0%	0.0%	1.3%	0.0%

Table 4.8-3 Comparison of HP Use – Program Supplied/Not Supplied by Golden – Proportions (2)

	All HP		HP Only	
	Golden	**Not Golden**	**Golden**	**Not Golden**
Number of Respondents	59	100	25	47
HP only	42.4%	47.0%		
Vaccination also	33.9%	31.0%		
General Protection also	44.1%	42.0%		
Proportion with Asthma	5.1%	16.0%	0.0%	4.3%
Proportion with Eczema	17.0%	20.0%	4.0%	12.8%
Proportion with Ear/Hearing	15.3%	26.0%	8.0%	21.3%
Proportion with Allergies	23.7%	29.0%	16.0%	12.8%
Proportion with Behaviour Issues	8.5%	12.0%	0.0%	6.4%
Proportion with Measles	6.8%	18.0%	0.0%	12.8%
Proportion with Whooping Cough	10.2%	17.0%	0.0%	17.0%
Proportion with Mumps	1.7%	1.0%	0.0%	0.0%

Figure 4.8-1 Cumulative Rankings of General Wellbeing



4.9 Tables of Results

Table 4.9-1: Summary of Results from Follow-Up of Non-Respondents

RESEARCH TOPIC A1 - FOLLOW UP ON NON-RESPONDENTS TO EXISTING RESEARCH												
							Completed					
Date		Numbers Sent			Responded		Orig. Q'airre		Left Address		No Response	
Sent	Series	Letters	Children		Let.	Child.	Let.	Child.	Let.	Child.	Let.	Child.
25-Apr-01	11	19	22									
25-Apr-01	12	23	24									
25-Apr-01	13	25	25									
		67	**71**		**17**	**17**	**0**	**0**	**8**	**8**	**42**	**46**
				%	25.4%	23.9%	0.0%	0.0%	11.9%	11.3%	62.7%	64.8%
							*	*				
31-May-01	14	**45**	**48**		**19**	**19**	**3**	**3**	**3**	**3**	**20**	**23**
				%	42.2%	39.6%	6.7%	6.3%	6.7%	6.3%	44.4%	47.9%
							*	*				
06-Aug-02	15	**45**	**51**		**16**	**17**	**7**	**7**	**2**	**2**	**20**	**25**
				%	35.6%	33.3%	15.6%	13.7%	4.4%	3.9%	44.4%	49.0%
TOTALS	**	**157**	**170**		**52**	**53**	**10**	**10**	**13**	**13**	**82**	**94**
				%	33.1%	31.2%	6.4%	5.9%	8.3%	7.6%	52.2%	55.3%

* Does not include those 8 respondents who returned a completed questionnaire plus filled in a Questionnaire Response

** Note that there were 13 families where 1 letter was sent , but 2 children in the family were on the Program

QUESTION 1: WHY DIDN'T YOU RETURN THE KIT QUESTIONNAIRE?		
	Response	**%**
Lost It	9	16.7%
Couldn't Be Bothered	3	5.6%
Concerned With Confidentiality	0	0.0%
Other	32	59.3%
I did return the kit questionnaire	8	14.8%
No Response	2	3.7%
Total	**54**	**100.0%**
* Includes multiple responses		

QUESTION 2: DID YOU USE THE KIT?		
	Response	**%**
Partially	24	45.3%
Fully	19	35.8%
Not At All	6	11.3%
No Response	4	7.5%
Total	**53**	**100.0%**

QUESTION 3: HOW WOULD YOU DESCRIBE THE KIT'S SUCCESS IN PREVENTING DISEASE?		
	Response	**%**
Successful	31	58.5%
Unsuccessful	0	0.0%
Partially Successful	2	3.8%
Don't Know	9	17.0%
Did Not Use The Kit	6	11.3%
No Response	5	9.4%
Total	**53**	**100.0%**

QUESTION 4: RANK YOUR LEVEL OF SATISFACTION WITH THE KIT BETWEEN 1 AND 10 (1 = totally dissatisfied; 10 = totally satisfied)		
	Response	**%**
1	1	1.9%
2	0	0.0%
3	0	0.0%
4	0	0.0%
5	3	5.7%
6	1	1.9%
7	2	3.8%
8	3	5.7%
9	5	9.4%
10	24	45.3%
No Response	14	26.4%
Total	**53**	**100.0%**

QUESTION 5: WHICH STATE DO YOU LIVE IN?		
	Response	**%**
NSW	3	5.7%
VIC	37	69.8%
QLD	5	9.4%
WA	0	0.0%
SA	1	1.9%
TAS	4	7.5%
NT	0	0.0%
ACT	0	0.0%
No Response	3	5.7%
Total	**53**	**100.0%**

QUESTION 6: WOULD YOU LIKE TO PARTICIPATE IN A GENERAL HEALTH SURVEY OF AUSTRALIAN CHILDREN?		
	Response	**%**
Yes	35	66.0%
No	11	20.8%
No Response	7	13.2%
Total	**53**	**100.0%**

Table 4.9-2 Summary of General Health Survey for School/Not School Responses

(a) Age						
	School		**Not School**		**Combined**	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Less than 4 years	0	0.0	0	0.0	0	0.0
4 years, under 5	5	1.7	37	7.5	42	5.4
5 years, under 6	29	10.1	86	17.4	115	14.7
6 years, under 7	25	8.7	71	14.3	96	12.3
7 years, under 8	33	11.5	85	17.2	118	15.1
8 years, under 9	37	12.9	44	8.9	81	10.4
9 years, under 10	35	12.2	47	9.5	82	10.5
10 years, under 11	36	12.6	56	11.3	92	11.8
11 years or over	83	29.0	66	13.3	149	19.1
No response	3	1.0	3	0.6	6	0.8
TOTAL	**286**	**100.0**	**495**	**100.0**	**781**	**100.0**

(b) Sex						
	School		**Not School**		**Combined**	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Male	130	45.5	253	51.1	383	49.0
Female	137	47.9	217	43.8	354	45.3
No response	19	6.6	25	5.1	44	5.6
TOTAL	**286**	**100.0**	**495**	**100.0**	**781**	**100.0**

(c) Birth weight	**School**		**Not School**		**Combined**	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
under 1 kg	2	0.7	3	0.6	5	0.6
1 kg, under 2 kg	10	3.5	6	1.2	16	2.0
2 kg, under 3 kg	61	21.3	65	13.1	126	16.1
3 kg, under 4 kg	163	57.0	331	66.9	494	63.3
4 kg, under 5 kg	39	13.6	70	14.1	109	14.0
5 kg and over	2	0.7	2	0.4	4	0.5
No response	9	3.1	18	3.6	27	3.5
TOTAL	**286**	**100.0**	**495**	**100.0**	**781**	**100.0**

(d) How long breastfed:

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Not breastfed	39	13.6	11	2.2	50	6.4
under 3 months	41	14.3	34	6.9	75	9.6
3 months, under 6 months	43	15.0	33	6.7	76	9.7
6 months, under 12 months	61	21.3	129	26.1	190	24.3
12 months, under 18 months	64	22.4	131	26.5	195	25.0
18 months, under 24 months	23	8.0	58	11.7	81	10.4
24 months and over	11	3.8	91	18.4	102	13.1
No response	4	1.4	8	1.6	12	1.5
TOTAL	**286**	**100.0**	**495**	**100.0**	**781**	**100.0**

(e) APGAR Score First								
		School		Not School		Combined	
		Nos.	%	Nos.	%	Nos.	%
0		0	0.0	1	0.2	1	0.1
1		3	1.0	2	0.4	5	0.6
2		5	1.7	1	0.2	6	0.8
3		0	0.0	3	1.6	3	1.0
4		3	1.0	5	1.0	8	1.0
5		5	1.7	12	2.4	17	2.2
6		15	5.2	12	2.4	27	3.5
7		32	11.2	29	5.9	61	7.8
8		44	15.4	59	11.9	103	13.2
9		60	21.0	159	32.1	219	28.0
10		7	2.4	30	6.1	37	4.7
No Response		112	39.2	182	36.8	294	37.6
TOTAL		**286**	**100.0**	**495**	**101.0**	**781**	**100.6**

(e) APGAR Score Second						
	School		Not School		Combined	
	Nos.	%	Nos.	%	Nos.	%
0	0	0.0	0	0.0	0	0.0
1	1	0.3	0	0.0	1	0.1
2	1	0.3	2	0.4	3	0.4
3	0	0.0	0	0.0	0	0.0
4	0	0.0	0	0.0	0	0.0
5	1	0.3	2	0.4	3	0.4
6	2	0.7	1	0.2	3	0.4
7	3	1.0	6	1.2	9	1.2
8	15	5.2	12	2.4	27	3.5
9	73	25.5	130	26.3	203	26.0
10	73	25.5	137	27.7	210	26.9
No Response	117	40.9	205	41.4	322	41.2
TOTAL	**286**	**100.0**	**495**	**100.0**	**781**	**100.0**

(f) If premature, by how many weeks:						
	School		**Not School**		**Combined**	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Not premature	210	73.4	404	81.6	614	78.6
to 1 week	0	0.0	2	0.4	2	0.3
1 to under 2 weeks	6	2.1	10	2.0	16	2.0
2 to under 3 weeks	27	9.4	27	5.5	54	6.9
3 to under 4 weeks	9	3.1	10	2.0	19	2.4
4 to under 6 weeks	13	4.5	24	4.8	37	4.7
6 weeks or over	20	7.0	11	2.2	31	4.0
up to 1 week late	0	0.0	1	0.2	1	0.1
1 - 2 weeks late	1	0.3	6	1.2	7	0.9
No Response	0	0.0	0	0.0	0	0.0
TOTAL	**286**	**100.0**	**495**	**100.0**	**781**	**100.0**

Did your child receive a Vitamin K injection following birth?

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	195	68.2	266	53.7	461	59.0
No	44	15.4	156	31.5	200	25.6
No Response	47	16.4	73	14.7	120	15.4
TOTAL	**286**	**100.0**	**495**	**100.0**	**781**	**100.0**

Question 1 (a) - Was your child given orthodox vaccines?

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	204	71.3	249	50.3	453	58.0
No	62	21.7	238	48.1	300	38.4
No Response	20	7.0	8	1.6	28	3.6
TOTAL	**286**	**100.0**	**495**	**100.0**	**781**	**100.0**

Question 1 (b) - Did your child use a homoeopathic preventative program?

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	6	2.1	153	30.9	159	20.4
No	229	80.1	291	58.8	520	66.6
No Response	51	17.8	51	10.3	102	13.1
TOTAL	**286**	**100.0**	**495**	**100.0**	**781**	**100.0**

Question 1 (c) - Did your child use general/constitutional prevention?

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	40	14.0	150	30.3	190	24.3
No	163	57.0	241	48.7	404	51.7
No Response	83	29.0	104	21.0	187	23.9
TOTAL	**286**	**100.0**	**495**	**100.0**	**781**	**100.0**

Question 1 (d) - If "yes" to any of the above, please give details

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Response	153	53.5	346	69.9	499	63.9
Not Applicable	56	19.6	86	17.4	142	18.2
No Response	77	26.9	63	12.7	140	17.9
TOTAL	**286**	**100.0**	**495**	**100.0**	**781**	**100.0**

Question 2 (a) Please rank the general health of your child between 1 and 10 (1 = very poor general health; 10 = excellent general health)?						
	School		**Not School**		**Combined**	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
1 very poor general health	0	0.0	2	0.4	2	0.3
2	0	0.0	0	0.0	0	0.0
3	0	0.0	1	2.4	1	1.2
4	2	0.7	1	0.2	3	0.4
5	3	1.0	4	0.8	7	0.9
6	4	1.4	10	2.0	14	1.8
7	10	3.5	37	7.5	47	6.0
8	35	12.2	87	17.6	122	15.6
9	55	19.2	122	24.6	177	22.7
10 excellent general health	132	46.2	190	38.4	322	41.2
No Response	45	15.7	41	8.3	86	11.0
TOTAL	**286**	**100.0**	**495**	**102.2**	**781**	**101.0**

Has your child had any of the following? - if "yes" please give age(s) and details

Question 2 (b) Asthma

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	71	24.8	70	14.1	141	18.1
No	214	74.8	425	85.9	639	81.8
No Response	1	0.3	0	0.0	1	0.1
TOTAL	**286**	**100.0**	**495**	**100.0**	**781**	**100.0**

Question 2 (c) Was this condition diagnosed by a medical practitioner?

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	71	88.8	65	80.2	136	84.5
No	8	10.0	13	16.0	21	13.0
No Response	1	1.3	3	3.7	4	2.5
TOTAL	**80**	**100.0**	**81**	**100.0**	**161**	**100.0**

Question 2 (d) Eczema

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	61	21.3	102	20.6	163	20.9
No	221	77.3	392	79.2	613	78.5
No Response	4	1.4	1	0.2	5	0.6
TOTAL	**286**	**100.0**	**495**	**100.0**	**781**	**100.0**

Question 2 (e) Was this condition diagnosed by a medical practitioner?

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	56	70.9	58	51.8	114	59.7
No	21	26.6	48	42.9	69	36.1
No Response	2	2.5	6	5.4	8	4.2
TOTAL	**79**	**100.0**	**112**	**100.0**	**191**	**100.0**

Question 2 (f) Ear / hearing problems

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	43	15.0	96	19.4	139	17.8
No	240	83.9	396	80.0	636	81.4
No Response	3	1.0	3	0.6	6	0.8
TOTAL	**286**	**100.0**	**495**	**100.0**	**781**	**100.0**

Question 2 (g) Was this condition diagnosed by a medical practitioner?

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	34	56.7	78	81.3	112	71.8
No	22	36.7	17	17.7	39	25.0
No response	4	6.7	1	1.0	5	3.2
TOTAL	**60**	**100.0**	**96**	**100.0**	**156**	**100.0**

Question 2 (h) Allergies

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	56	19.6	130	26.3	186	23.8
No	223	78.0	361	72.9	584	74.8
No response	7	2.4	4	0.8	11	1.4
TOTAL	**286**	**100.0**	**495**	**100.0**	**781**	**100.0**

Question 2 (i) Was this condition diagnosed by a medical practitioner?

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	38	50.0	53	36.6	91	41.2
No	28	36.8	79	54.5	107	48.4
No response	10	13.2	13	9.0	23	10.4
TOTAL	**76**	**100.0**	**145**	**100.0**	**221**	**100.0**

Question 2 (j) Behavioral problems

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	18	6.3	48	9.7	66	8.5
No	263	92.0	442	89.3	705	90.3
No response	5	1.7	5	1.0	10	1.3
TOTAL	**286**	**100.0**	**495**	**100.0**	**781**	**100.0**

Question 2 (k) Was this condition diagnosed by a medical practitioner?

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	9	25.7	9	13.4	18	17.6
No	24	68.6	49	73.1	73	71.6
No response	2	5.7	9	13.4	11	10.8
TOTAL	**35**	**100.0**	**67**	**100.0**	**102**	**100.0**

The following infectious diseases

Question 2 (l) Measles

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	27	9.4	53	10.7	80	10.2
No	250	87.4	436	88.1	686	87.8
No response	9	3.1	6	1.2	15	1.9
TOTAL	**286**	**100.0**	**495**	**100.0**	**781**	**100.0**

Question 2 (m) Was this condition diagnosed by a medical practitioner?

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	23	48.9	28	41.2	51	44.3
No	17	36.2	32	47.1	49	42.6
No response	7	14.9	8	11.8	15	13.0
TOTAL	**47**	**100.0**	**68**	**100.0**	**115**	**100.0**

Question 2 (n) Whooping cough

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	8	2.8	57	11.5	65	8.3
No	272	95.1	433	87.5	705	90.3
No response	6	2.1	5	1.0	11	1.4
TOTAL	**286**	**100.0**	**495**	**100.0**	**781**	**100.0**

Question 2 (o) Was this condition diagnosed by a medical practitioner?

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	7	25.0	24	33.3	31	31.0
No	18	64.3	42	58.3	60	60.0
No response	3	10.7	6	8.3	9	9.0
TOTAL	**28**	**100.0**	**72**	**100.0**	**100**	**100.0**

Question 2 (p) Mumps

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	2	0.7	5	1.0	7	0.9
No	276	96.5	487	98.4	763	97.7
No response	8	2.8	3	0.6	11	1.4
TOTAL	**286**	**100.0**	**495**	**100.0**	**781**	**100.0**

Question 2 (q) Was this condition diagnosed by a medical practitioner?

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	1	4.2	1	5.9	2	4.9
No	19	79.2	14	82.4	33	80.5
No response	4	16.7	2	11.8	6	14.6
TOTAL	**24**	**100.0**	**17**	**100.0**	**41**	**100.0**

Question 2 (r) Any other infectious disease

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	131	45.8	282	57.0	413	52.9
No	152	53.1	212	42.8	364	46.6
No response	3	1.0	1	0.2	4	0.5
TOTAL	**286**	**100.0**	**495**	**100.0**	**781**	**100.0**

Question 2 (s) Was this condition diagnosed by a medical practitioner?

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	86	58.9	141	49.0	227	52.3
No	56	38.4	128	44.4	184	42.4
No response	4	2.7	19	6.6	23	5.3
TOTAL	**146**	**100.0**	**288**	**100.0**	**434**	**100.0**

Question 3: Does your child have ongoing chronic health problems (including any noted above)?						
	School		**Not School**		**Combined**	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	50	17.5	105	21.2	155	19.8
No	229	80.1	370	74.7	599	76.7
No response	7	2.4	20	4.0	27	3.5
TOTAL	**286**	**100.0**	**495**	**100.0**	**781**	**100.0**

Question 3: If "yes" please give details						
	School		**Not School**		**Combined**	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Response	56	94.9	149	99.3	205	98.1
No Response	3	5.1	1	0.7	4	1.9
TOTAL	**59**	**100.0**	**150**	**100.0**	**209**	**100.0**

Question 4 (a) How many times has your child been hospitalised?						
	School		**Not School**		**Combined**	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
0 Times	150	52.4	319	64.4	469	60.1
1 - 2	108	37.8	143	28.9	251	32.1
3 - 4	15	5.2	19	3.8	34	4.4
5 - 6	0	0.0	8	1.6	8	1.0
7 - 10	2	0.7	2	0.4	4	0.5
11 - 16	5	1.7	1	0.2	6	0.8
17 or more	1	0.3	0	0.0	1	0.1
No response	5	1.7	3	0.6	8	1.0
TOTAL	**286**	**100.0**	**495**	**100.0**	**781**	**100.0**

Question 4 (b) If hospitalised, how long were the stays in hospital?						
	School		**Not School**		**Combined**	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Less than a full day	7	2.4	17	3.4	24	3.1
1 - 2 days	58	20.3	64	12.9	122	15.6
3 - 4	29	10.1	30	6.1	59	7.6
5 - 6	4	1.4	10	2.0	14	1.8
1 week, under 2 weeks	17	5.9	26	5.3	43	5.5
2 weeks, under 3 weeks	10	3.5	5	1.0	15	1.9
3 weeks or more	5	1.7	13	2.6	18	2.3
Not applicable	150	52.4	319	64.4	469	60.1
No response	6	2.1	11	2.2	17	2.2
TOTAL	**286**	**100.0**	**495**	**100.0**	**781**	**100.0**

Question 5: (a) Does your child receive any special treatments to strengthen their general health, such as: Naturopathic, homoeopathic, herbal, nutritional, special diet.

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	51	17.8	342	69.1	393	50.3
No	231	80.8	126	25.5	357	45.7
No response	4	1.4	27	5.5	31	4.0
TOTAL	**286**	**100.0**	**495**	**100.0**	**781**	**100.0**

0uestion 5: (b) If "yes", please give brief details

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Response	52	91.2	377	99.2	429	98.2
Not applicable	0	0.0	0	0.0	0	0.0
No response	5	8.8	3	0.8	8	1.8
TOTAL	**57**	**100.0**	**380**	**100.0**	**437**	**100.0**

Question 6: Has your child been sufficiently unwell for you to have consulted one or more of the following health professionals

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	173	60.5	370	74.7	543	69.5
No	87	30.4	65	13.1	152	19.5
No response	26	9.1	60	12.1	86	11.0
TOTAL	**286**	**100.0**	**495**	**100.0**	**781**	**100.0**

(a) Medical practitioner

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	192	67.1	340	219.4	532	219.8
No	87	30.4	93	60.0	180	74.4
Not applicable	0	0.0	0	0.0	0	0.0
No response	7	2.4	62	40.0	62	25.6
TOTAL	**286**	**100.0**	**155**	**319.4**	**242**	**319.8**

(b) Naturopath

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	24	8.4	184	59.2	208	26.6
No	170	59.4	152	48.9	322	41.2
Not applicable	0	0.0	0	0.0	0	0.0
No response	92	32.2	159	51.1	251	32.1
TOTAL	**286**	**100.0**	**311**	**159.2**	**781**	**100.0**

(c) Homoeopath

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	10	3.5	250	102.0	260	33.3
No	178	62.2	126	51.4	304	38.9
Not applicable	0	0.0	0	0.0	0	0.0
No response	98	34.3	119	48.6	217	27.8
TOTAL	**286**	**100.0**	**245**	**202.0**	**781**	**100.0**

(d) Other natural therapist

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	8	2.8	75	17.9	83	10.6
No	175	61.2	182	43.3	357	45.7
Not applicable	0	0.0	0	0.0	0	0.0
No response	103	36.0	238	56.7	341	43.7
TOTAL	**286**	**100.0**	**420**	**117.9**	**781**	**100.0**

(e) Chiropractor/osteopath

	School		Not School		Combined	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	17	5.9	158	46.9	175	22.4
No	170	59.4	152	45.1	322	41.2
Not applicable	0	0.0	0	0.0	0	0.0
No response	99	34.6	185	54.9	284	36.4
TOTAL	**286**	**100.0**	**337**	**146.9**	**781**	**100.0**

(f) Other (please specify below)						
	School		**Not School**		**Combined**	
	Nos.	**%**	**Nos.**	**%**	**Nos.**	**%**
Yes	38	13.3	90	22.2	128	16.4
No	154	53.8	150	37.0	304	38.9
Not applicable	0	0.0	0	0.0	0	0.0
No response	94	32.9	255	63.0	349	44.7
TOTAL	**286**	**100.0**	**405**	**122.2**	**781**	**100.0**

5 Discussion about the Safety and Effectiveness of Homoeoprophylaxis

5.1 Introduction

The aim of this thesis is to determine whether HP can safely prevent targeted infectious diseases.

It must be stated at the outset of this discussion that the study of this thesis may be biased because the long-term HP program studied here has been used, with minor amendments, since 1986, implying a satisfaction with the relative safety and efficacy of the program being studied.

Every effort has been made to ensure that data collection and classification has been objective, and that conclusions are reasonably based on the data and the data alone, thus limiting the likelihood of this potential bias. The aim of allowing the data to provide the final answer has been paramount, and unexpected results have been welcomed as growing the body of established knowledge in the field.

The determination whether HP can safely prevent targeted infectious diseases required a test to be developed. The test suggested in Chapter 2.2.2 was whether HP yields results that are consistent, predictable, repeatable and observable. It is clear that some results reported in this thesis pass this test, and some do not.

The effectiveness of HP and the safety of HP are both important aspects of the topic. However, **if** the conclusions presented in Chapter 7 are in any way controversial it will inevitably relate to the issue of effectiveness, for one very simple reason.

Homoeopathic remedies are prepared using a series of dilutions and succussions (or triturations for solids). In the potencies used for HP, no molecules of any active

ingredient are present in the final product. “Nothing” cannot be toxic. Therefore even orthodox critics of HP would acknowledge that there is no toxic risk associated with their use.

These critics may argue that HP involves an indirect risk because its use causes vaccines not to be used, and therefore they may argue that the risk of a child acquiring an infectious disease increases if HP is used (this argument is not relevant if the parents of a child have already decided not to vaccinate irrespective of whether they use HP or not).

So the level of effectiveness of HP would, for such critics, determine its level of safety. If it could be shown that HP is as effective as vaccination, then their one issue relating to safety would be resolved.

The fact that orthodox health authorities state in “official” documents that HP is ineffective, means that any finding to the contrary will be viewed with suspicion. This is especially so because their statement is not based on research or evidence, but solely on the fact that the homoeopathic paradigm is different and apparently incompatible to the orthodox “scientific” paradigm, i.e., it is “impossible” for HP to be effective.

In fact the people who remain to be convinced that HP is not directly unsafe come from that small section of the homoeopathic community itself who feel that the long-term use of high potency remedies for prevention may in some “energetic” way damage the recipient.

So the discussion in this Chapter will be divided into a discussion of effectiveness and a discussion of safety. The first part will be clearly aimed at the majority of the orthodox community who believe that HP is ineffective. The second part will be especially aimed at those few homoeopaths who believe that a long-term HP program is unsafe.

Of course, if objective evidence can be presented supporting effectiveness and/or safety then it should be acceptable to an objective analyst whatever their professional background.

5.2 The Effectiveness of Homoeoprophylaxis

HP has been used for over 200 years. Those practitioners who have reported their use of HP describe a generally positive experience showing that recipients of HP were less likely to acquire an infectious disease to which they were exposed, than others with no protection.

It is reasonable to ask - should the accumulated weight of clinical evidence eventually become sufficient for the repeated experience of responsible and competent practitioners to be accepted as proof of effectiveness?

If the answer was “yes”, then HP would be generally accepted already. The fact that the answer by health authorities is “no” means that rigorous data collections are needed to provide generally accepted proof of effectiveness.

The previous reports showing the effectiveness of HP, reported in Table 2.5-1, and the new results reported in Chapter 5, are combined here into a complete list of research findings into the effectiveness of HP and are shown in Table 6.2-1.

The types of reports are varied. For example, most reports examined the use of HP in specific epidemic situations with follow-up continuing for no more than one year. In some of these reports the genus epidemicus remedy was tested, and in others the related Nosode was used.

Golden’s research published in 1997 as well as the new research undertaken as part of this thesis examined the non-epidemic use of HP with follow-up continuing up to 10 years, with use of both the relevant Nosode and the genus epidemicus remedy from previous outbreaks.

The effectiveness of short-term HP use reported in the literature was consistently around 90% (varying between 82% and 97.5%). The effectiveness of long-term HP programs was also around 90%.

In this study, the results of using Golden's long-term HP program are completely consistent with all the human studies of effectiveness that have been undertaken. So it can be concluded, subject to the limitations of the data, that the effectiveness of HP of around 90% is supported on the basis of practical results that are consistent, predictable, repeatable and observable.

However the limitations of the data must be acknowledged as they mean that the findings are qualified. These limitations include the following:

- The sample size
- The low incidence of the targeted infectious diseases
- The reliance on parental assessments to evaluate exposure and incidence
- The difficulty in assessing disease incidence even among experienced practitioners
- The presence of biases inherent in the study

Table 5.2-1 Some Measures of Effectiveness of Homoeoprophylaxis

Year	Researcher	Numbers of Participants	Length of Survey	Ages		Type of Remedy Used	Effectiveness %
	Evidence collected prior to this thesis						
1907	Eaton	2,806	< 1 year			Nosode	97.5
1950	Taylor-Smith	82 (12 definitely exposed)	< 1 year	all ages		G.E. remedy	100.0
1963	Gutman	385	< 1 year	adults		Nosode	86.0
1975	Castro & Nogeira	HP 18,640 Not HP 6,340	< 1 year			Nosode	95.7
1987	English	694	2 years	children		Nosode	87.0 – 91.5
1987	Fox	61	5 years	children		Nosode	82.0 - 95.0
1998	Mroninski et al	HP 65,826 Not HP 23,539	6 months 12 months	0 – 20 years		Nosode	95.0 91.0
1997	Golden	593 children 1,305 questionnaires	10 years	1-5 years		Nosode and GE	88.8
1999	Jonas	142 mice				Nosode	22.0
	Evidence collected/examined as part of this thesis						
2003	Golden	2,342	15 years	1 - 5 years		Nosode and GE	90.4
2003	Golden	HP 159 Not HP 622	2 years	4 - 12 years		Nosode and GE	79.2

The long-term use of Golden's HP program comprising mainly Nosodes has been the focus of the research reported in Chapter 5. The potential biases and weaknesses of earlier research were identified to provide a checklist against which the new research reported in Chapter 5 could be tested.

In order to validate the effectiveness Golden's HP program, the eight additional tests listed in Chapter 5.1 were undertaken. They showed the following:

1. When a high level of accountability of responses (> 70%) was obtained during collection of an additional 5 years of data, the figure for effectiveness was practically unchanged.
2. When parents who did not originally respond to the surveys were contacted to determine whether their experience with the HP program was similar to that of respondents, it was found that their experience was similar, and therefore it can assumed that the original figures were reliable.
3. When parents who reported that their child acquired an infectious disease covered by the HP program were contacted to verify the accuracy of their report, it was found that the resulting figure for effectiveness was practically unchanged.
4. When parents who reported that their child was exposed to an infectious disease covered by the HP program were contacted to verify the accuracy of their report, it was found that the resulting figure for effectiveness was practically unchanged.
2. When the figures obtained for the long-term use of the author's HP program were compared to national attack rates for relevant infectious diseases (where available), it was found with P>95% that HP was efficacious.
3. When the reliability of the results were tested using indices of *sensitivity* and *specificity*, the results were found to be very reliable.
7. When the effectiveness HP was compared to other methods of disease prevention through the General Health Study, it was found that the results were not statistically significant. However the data appeared to indicate that the effectiveness of HP lay between that of vaccination and either general protection or no protection.
8. When the effectiveness of HP programs supplied by Golden is compared to that of other HP programs it is found with P=95% that Golden's program is more effective.

Thus, the results reported in section 5.1 did not fail any of the above tests that were applied to them.

However, one potential weakness in the long-term study that could not be corrected was the size of the data collection (2,342 responses). Given that the risk of exposure to the infectious diseases studied is low, an extremely large number of responses would be needed to ensure that the figure for effectiveness could not be challenged on any valid statistical basis.

A further question relating to the overall reliability of the data arose from the widely different disease incidence rates (per 781 children) between diseases reported in the General Health Survey and the ABS national averages respectively for measles (50 and 0.05), mumps (1 and 0.04) and whooping cough (30 and 3.1). It was concluded in Section 5.3.1.3 that the survey group were very different to the national population in terms of the incidence of the targeted infectious diseases and that the national notifications probably underestimated the true incidence of these diseases, especially for measles.

This conclusion is reinforced by examining the comparable figures for 781 children from the long-term HP study, which show an expected average incidence for measles of 25, for mumps of 3 and for whooping cough of 18. These figures are largely based on parental diagnoses which would be expected to overestimate the incidence of the diseases. These long-term figures are certainly still well above the national average. However it would be interesting to see what national averages would be if every parent in Australia was asked whether their child had contracted one of the targeted diseases. The resulting effect on the reliability of the figures for HP effectiveness due to these differences is uncertain.

The potential problem associated with confounding variables has been considered. It is only a potential problem in the General Health Survey. In that study, respondents using the four immunisations options (vaccination, HP, general protection, and no protection) appeared fairly evenly spread across variables such as the incidence of chronic illness, whether seen by a therapist, and whether breastfed. The one exception

related to question 5 in the General Health Survey ' Does your child receive any special treatments to strengthen their general health, such as: naturopathic, homoeopathic, herbal, nutritional, special diet - yes / no'. The responses showed that many more children using HP (89.5%) and general protection (77.3%) used special treatments than did vaccinated children (45.8%) or children given no form of immunisation (42.2%).

This might suggest that children in the first two categories would be healthier than other children, and thus bias the results. However these two groups needed to consult a practitioner for health problems slightly more often (90.5% and 83.8% respectively), than did vaccinated children (82.9%). This would appear to suggest that they are not inherently healthier than the vaccinated group, and may in fact be using special treatments because of existing health problems. Thus the issue of confounding remains unresolved, and possibly worthy of further study.

Finally, it must be noted that the findings of the General Health Survey showed that different HP programs produce different levels of effectiveness and safety. This means that the conclusions drawn regarding the HP program studied in this thesis cannot be automatically extended to every available HP program. This is a significant point when considering implications for public health policy as in Section 6.4 below. HP programs would need to satisfy certain fundamental requirements regarding remedy choice, potency and dose in order to ensure a similar result to that found with Golden's program.

Thus we have a method of disease prevention that has been used for 200 years throughout the world by practitioners with both orthodox and complementary medicine training. Its effective use as a method of disease prevention has been documented clinically since 1801, and the practical results show an effectiveness that is consistent, predictable, repeatable and observable.

We can conclude with 95% confidence, **based on the data provided**, that the effectiveness of Golden's HP program being studied ranges between 87.3% and 93.1%. However, the qualifying statement "based on the data provided" means that the conclusion will remain open to challenge until a larger data base is collected with a clearly defined control group against which to make comparisons.

5.3 The Safety of Homoeoprophylaxis

As stated at the beginning of this Chapter, HP remedies are not physically toxic and therefore there is little chance of adverse reactions based on molecular toxicity. However, it is still appropriate study any reactions to the remedies, as well as show that no other long-term adverse health events are related to the use of the method.

The safety of HP is assessed in the following seven ways:

(1) Clinical observations over the last 200 years, discussed in Chapter 2, have consistently reported on the safety of HP.

(2) Conceptually it was shown in Chapter 3 that HP is consistent with the Law of Similars. So there is no apparent reason why an appropriately structured HP program should cause any long-term adverse health effects.

(3) Immediate reactions to doses of HP reported in Chapter 5, were found in 9.2% of children using the kit, or an estimated 1.6% of doses. The reactions themselves were typically mild and brief.

(4) The long-term health of children using the HP program was reported in Chapter 5 by their parents to be very good 92.3% of the time, with only 7.7% of negative reports.

(5) The general health of children using HP was assessed by their parents, in Chapter 5, to be greater than the assessment given by parents of children who used vaccination, general protection and no protection at all.

(6) The absolute safety of HP was measured in Chapter 5 by examining the likelihood that HP would increase the chance of a child acquiring asthma, eczema,

ear/hearing, allergies and behavioural problems. In no condition was HP likely to cause an increase in the incidence of a condition.

(7) The relative safety of HP was measured in Chapter 5 by comparing the likelihood of HP causing the conditions mentioned above with the comparable likelihood that the conditions could be caused by vaccination, general protection and no protection at all. HP was the safest option with 2 of the 5 conditions, and the second safest in another 2. In three of the four conditions the results were statistically significant. The one measure suggesting associating the use of HP with a decline in long-term health was that children using HP were apparently more likely than children using general protection or no method of protection to have ear and hearing problems (see tables 5.2-7 and 5.2-8, pages 150 and 152). Even though the figures relating HP to ear/hearing problems were not statistically significant, this apparent trend is worthy of further research, especially since a negative association would certainly be inconsistent with the findings relating to the other health conditions.

Thus, every measure used to rank the safety of HP shows that HP presents no significant level of risk to those using the method. In fact, there is evidence that the long-term use of HP may in fact improve the long-term health of recipients as indicated by parental comments as well as being measured by a statistically significant reduction in the likelihood of acquiring specified chronic health conditions if HP is used.

This finding would be unlikely if long-term HP in any way "energetically" damaged the recipient, as questioned by a few homoeopaths.

The results showing a level of reactions to the HP remedies pose something of a dilemma for supporters of the orthodox medical paradigm who believe that molecules of active material are required to produce molecular reactions, as expressed in physical symptoms. A similar result is found with homoeopathic treatment where reactions to potentised remedies are regularly experienced, as well as with homoeopathic provings where reactions form the basis of the proving result.

A homoeopath would reply that the “energy” contained within potentised remedies is very real and active, even though not readily measurable using present day technology. Such a statement may be too vague for an orthodox scientist, but such reactions to potentised remedies are observable and, in the case of provings, measurable and repeatable and predictable.

An unprejudiced observer would conclude that we have here something needing a scientific explanation, and not simply conclude that what has been observed over 200 years did not actually occur.

5.4 Implications for Public Health Policy

State and Federal health authorities in Australia presently spend considerable resources promoting childhood vaccination programs. The desirability of preventing certain infectious diseases is an aim shared by these authorities as well as by homoeopaths who provide HP programs to parents who request them.

It may be concluded that an appropriately structured long-term HP program offers an alternative to vaccination that is unquestionably safer, and very possibly of a similar level of effectiveness.

In Chapter 5.4 it was found that many parents make a choice between either (1) vaccination or (2) doing nothing to prevent infectious diseases.

If parents who choose not to vaccinate because of their concerns as to the safety of vaccination were encouraged to use HP, then the national rates of protection against infectious diseases would increase because no such safety concerns would be held regarding HP by most of these parents. National levels of herd immunity would increase given that HP clearly has some protective effect.

Based on the results reported above, if parents were encouraged to either vaccinate or use HP, rates of asthma, eczema, allergies as well as other problems would fall as some decided to use HP instead of vaccination.

It is not for one moment suggested that vaccination programs be replaced by the use of appropriate HP programs. However, the findings of this study clearly support the possibility **that an appropriately structured dual disease-prevention system, where parents were encouraged to either vaccinate or use HP, would increase national coverage against infectious diseases and reduce the national incidence of certain chronic health conditions.**

If State and National health authorities were given objective advice concerning these options, the cost-benefit implications for public health policy would be considerable.

5.5 Implications for Future Research

The research reported in this thesis is not perfect, especially when estimating the effectiveness of HP. However, many of the identified weaknesses in the research could be corrected if a much larger data base of responses was obtained. This challenge is fundamentally a matter of resources, as the collection of the data in this study has been time consuming and, on an individual level, expensive.

However, the General Health Study in particular could readily be expanded to obtain many thousands of responses, especially if support was received from State Education departments to distribute the questionnaire in primary schools nationwide, and attempts to block the research were not made by State Health Departments, as occurred during this research.

Secondly, it would be ideal if a long-term study was undertaken involving parents who (1) had decided not to vaccinate their child and (2) who were unconcerned if their child contracted Measles.

In such cases a double-blind, placebo-controlled, randomised trial could be undertaken to obtain statistically significant evidence as to the effectiveness and safety of HP against Measles.

In fact a pilot of such a study was proposed as part of this thesis, but was rejected by the ethics committee.

Hundreds of millions of dollars have been spent over the years researching vaccines. A mere fraction of these resources would easily cover the costs of the above two research projects, and would enable a conclusive scientific finding as to whether HP can provide a safe and effective means of disease prevention.

This study has shown that the case for such research is compelling, since the use of HP offers the potential to benefit children through both a greater level of national protection against targeted infectious diseases, as well as through lower levels of chronic health conditions.

PART 4: CONCLUSIONS

6 Conclusions

The following conclusions are made from the above analysis and discussion.

6.1 The Potential Value of Homoeoprophylaxis in the Safe Prevention of Infectious Disease

An appropriately designed HP program is able to offer some level of protection against targeted infectious diseases.

The precise level of effectiveness can only be estimated based on 200 years of recorded clinical experience, and a limited number of statistical trials covering both long and short term usage.

On the balance of probabilities it appears as though HP potentially offers a level of protection exceeding 90%, although this figure requires further research to be more fully validated.

It may be concluded that even though generally mild and brief reactions to an appropriate HP program do occur in less than 2% of doses, these do not pose any threat to the long-term health of users.

Further there is statistically significant evidence that an appropriate HP program is associated with an improvement in the long-term health of recipients.

It is therefore concluded, subject to the limitations of the data already noted, that HP provides a safe and a relatively effective level protection against targeted infectious diseases.

6.2 Suggestions for Public Health Policy

State and Federal health authorities in Australia should consider the introduction of an appropriately structured dual disease-prevention system where parents were encouraged to either vaccinate or use HP. This would increase national coverage against infectious diseases and reduce the national incidence of certain chronic health conditions.

If State and National health authorities were given objective advice concerning these options, the implications for public health policy would be considerable.

6.3 Suggestions for Future Research

The General Health Study should be repeated with the aim to collect at least five thousand responses. This figure is obtainable with a reasonable outlay of resources if support is received from State Education Departments to distribute the questionnaire in primary schools nationwide.

Secondly, a long-term study involving parents who (1) had decided not to vaccinate their child and (2) who were unconcerned if their child contracted Measles, should be considered.

This could allow a double-blind, placebo-controlled, randomised trial to be undertaken. Timely collection of data would be difficult to obtain due to the relatively small numbers of parents meeting the above entry criteria, but the provision of statistically significant evidence as to the effectiveness and safety of HP could make the effort worthwhile.

Hundreds of millions of dollars have been spent over the years researching vaccines. A mere fraction of these resources would easily cover the costs of the above two research projects, and would enable a scientific finding as to whether HP can provide a safe and effective means of disease prevention.

Thirdly, a cost-benefit analysis of vaccination and HP could be undertaken based on the results of this study. This would provide authorities with further reason to support the above two projects.

6.4 Final Conclusions

This study has shown that the use of HP offers the potential to benefit children through both a greater level of national protection against targeted infectious diseases, as well as through lower levels of chronic health conditions.

The case for further research is compelling.

REFERENCES AND BIBLIOGRAPHY

REFERENCES

Reference	Section
Australian Bureau of Statistics (1999) *Health – Mortality and Morbidity: Asthma.* Australian Social Trends, 1999. Canberra.	5.2.2.2.1
Australian Bureau of Statistics (2001a) *Regional Statistics Tasmania, Health Related actions.* National Health Survey, 2003. Publication 4364.2001. Canberra.	5.3.1.3
Australian Bureau of Statistics (2001b) *Summary of Results, Australia.* National Health Survey, 2003. Publication 4364.0. Canberra.	5.2.2.2.1 5.3.1.2
Australian Bureau of Statistics (2002) *Occasional Paper: Vaccination Coverage in Australian Children* - ABS Statistics and the Australian Childhood Immunisation Register (ACIR) Publication 4813.0.55.001. Canberra.	5.3.1.1
Australian Bureau of Statistics (2003a) *Population by Age and Sex – 2001 Census Edition – Final*. Publication 3201.0. Canberra.	5.3.1.1
Australian Bureau of Statistics (2003b) *Australian Demographic Statistics – 2001 Census Edition – Final.* Publication 3101.0. Canberra.	5.3.1.3
Australian Bureau of Statistics (2003c) *Breastfeeding in Australia*, Electronic delivery Publication 4810.0.55.001. Canberra.	5.3.1.1
Australian Bureau of Statistics (2003d)	5.3.1.3

Health and Communicable Diseases Year Book of Australia, 2003. Publication 1301.0. Canberra.	4.3.1.2
Bell et al (2004) Individual differences in response to randomly assigned active individualised homoeopathic and placebo treatment in fibromyalgia: Implications of a double-blind optional crossover design *J Alternative & Complementary Medicine,* 10, pages 269-283.	4.1.1.3
Bellavite P and Signorini A (2003) *Emerging Science of Homoeopathy: Complexity, Biodynamics and Nanopharmacology* North Atlantic Books. Berkeley, California.	2.2.2
Blackie M (1976) *The Challenge of Homoeopathy* Unwin Paperbacks. London. 1981 reprint, page 184	2.3
Boenninghausen CMF von (1848) Concerning the Curative Effects of Thuja in Small-pox *Lesser Writings*, page 3. B. Jain Publishers Pty Ltd. New Delhi. 1986 reprint.	2.3
Boenninghausen CMF von (1849) Brief Instructions for Non-Physicians Concerning the Prophylaxis and Treatment of Asiatic Cholera *Lesser Writings*, page 303. B. Jain Publishers Pty Ltd. New Delhi. 1986 reprint.	2.3
Braun-Fahrlander C et.al. (2002) Environmental exposure to endotoxin and its relation to asthma in school-age children *New England Journal of Medicine*. 347. Pages 869-887.	3.2.1
Burnett JC (1884) *Vaccinosis and its Cure by Thuja; with Remarks on Homoeoprophylaxis* W H L 1992 reprint	2.3
Castro D and Nogeira G.G (1975)	2.5.1

Use of the Nosode Meningococcinum as a preventative against meningitis *J Am Inst Hom* 68: 211-219	3.1.2
Close S (1920) *The Genius of Homoeopathy* Jain Publishers, New Delhi. 1991 reprint. Page 20.	2.3
Coulter H (1975) *Divided Legacy* North Atlantic. Berkeley. Vol III. Page 268.	2.2.2
Cucherat M., et.al. (2000) Evidence of clinical effectiveness of homoeopathy. A meta-analysis of clinical trials. *Eur. J Clin Pharmacol* Apr; 56(1): 27-33	2.2.2
Dahl M., et, al. (2004) Viral-induced T helper type 1 responses enhance allergic asthma by effects on lung dendritic cells *Nature Immunology*, DOI:10. Pages1038/ni1041	3.2.1
Day CE (1987) Isopathic prevention of kennel cough - is vaccination justified? *Int J Vet Homoeopath* 2(1):45-50, also Vol 2 Nov 87, p57-58	2.5.1
Diamantidis S (1990) *Homoeopathic Medicine – Theory, Methodology, Applications.* S.A. Dimantidis. Athens. Pages 286-7.	2.2.1
Dudgeon (1853) *Lectures on the Theory and Practice of Homoeopathy* B.Jain Publishing Pty Ltd. New Delhi. Pages 541, 542.	2.5.1
Dutta A.C. (1983) *Homoeopathy in the Light of Modern Science* Jain Publishing Co. New Delhi. Pages 18,19.	2.2.1
Eaton CW (1907) Variolinum A paper read before the American Institute of Homoeopathy.	2.5.1

J Am Inst Hom	
Eisfelder HW (1957a) Oral immunization of anterior poliomyelitis - a preliminary report. *Homoeopathy* 7(9): 144-147	3.1.1 3.2.3
Eisfelder HW (1957b) Oral immunization of anterior poliomyelitis – a two year report. *J Am Inst Hom* 51:9-10	3.1.1 3.2.3
Eisfelder HW (1958) Oral immunization of anterior poliomyelitis – a final report. *J Am Inst Hom* 54: 166-167	3.1.1 3.2.3
Eizayaga FX (1991) *Treatise on Homoeopathic Medicine* E Marecel, Buenos Aires, pages 282-286	2.3.5 2.5.1 3.1.1
English JM (1987a) Pertussin 30 - preventative for whooping cough? A Pilot Study *Br Homeopath J* 76: 61-65	2.5.1
English JM (1987b) Symptoms and Treatment of Whooping Cough *Br Homeopath J* 76: 66-68	2.5.1
Fox D.A (1987) Whooping cough prophylaxis with Pertussin 30 *Br Homoeopath J* 76(2):69-70	2.5.1
Fletcher RH, Fletcher SW. (1979) Clinical research in general medical journals: a 30-year perspective. *N Engl J Med*. 301: pp.. 180–83.	4.1.1.2
Gaier H (1991) *Thorsons Encyclopaedic Dictionary of Homoeopathy.* Thorsons. London. Pp. 290-309.	3.5.1
Golden I Neustaedter R (1996) In defence of homoeoprophylaxis and Response to Golden article *Resonance* Mar-Apr;18(2):26-28	3.3
Golden I (1986)	1

Vaccination – A Homoeopathic Perspective *Nature & Health.* Vol. 7, No. 3. pp. 67-70.	
Golden I (1987) A Discussion Paper on a Possible Mechanism of Homoeopathic prophylaxis *Aust. Hom. Assn* June**;** 3-10	3.3
Golden I (1989a) A possible mechanism of homeopathic prophylaxis *J Am Inst Homeopath* 82(2):69-76	3.3
Golden I (1997) *Homoeoprophylaxis – A Ten Year Clinical Study* Isaac Golden Publications, Daylesford, Australia	2.5.1, 2.5.2 4.1.1.2.6 5.2.1
Golden I (1998) *Vaccination? A Review of Risks and Alternatives* Isaac Golden Publications, Daylesford, Australia. Revised 5th edition	1
Golden I (2001) *Homoeoprophylaxis – A Practical and Philosophical Review* Isaac Golden Publications, Daylesford, Australia. 3rd edition	2.3 3.1.1 4.1.1.8
Golden I (2002a) Attitudes to and use of Homoeoprophylaxis by Australian Homoeopaths. *Similia* Vol 14 No.2, 26-29	Intro 1 2.4.2 4.1.1.3
Gutman W (1963) Homoeopathic oral vaccine against influenza *Homoeopathy* 13(12): 185, 187	2.5.1
Hahnemann S (1801) The Cure and Prevention of Scarlet Fever *Lesser Writings* B Jain Publishers, New Delhi. pp. 369-385.	2.2.2 2.2.3
Hahnemann S (1828) *Chronic Diseases*	2.2.3

B Jain Publishers, New Delhi	
Hahnemann S (1830) *Materia Medica Pura Vol II* B Jain Publishers, New Delhi. 1988 reprint. p. 401.	2.2.2
Hahnemann S (1843) *Organon of the Healing Art* B Jain Publishers, New Delhi. 6th edition	2.2.3 3.2.5 3.3.2
Hoover TA (2001) Homeopathic prophylaxis: fact or fiction. *J Am Inst Homeopath* 94 (3): 168-175	2.2.3 2.5.1
Hulley SB, ET AL Eds. (2001) *Designing clinical research: an epidemiologic approach*, 2nd edn. Baltimore: Lippincott Williams and Wilkins.	4.1.1.2
Jonas WB (1999) Do homeopathic nosodes protect against infection? An experimental test. *Alternative Therapies in Health and Medicine* 5 (5): 36-40	2.5.1 2.3.6
Kelsey et al (1986) *Methods in Observational Epidemiology* Oxford University Press. New York. Pages 286-288.	5.1.1.6
Kent JT (1900) *Lectures on Homoeopathic Philosophy* B Jain Publishers, New Delhi. 5th Edition. Page 229.	2.3
Kleijnen J., et.al. (1991) Clinical Trials of Homoeopathy *British Medical Journal* 302; 316-23	2.2.2
Kotok A (2000) *The history of homeopathy in the Russian Empire until World War I, as compared with other European countries and the USA: similarities and discrepancies.* http://www.homeoint.org/books4/kotok/index.htm	2.2.1
Kuhn TS. (1970)	4.1.1.2

The structure of scientific revolutions. 2nd Edition. University of Chicago Press, Chicago. Page 210	
Kune G (2002) Private communication with Golden, 7.7.02. Melbourne.	2.5.3
Lancaster et al. (1996) *A.I.H.W. National Perinatal Statistics Unit*. ABS Cat. No. 3304.0	5.3.1.1
Lessell CB (1993) *The World Traveller's Manual of Homoeopathy* C W Daniel Co Ltd, Saffron Walden, UK. p. 14	2.3.5
Linde K., et.al (1997) Are the clinical effects of homoeopathy placebo effects? A meta-analysis of placebo-controlled trials. *Lancet*. 350:834-43	2.2.2
Little D (2000) Prophylaxis in Homoeopathy – The Origin of Homoeoprophylaxis. *http://www.simillium.com/Thelittlelibrary/Homoeopathicphilosophy/prophylaxis.htm*	3.1.2
Lockie A (1989) *The Family Guide to Homoeopathy* Guild Publishing, Aylesbury, Bucks, England. p. 17	2.3.5
MacLeod G (1974) Coli-bacillosis of calves, or scour in calves and the rational approach to treatment and prevention *Homoeopathy* 24: 30-31	2.5.1
MacLeod G (1994) *Pigs: the homoeopathic approach to the treatment and prevention of diseases* C.W. Daniel Company Ltd, Saffron Walden, UK	2.5.1
Mathur KN (1979) *Principles of Prescribing*	2.3

Jain Publishers, New Delhi. 2nd edition (1987 reprint), pages 50, 53	
Matricardi PM, et.al., (2002) Hay fever and asthma in relation to markers of infection in the United States. *J Allergy Clin Immunol.* 110. Pages 381-387.	3.2.1
Mroninski C, Adriano E, Mattos G (2001) Meningococcinum: Its protective effect against meningococcal disease. *Homoeopathic Links* Winter Vol 14(4). 230-4	2.5.1 3.1.2
National Health and Medical Research Council (NH&MRC) (2000) *The Australian Immunisation Handbook*, 7th Edition. Commonwealth of Australia, Canberra	5.1.1.7
Nemours Foundation (2001) http://kidshealth.org/parent/infections/lung/measles_p3.html	5.1.1.7
Neustaedter R (1990) Measles and Homœopathic Vaccinations *The Homeopath* 10.2, page 31.	2.3.6
Neustaedter R (1995) Homeopathic prophylaxis - is it valid? *Resonance* Nov-Dec;17(6):12-14,30	3.2.1 3.3
Odent M et.al. (1994a) Atopic Eczema *Lancet*. 344, p.140	4.3
Odent M et.al (1994b) Pertussis vaccination and asthma: Is there a link? *JAMA*. 272: pp.592-3.	4.3 5.2.2.2.2
Pearson K. (1937) The grammar of science. 3rd Edition. London. Page 357.	4.1.1.3
Popper KR. (1960) *The logic of scientific discovery.* Hutchinson, London. Page 479.	4.1.1.2
Rothman KJ, Greenland S. (1998)	4.1.1.2

Modern Epidemiology. 2nd Edition. Lippincott, Williams and Wilkins.	
Schleqel M, et.al. (1999) Comparative effectiveness of three mumps vaccines during disease outbreak in eastern Switzerland: cohort study *Br Med J* August 7	5.1.1.7
Sankaran P (1961) *Prophylactics in Homoeopathy* The Homoeopathic Medical Publishers,	2.3
Sethi B (1991) *Homoeo Prophylactic Remedies* Jain Publishers, New Delhi. pages 22, 47, 56, 78 reprint.	2.3
Shepherd D (1967) *Homoeopathy in Epidemic Diseases* C.W. Daniel Company Ltd, Saffron Walden, UK. Pages 15, 51, 81	2.2.2 2.3.5
Speight LJ (1982) *Homoeopathy and Immunisation* Health Science Press, London. p. 3	2.3
Taylor-Smith A (1950) Poliomyelitis and prophylaxis *Br Hom J* XL: 65-77.	2.5.1
Traub M (1994) Homeopathic prophylaxis *J Naturopath Med* 5(1):50-61,	2.2.3 3.3
Ullman D (1991a) The International homoeopathic renaissance. *Berlin J. Res. Homoeopathy* 1(2): 118	2.2.1
Ullman D (1991b) *A Condensed History of Homeopathy* http://www.homeopathic.com/articles/intro/history.php	2.2.2
Ullman D (1995) *The Present Status of Homeopathy Internationally* Homoeopathic Educational Services. Berkeley, CA.	2.2.1

Vickers AJ, Smith C. (2001) Homoeopathic Oscillococcinum for preventing and treating influenza and influenza-like syndromes (Cochrane Review). *The Cochrane Library* Issue 3, Oxford: Update Software. Pages 5-7.	2.5.1 2.3.6
Walach H (2003) Reinventing the wheel will not make it rounder: controlled trials of homoeopathy reconsidered. *The Journal of Alternative and Complementary Medicine*. 9:1, pp.7-13.	
Wharton R., Lewith G. (1986) Complementary medicine and the general practitioner. *Brit. Med. J.* 292: 1498	2.2.1
BIBLIOGRAPHY (not included in References)	
Adams QM (1956) Infectious diseases and their nosodes - Morbillinum *Br Homoeopath J* 45: 263	
Agrawal YR (1987) *Prophylactics in Homoeopathy* Vijay Publications Delhi	
Agrawal YR (1994) Plague prevention, Phosphorus and postponement *Advent Hom* Oct-Dec;11(4):12-13	
Aickin M, Ritenbaugh C (1996) Analysis of multivariate reliability structures and the induced bias in linear model estimation. *Stat Med* 15:1647-61.	
Anonymous (1915a) Prevention is better than cure (E)	

Br Homoeopath J 5: 337	
Anonymous (1915b) Prevention of infectious diseases (E) *Br Homoeopath J* 5: 436	
Anonymous (1961) Polio prevention *Homoeopathy* 11(6): 81-83	
Anonymous (1964) Fatal poliomyelitis after homoeopathic vaccine (letter) *Homoeopathy* 14(10): 154	
Anonymous (1986) Homoeo-prophylaxis - testimony from masters *Indian J Homoeopath Med* 21(4):18-20	
Arul M (1996) Homoeopathic way of immunisation *Homoeopath Heritage* Dec; 21(12):707-709	
Attena F, Toscano G, Agozzino E, Del Giudice N. (1995) A randomized trial in the prevention of influenza-like syndromes by homoeopathic management. *Revue d Epidemiologie et de Sante Publique* 43: 380-2	
Bach E (1921) Vaccines and homoeopathic remedies *Br Homoeopath J* 11: 21	
Bach E (1927) Vaccines potentized *Br Homoeopath J* 17: 204	
Baig MA (2001) Homoeopathic vaccines: a possible approach in treating HIV/AIDS. *National Journal of Homoeopathy* 3 (5): 325-331	
Baig MA (2002) New medicines for the new millennium: of likes cure likes, like can also prevent like.	

Homoeopathic Links 15 (1): 19-20	
Basso O, Olsen J, Bisanti L, Karmaus W, and the European Study Group on Infertility and Subfecundity (1997) The performance of several indicators in detecting recall bias. *Epidemiology* 8:269-79.	
Batra GS (1998) Resistance/immunisation in the real sense *Homoeopath Heritage* 23(2):93-7	
Bayley MB (1939) *The 'Schick' inoculation for immunisation against diphtheria* London, Clapton and District Anti-Vivisection Society National Vaccination League	
Boyson WA (1966a) Time and nosodes *J Am Inst Homeopaths* 59(7). 209-11	
Boyson WA (1966b) Thirty years as clinical research and confirmations of the intestinal nosode Sycotic co *J Am Inst Homeopaths* 59(7). 238-40	
Bradburn NM, Rips LJ, Shevell SK (1987) Answering autobiographical questions: The impact of memory and inference on surveys. *Science* 236:157-61.	
Bungetzianu G (1988) The results obtained by the homeopathical dilution (15 CH) of antiinfluenzal (Anti-Flu-) vaccine *Proc 43rd LMHI Congr*, Athens, Greece:143	
Burnett JC (1938) Nature of homoeoprophylaxis (contd) *Homoeopathy* 7(7): 214-218,171-172	
Chand H (1950)	

Prophylaxis in poliomyelitis epidemics (L) *Br Homoeopath J* 40; 310	
Chand H (1986) Prophylaxis in poliomyelitis epidemics *Hahnemann Glean* 53(5):150	
Clarke JH (1908) Internal or homoeopathic vaccination: the victory in Iowa *Homoeopathic World* 43(11): 489-501	
Coates J (1992) Vaccination horror - homeopathic success *Homeopathy Today* 12(6):8-9	
Concon AA (1967) Homeo Prophylaxis *The Indian Homoeopathic Gazette* April	
Cook T (1997) Malaria: homeopathic prophylaxis and treatment *J Am Inst Homeopath* Summer;90(2):76-77	
Cook T (1999) Malaria: homoeopathic prophylaxis and treatment *Homoeopath Int* 12(3):12-3	
Curtis S (1994) *A handbook of homoeopathic alternative to immunisation* Winter Press, London.	
Dietz V Jacobs J (1997) Vaccination: attitudes and practices of physicians who use homeopathy *Alternat Complement Ther* Dec;3(6):414-418	
Engineer SJ Engineer LS Vakil AE (1990) Antibody formation by Baptisia tinctoria in experimental animals *Br Homoeopath J* 79: 109-113	
English JM (1995) The rights and wrongs of measles vaccination	

Br Homoeopath J Jul; 84(3):156-163	
Everitt DW (1969) Oral vaccines *Homoeopathy* 19(4): 44-45	
Fausel SL (1998) Debate regarding vaccination procedures and homeopathy *J Am Vet Med Assoc* 213(6):798-799	
Fisher P (1990) Enough nonsense on immunisation (E) *Br Homoeopath J* 79: 198	
Gibson DM (1958) Nosodes and prophylaxis *Homoeopathy* 8(7): 111-112	
Golden I (1988) A Survey of the Effectiveness of a Homoeopathic Prophylactic Kit *J Aust Fed Hom* Vol. 1, No. 8; 1-6	
Golden I (1989b) Immunisation – A Survey of the Homoeopathic Alternative *Nature & Health* Vol. 10, No. 1; 37-39	
Golden I (1999) Homoeopathic Disease Prevention. *Homoeopathy Online* Sept.	
Golden I (2002b) Meningococcal Disease and Homoeopathic Prevention. *Informed Choice* Spring 43-45	
Griggs WB (1967) Clinical research with confirmations of the intestinal nosode Sycotic co *J Am Inst Homeopath* 60(5): 152-3	
Grimmer AH (1954) Homoeopathic prophylaxis *Homoeopathy* 4(7):142-145	
Hamilton J (1943)	

Homoeopathy, positive health and prevention of disease *Br Homoeopath J* 33: 3	
Harling ME (1974) Thoughts on prophylaxis *Br Homoeopath J* 63: 161	
Head CJ (1999) *An educated decision: one approach to the vaccination problem using homeopathy* Lavender Hill Publishing, London.	
Henneckens CH, Buring JE (1987) *Epidemiology in Medicine.* Little Brown and Company ed. Mayrent SL.	
Hindle RC (1991) Immunisation and homoeopathy *N Z Med J* 104(910):171	
Ipsen J, Olsen J (1984) Estimating sensitivity and specificity in order to correct for misclassification. *Scand J Soc Med* 12:111-4	
Kanji Lal JN (1987) Can homoeopathy allow vaccination ? *Hahnemann Homoeopath Sand* 11(3):65-73	
Kanjilal ST (1979) Is vaccine of today homoeopathic nosode of yesterday *Hahnemann Glean* 46(4): 166-167	
Lee F (1991) Attitude to vaccination *Br Homoeopath J* 80 : 70	
Lewith G, Brown PK, Tyrell DA (1989) Controlled study of the effects of a homoeopathic dilution of influenza vaccine on antibody titres in man *Complement Med Res* 3(3):22-4	

Maceoin D, Cope E (1988) A hearing for an alternative approach to vaccine *Guardian* Oct; 19	
Macnish D (1912a) Vaccine therapy in homoeopathic practice *Homoeopathic World* 47((8): 363-374	
Macnish D (1912b) Vaccine therapy in homoeopathic practice *Br Homoeopath J* 2: 368	
Margutti VM (1976) Homoeopathic methodology in disease prevention *J Am Inst Homeopath* 69(3): 145-148	
McAusland S (1963) Oral influenza vaccines (L) *Br Homoeopath J* 52: 72	
Mitchell GR (1957) Infectious diseases and their nosodes. *Br Homoeopath J* 46: 46	
O'Driscoll C (1997) Vaccination - safety claims rebuffed *Homoeopath Int* Autumn;11(2):10	
Peters JC (1867) *Notes on the origin, nature, prevention and treatment of asiatic cholera* D Van Nostand, New York.	
Pulford A (1937) Vaccination, smallpox and homoeopathy *Homoeopathy* 6(7): 225	
Pulford A (1994) Are serums, vaccines, etc. homoeopathic? *Homoeopath Heritage* Feb;19(2):87-91	
Rawat PS (1998) How to prevent non-virus polio	

Homoeopath Heritage 23(1):45-7	
Rinneberg A-L (1991) The therapy of tonsillitis and prophylaxis against its recurrence *Biol Ther* 9(1):111-114	
Rosenthal C (2001) A drop of nature: homeopathic approach to vaccination in Israel. *Homoeopathic Links* 14 (4): 229-230	
Sankaran P (1978) *Some Notes on the Nosodes* The Homoeopathic Medical Publishers	
Sarangi AP (1994) Plague - its homoeopathic treatment and prevention *Homoeopath Heritage* Dec;19(12):769-70	
Schmidt P (1959) Homoeopathic Prophylaxis *J of Homoeopathic Medicine* 1(1)	
Schmidt P (1994) Homoeopathic prophylaxis against malaria - caveat emptor! *Homoeopath Links* Winter;7(4):41	
Severyn K (1996) Vaccination update *J Am Inst Homeopath* Win;89(4):217-221	
Shafran B (1999) The use of injectable homeopathic preparations in flu prophylaxis. *Biomed Ther* Jan;17(1):30	
Smith AT (1950) Poliomyelitis and prophylaxis *Br Homoeopath J* 40: 65	
Sulfaro F Fasher B Burgess MA (1994) Homoeopathic vaccination. What does it mean? *Med J Aust* 161:305-307	
Taylor SM Mallon TR Green WP (1989)	

Effectiveness of a homoeopathic prophylaxis against experimental infection of calves by the bovine lungworm Dictyocaulus viviparus *Vet Rec* Jan 7;124(1):15-7	
Underhill E (1982) The common cold Prophylaxis and treatment *Homeotherapy* 8(5): 135-138	
Vakil P (1997) A proving of pertussis vaccine. *Proc. 52nd LMHI Congr*., Seattle, USA, 100-103	
Wagner H (1997) Herbal immunostimulants for the prophylaxis and therapy of colds and influenza *Eur J Herbal Med*, Spring; 3(1):22-30	
Wheeler CE (1911) Experiment in prophylaxis *Br Homoeopath J* 1: 544	
Wheeler CE (1912) Scientific basis of vaccine therapy as a homoeopathic procedure *Homoeopathic World* 47(9): 374-379,395-401,	
Zaheer Rozina A (2001) Virionum, the nosode of HIV: as remedy and as vaccine! *Homoeopathic Links,* 14 (4): 235-238	

Appendices

Contents

Tables

Appendix 1: Materials Used in HP Research and the General Health Survey

1.1 The Homoeoprophylaxis Programs

1.1.1 The Current Program

Table 1.1-1 The Current Homoeoprophylactic Program

CODE	MEDICINE	QUANTITY	AGE ADMINISTERED (Months)
A1	Pertussin (200)	30 pills	1 2 13 32
A2	Pertussin (M)	6 pills	2 13 32
A3	Pertussin (10M)	6 pills	2 13 32
B1	Tetanus Toxin (200)	30 pills	11 12 24 41 60
B2	Tetanus Toxin (M)	8 pills	12 24 41 60
B3	Tetanus Toxin (10M)	8 pills	12 24 41 60
C1	Lathyrus Sativus (200)	30 pills	4 5 16 26 56
C2	Lathyrus Sativus (M)	8 pills	5 16 26 56
C3	Lathyrus Sativus (10M)	8 pills	5 16 26 56
D1	Diphtherinum (200)	30 pills	9 10 22 50
D2	Diphtherinum (M)	6 pills	10 22 50
D3	Diphtherinum (10M)	6 pills	10 22 50
E1	Morbillinum (200)	30 pills	14 15 54
E2	Morbillinum (M)	4 pills	15 54
E3	Morbillinum (10M)	4 pills	15 54
F1	Parotidinum (200)	30 pills	19 20
F2	Parotidinum (M)	2 pills	20
F3	Parotidinum (10M)	2 pills	20
H	Haemophilis (M)	30 pills	6 7 17 28 46
			7 17 28 46
			7 17 28 46
M	Ledum Palustre (30)	30 pills	given as needed for a wound

Explanatory Notes:

- One dose consists of two tablets or pilules of the medicine indicated. The pilules may be dissolved in a little water if preferred.

  Each dose must be administered at least 45 minutes before or after eating or drinking.
- The order of remedies may be changed. Other remedies may be included in the program, or some existing medicines removed, depending on the requirements of the patient.
- The 1991 program is a direct result of research that clearly suggested the need for triple doses, not because single doses are ineffective, but to lessen the chance of a single dose being antidoted.

  The concept of ascending doses has been subject to discussion (both in literature and clinical practice) for many years, and is compatible with Hahnemann's idea of increasing potencies. It must be stressed that the original Kit is effective if used properly; however, any program may be enhanced as new information becomes available. Dr Hahnemann offered the clearest example of how intellectual evolution can lead to practical change.
- The Kit was generally available throughout Australia until 13 January 1993. Sale of the Kit was then restricted by the Government under TGA regulations, and it cannot be posted interstate or overseas.
- Instructions and a questionnaire are included with each Kit. Information from questionnaires is kept completely confidential and forms the basis of continuing research into the effectiveness of the program.

The basic program for protection from birth is summarised in Table 1.1-2 below.

Table 1.1-2 The Current Homoeoprophylactic Program (Summary)

MEDICINE		**AGE ADMINISTERED (Months)**
A	Pertussin	1 *2 *13 *32
B	Tetanus Toxin	11 *12 *24 *41 *60
C	Lathyrus Sativus	4 *5 *16 *26 *56
D	Diphtherinum	9 *10 *22 50
E	Morbillinum	14 *15 54
F	Parotidinum	19 *20
H	Haemophilis	6 *7 *17 *28 *46

* Triple doses to be used; e.g., for Pertussin*, take 2 tabs each of Pertussin (200), Pertussin (M) and Pertussin (10M), evenly spaced over 24 hours (i.e. a dose every 8 hours).

The Supplementary Program

The current supplementary program is shown in Table 1.1-3 .

Table 1.1-3 The Current Supplementary Program

CODE	MEDICINE	DISEASE
A1	Pertussin (200)	Whooping Cough
M	Ledum Palustre (30)	Tetanus
C1	Lathyrus Sativus (200)	Poliomyelitis
D1	Diphtherinum (200)	Diphtheria
E1	Morbillinum (200)	Measles
F1	Parotidinum (200)	Mumps
H	Haemophilis (M)	Hib Meningitis

Explanatory Notes:

- If desired, boosters may be given every 10 years, or as required.
- The 200th potencies of each remedy replace the 30th potencies used in the original (1986) supplementary program.
- Use of the remedies is optional; for example, many parents decide not to use Parotidinum since Mumps is such a benign disease in childhood, and natural infection is the most certain form of immunity.

1.1.2 The Original (1986) Homoeopathic Prophylactic Kit

The following Kit was assembled to cover both programs. The medicines were labelled with letters of the alphabet for convenience. *Note:* For both programs, one dose consisted of two tablets or pilules of the medicine indicated. The Rubella Nosode was given to girls only.

Table 1.1-4 The Original Homoeoprophylactic Program

CODE	MEDICINE	QUANTITY	AGE ADMINISTERED (Months)
A	Pertussin (M)	10 pills	1 2 10 22 32
B	Tetanus Toxin (M)	14 pills	3 6 12 18 30 42 56
C	Lathyrus Sativus (200)	12 pills	4 9 20 36 48 60
D	Diphtherinum (M)	8 pills	5 16 28 40
E	Morbillinum (M)	4 pills	13 25
F	Parotidinum (M)	4 pills	14 26
G	Rubella (M)	4 pills	*12 *14 *years
L	Pertussin (30)	30 pills	)
M	Ledum Palustre (30)	12 pills	)
N	Lathyrus Sativus (30)	10 pills	)
O	Diphtherinum (30	18 pills	) *Supplementary use*
P	Pulsatilla (6)	30 pills	) (see below)
Q	Morbillinum (30)	10 pills	)
R	Parotidinum (30)	10 pills	)
S	Pilocarpine (12)	30 pills	)
T	Arsenicum Album (12)	30 pills	)

Table 1.1-5 The Original Homoeoprophylactic Program (Summary)

MEDICINE		**AGE ADMINISTERED (Months)**						
A	Pertussin (M)	1	2	10	22	32		
B	Tetanus Toxin (M)	3	6	12	18	30	42	56
C	Lathyrus Sativus (200)	4	9	20	36	48	60	
D	Diphtherinum (M)	5	16	28	40			
E	Morbillinum (M)	13	25					
F	Parotidinum (M)	14	26					
G	Rubella (M)	*12	*14		* years			

Table 1.1-6 The Original Supplementary Program

CODE	MEDICINE	Disease
L	Pertussin (30)	Whooping Cough
M	Ledum Palustre (30)	Tetanus
N	Lathyrus Sativus (30)	Poliomyelitis
0	Diphtherinum (30)	Diphtheria
P	Pulsatilla (6)	Measles/Rubella
Q	Morbillinum (30)	Measles
R	Parotidinum (30)	Mumps
S	Pilocarpine (12)	Mumps
T	Arsenicum Album (12)	Colds/Influenza

1.2 Questionnaires

Table 1.2-1: The Questionnaire Provided With the Program

CONFIDENTIAL - HOMOEOPATHIC KIT - 1998 QUESTIONNAIRE - DUE 1.2.98

Child's Name: ..... File No: .....

Address:.....

File No: …… Male/Female Age as at 1.2.1998 …… months

1. At what age did your child commence the Programme? …….. months

2.. Was your child vaccinated before commencing the Programme?Yes/No.

3. If "Yes" to Q.2, state the number of vaccines and approximate ages

.....……

…….....

4. Did your child have any reactions to previous vaccines? Yes/No

5. If Yes to Q4., please state any adverse reactions to the vaccines?

…….....

.....…….....

6. Did your child react to Medicines in the Kit? Yes/No.

7. If "Yes" to Q.6, please give details …….....

……..

.....…….....

8. Has your child suffered from any of the diseases covered by the Main Programme? Yes/No.

9. If "Yes" to Q.8, did the disease occur before or after commencing the Main Programme? Before/After.

10. If "After" to Q.9, Please give details ….....
……

11. Has your child definitely been exposed to any diseases covered by the Main programme? (This is a most important question). Yes/No.

12. If "Yes" to Q.11, please give full details .....
……
……
……

13. Please describe any variations from the Programme which have occurred.
.....
.....

14. Any other comments? - please describe: .....
.....
.....
.....

Please use the space below if needed to amplify any of the answers above.

NOTE: Next years questionnaire will cover the year from 1.2.1998 to 1.2.1999. The questions will be similar. Please keep a note of any significant events, especially exposure to diseases. Thank you.

Table 1.2-2: The Questionnaire Provided for Follow-Up Responses

CONFIDENTIAL - HOMOEOPATHIC KIT - 1999 QUESTIONNAIRE - DUE 1.2.99

Child's Name: ..... File No: .....

Address:.....

NOTE: THE FOLLOWING QUESTIONS CONCERN THE PERIOD 1.2.98 TO 1.2.99.

1 . Has your child been vaccinated since 1.2.1998? Yes/No.

2. If "Yes" to Q.1, state the number of vaccines and approximate ages

.....…….

…….....

3. Please state any adverse reactions to the vaccines? .....

…….....

.....…….....

4. Has your child reacted to Medicines in the Kit since 1.2.98? Yes/No.

5. If "Yes" to Q.4, please give details …….....

……..

.....…….....

6. Has your child suffered from any of the diseases covered by the Main Programme since 1.2.1998? Yes/No.

7. If "Yes" to Q.6, did the disease occur before or after commencing the Main Programme? Before/After.

8. If "After" to Q.7, Please give details …….....

……

9. Has your child definitely been exposed to any diseases covered by the Main programme since 1.2.1998?

(This is a most important question). Yes/No.

10. If "Yes" to Q.9, please give full details .....

……

……

……

11. Please describe any variations from the Programme which have occurred since 1.2.1998.

.....

.....

12. Any other comments? - please describe: .....

.....

.....

.....

Please use the space below if needed to amplify any of the answers above.

NOTE: Next years questionnaire will cover the year from 1.2.1999 to 1.2.2000. The questions will be similar. Please keep a note of any significant events, especially exposure to diseases. Thank you.

1.3 Non-Respondents

Table 1.3-1: Questionnaire Sent to Follow-Up Non-Respondents

Isaac Golden.
P.O. Box 181.
Daylesford. 3460
(03) 5348 3667

Dear Parents,

Some years ago you purchased a homoeopathic disease prevention Kit from me.

I have been researching the safety and effectiveness of the program for 16 years, and am completing this research through a formal study at the Graduate School of Integrative Medicine at Swinburne University, Melbourne.

Part of this research involves contacting parents who purchased the Kit, but who have not returned the Questionnaire, to ask a few simple questions.

As you can see, the following page has only 6 questions, and there are no identifying marks if you wish to remain anonymous.

Your reply would be sincerely appreciated, even if you did not use the Kit at all, or even if your experience was negative or positive.

Every reply is valuable, and adds to the reliance we can place on the existing research.

Thanking you,

Isaac Golden

KIT QUESTIONNAIRE RESPONSE SURVEY

Question 1: Why didn't you return the Kit Questionnaire? (please circle one)

(a) lost it; (b) couldn't be bothered; (c) concerned with confidentiality;

(d) other (please state) …….
…….

Question 2: Did you use the kit? (please circle one)
(a) partially; (b) fully; (c) not at all

Question 3: How would you describe the Kit's success in preventing disease? (please circle one) (a) successful; (b) unsuccessful; (c) partially successful
(d) don't know; (e) did not use the kit

Question 4: Rank your level of satisfaction with the Kit between 1 and 10 (where 1 = totally dissatisfied and 10 = totally satisfied). …….

Question 5: Which State do you live in? NSW / VIC / QLD / WA / SA / TAS / NT/ ACT.

Question 6: Would you like to participate in a general health survey of Australian children between the ages of 5 years and 12 years? Yes/no

IF YES - please state your name and address so we can send you the survey.

……
……
……

Thank you for your valuable co-operation

Please return this form in the reply paid envelope attached,
or post to P.O. Box 181, Daylesford. 3460

1.4 Follow-up of Selected Respondents

Table 1.4-1 Letter to parents who reported a disease

Isaac Golden
P.O. Box 155.
Daylesford. 3460.

(03) 5348 3667.
21.8.03

Dear Parents,

I am writing to ask your help to complete a research project that I am undertaking at Swinburne University concerning your homoeopathic preventative kit.

Some time ago you returned a questionnaire stating that in ……. your child contracted Mumps.

I need to check the level of certainty as to the diagnosis of the disease, and would be most grateful if you would answer the following brief questionnaire as well as you can, and post back in the envelope supplied.

I am hoping to complete the research by the end of the year, so your early reply would be greatly appreciated.

Even if your memory does not enable you to answer the questions, your reply stating that you cannot remember is still very important to make the statistical analysis complete.

With best wishes,

Isaac Golden

QUESTIONNAIRE Kit No. ……

Reported Disease: ……Mumps…… (please circle one)

1. Was the disease diagnosed by a medical practitioner? yes/no

2. Was the disease diagnosed by a natural therapist? yes/no

3. Have you ever seen confirmed cases of this disease before? yes/no

4. Did other people your child associated with also have the disease? yes/no

5. For how long did your child experience symptoms of disease? …….. weeks

6.. Please tick if your child definitely experienced any of the symptoms in the following Table, and comment on the intensity of the symptom (you would not expect to tick all boxes)

Tick if "yes"	Symptom	Duration weeks	Intensity: low/med/high	Your Comment
	Sudden high fever			
	Slow progressive fever			
	Running nose			
	Cough			
	Red spots with white centres in the mouth			
	Difficult breathing			
	Noisy gasp (whoop) of air following a cough			
	Fatigue			
	Headaches			
	Neck pain			
	Other …			

Please return this questionnaire in the envelope provided

Table 1.4-2 Letter to parents who reported exposure to a disease

17.9.03

Dear Parents,

I am writing to ask your help to complete a research project that I am undertaking at Swinburne University concerning your homoeopathic preventative kit.

Some time ago you returned a questionnaire stating that your child was exposed to …….. in ……. .

I need to check the level of certainty as to the exposure to the disease, and would be most grateful if you would answer the following brief questionnaire as well as you can, and post back in the envelope supplied.

I am hoping to complete the research by the end of the year, so your early reply would be greatly appreciated.

Even if your memory does not enable you to answer the questions, your reply stating this is still very important to make the statistical analysis complete.

With best wishes,

Isaac Golden
P.O. Box 155.
Daylesford. 3460.
(03) 5348 3667.

QUESTIONNAIRE Kit No. ……

Reported Disease: ……

How many people who had the reported disease did your child come in contact with? (please circle one)
one person / 2-5 people / 6 or more people / I don't know / other ……...

2. Was the disease in the person(s) your child was exposed to diagnosed by a medical practitioner? (please circle one) yes/no/both/I don't know

Did the person(s) carrying the disease and your child definitely have close physical contact. (please circle one) yes/no/I don't know

What was the stage of infected person(s) disease when your child was Exposed? (please circle one) symptoms had not yet developed
disease had just begun
disease had been going for 2 or more weeks
I don't know
other …….

Was any of the exposure you reported above to children or parents in your own family? yes/no

Please briefly comment in the space below or over the page why you think your child was exposed to the disease reported.

Please return this questionnaire in the envelope provided. Thank you.

1.5 Questionnaire Sent for the General Health Survey

Table 1.5-1 - Questionnaire Sent for the General Health Survey

GENERAL HEALTH SURVEY

Dear Parents,

Thank you for agreeing to participate in this important new research project. It is only because of the willingness of parents like yourselves to assist in research that public awareness about important issues can be raised to new levels.

In the questionnaire following you will be asked a range of questions about the health of your child from birth to now.

Please answer carefully, as your answers are important to the success of the survey and the resulting implications for national public health policy.

Your answers are confidential, and this page with your personal details will be detached from the questionnaire pages so that your name and address will not appear on the questionnaire pages. We need your name etc in case there are follow-up questions. If you need more than one questionnaire please contact our office, or photocopy this copy.

We would greatly appreciate your early return of the questionnaire to enable results to be compiled during 2003.

Your details (please print answers)

Name: ……

Postal Address: …….

……Post Code……

Phone: (…..) …….. E-mail: ……

Your child's name: …….

Please return all these papers in the envelope, or directly to

Isaac Golden. P.O. Box 181. Daylesford. 3460

GENERAL HEALTH SURVEY

General Information about your child: (a) Age: ……yrs ……. mths. (b) Male/Female.

(c) Birthweight: ……. (d) How long breastfed: ……. months.

(e) APGAR Score: (1^{st}) ……(2^{nd}) ……. (f) If premature, by how many weeks: ……

(g) Did your child receive a Vitamin K injection following birth? yes/no

Question 1: (a) Was your child given orthodox vaccines? yes / no

(b) Did your child use a homoeopathic preventative program? yes / no

(c) Did your child use general/constitutional prevention? yes / no

(d) If "yes" to any of the above, please give details (i.e. diseases covered, what age)

……

……

……

Question 2: (a) Please rank the general health of your child between 1 and 10 (1= very poor general health; 10=excellent general health)? ……

Has your child had any of the following? - if "yes" pleases give age(s) and details.

(b) Asthma yes / no …….

(c) Was this condition diagnosed by a medical practitioner? yes / no

(d) Eczema yes / no …….

(e) Was this condition diagnosed by a medical practitioner? yes / no

(f) Ear /hearing problems yes / no ……..

(g) Was this condition diagnosed by a medical practitioner? yes / no

(h) Allergies yes / no ……..

(i) Was this condition diagnosed by a medical practitioner? yes / no

(j) Behavioural problems yes / no ……..

(k) Was this condition diagnosed by a medical practitioner? yes / no

The following infectious diseases

(l) Measles yes / no ……..

(m) Was this condition diagnosed by a medical practitioner? yes / no

(n) Whooping cough yes / no ……..

(o) Was this condition diagnosed by a medical practitioner? yes / no

(p) Mumps yes / no ……..

(q) Was this condition diagnosed by a medical practitioner? yes / no

(r) Any other infectious disease yes / no ……

(s) Was this condition diagnosed by a medical practitioner? yes / no

Question 3: Does your child have ongoing chronic health problems yes / no (including any noted above)?

If "yes" please give details ……

……

……

……

Question 4: (a) How many times has your child been hospitalise ……

(b) If hospitalised, how long were the stays in hospital ……

……

Question 5: (a) Does your child receive any special treatments to strengthen their general health, such as:

- naturopathic, homoeopathic, herbal, nutritional, special diet, yes / no

(b) If "yes", please give brief details ……

……

……

Question 6: (a) Has your child been sufficiently unwell for you to have consulted one or more of the following health professionals? yes/no

(b) If "yes", please mark all below

(a) Medical practitioner yes / no
(b) Naturopath yes / no
(c) Homoeopath yes / no
(d) Other natural therapist yes / no
(e) Chiropractor/osteopath yes / no
(f) Other (please specify below) yes / no

……

Thank you sincerely for your assistance in completing this survey. Would you please return it in the envelope provided, or to the following address:

General Health Survey.
P.O. Box 181
Daylesford. 3460.

If you have any questions concerning the survey please contact Isaac Golden at the above address, or at the following numbers: fax: (03) 5348 3667;
e-mail: homstudy@netconnect.com.au

2 Appendix 2: Materials Used in the Practitioner Survey

2.1 Practitioner Questionnaire

Table 2.1-1: Questionnaire to Professional Homoeopaths Concerning Their Attitude to and Use of Homoeoprophylaxis

Dear Colleague,

I have been researching the use of homoeopathically prepared remedies to assist in the prevention of infectious diseases for 16 years.

I am finalising this research through a PhD program at the Graduate School of Integrative Medicine at Swinburne University in Melbourne where a number of pieces of research will be undertaken.

I hope to conduct the world's first randomised, double-blind, placebo controlled trial of homoeoprophylaxis in humans. I also hope to conduct a large general health survey looking at the long term results of homoeoprophylaxis and other methods of disease prevention.

As part of the research, I would also like to determine practitioner attitudes to, and use of homoeoprophylaxis.

I would greatly appreciate your help in completing the following brief questionnaire, and returning it in the reply paid envelope attached.

Final results will be published next year for all to see.

If you would be prepared to display the attached information sheet in your clinic, I would be most grateful. And if you have any patients who may be interested in participating in the Randomised Clinical Trial or the National Health Survey, please ask them to contact me for further details

Thanking you in anticipation.

Isaac Golden

P.O. Box 181.

Daylesford. 3460

(03) 5348 3667

SURVEY OF THE ATTITUDES TO, AND USE OF HOMOEOPROPHYLAXIS (HP) AMONG QUALIFIED HOMOEOPATHS

Question 1: Did you first learn about HP either

(a) during your homoeopathic course,
(b) after your homoeopathic course,
(c) never learnt about HP. (please circle one)

Question 2: Have you read Hahnemann's 1801 essay "The Cure and Prevention of Scarlet Fever" yes / no

Question 3: Describe your use of HP.

(a) I currently use HP,
(b) I have previously used HP,
(c) I have never used HP. (please circle one)

Question 4: Do you intend to use HP in the future? yes / no /not sure

Question 5: Do you believe that HP is based on the Law of Similars?

yes / no / don't know

Question 6: Do you believe that it is appropriate to use HP (where requested) either

(a) for both long and short term disease prevention,
(b) only for short term (epidemic) disease prevention,
(c) never use it in any circumstances,
(d) other (please state)…….
…….

Question 7: Do you generally believe it is appropriate for a homoeopath to assist in the prevention of infectious disease if requested by a patient? yes / no

Question 8: Do you believe that a homoeopath should only treat infectious diseases once they have appeared, and should never assist in the prevention of infectious diseases? yes / no

Please state the professional association(s) you belong to ……

……

How many years have you been practicing homoeopathy ……

Which State do you live in? NSW / VIC / QLD / WA / SA / TAS / NT/ ACT.

If you have any other comments, please state them below:

Table 2.1-2: Letter to Practitioner Associations Requesting Their Help With the Practitioner Survey

Isaac Golden

PhD(MA), D.Hom., ND, B.Ec (Hon).

22.5.01

Dear Secretary,

I am writing to all Homoeopathic associations in Australia asking for your help.

I am currently undertaking PhD research at the Graduate School of Integrative Medicine, Swinburne University, Melbourne.

My thesis topic is "The Potential Value of Homoeoprophylaxis in the Prevention of Infectious Diseases, and the Maintenance of General health in Recipients"

I will be undertaking a number of pieces of research, hopefully including the world's first randomised, placebo controlled trial of HP in humans. If successful, this will provide "hard" evidence which as a profession we are often accused of not having.

However I am asking for your Association's help in circulating a questionnaire to practitioner members. One part of my overall research is a national practitioner survey examining the attitudes to and use of HP.

If you are willing, I would like to provide you with a covering letter and questionnaire plus a reply paid envelope to be inserted in your Newsletter to Professional members. If you advise me of numbers I will send the required material to you. I will attach the draft of the covering letter and questionnaire, and also of the general advertisement concerning the other two pieces of research where I will be seeking public involvement.

I am undertaking my research without private funding, and need all the help I can get to cover costs, hence my request for a favour to include this material in your next newsletter.

If you have any questions please do not hesitate to contact me, or if you are willing to help, please advise numbers of questionnaires etc which I should send you, and the address.

With sincere thanks in anticipation.

Kind regards Isaac Golden