A STUDY ON THE CURATIVE AND PREVENTATIVE EFFECTIVENESS OF HOMEOEPATHIC OSCILLOCOCCINUM ON INFLUENZA TYPE SYNDROMES

BY

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I, Lindi Porter, declare that this study represents my own work in both concept and execution.

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Approved for Final Submission

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DATE
I DEDICATE THIS STUDY TO MY PARENTS AND MY FIANCEÉ.

THANK YOU FOR ALL THE LOVE AND SUPPORT YOU HAVE SHOWN ME OVER THE PAST FIVE YEARS. I AM BLESSED TO HAVE YOUR INFLUENCE IN MY LIFE
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ABSTRACT

Influenza Type Syndromes is a descriptive diagnosis of the many cases encountered in general practice which present with a symptom complex like influenza. The purpose of this study is to determine the efficacy of Homoeopathic Oscillococcinum in the treatment of Influenza Type Syndromes both curative and preventatively. The aim is to establish the proposed initial improvement in the clinical manifestations after three days. Furthermore the 120 day follow-up period is aimed at demonstrating that recurring episodes of influenza symptoms, following the initial treatment, is minimal.

In this double blind trial a sample group of thirty patients were randomly divided into two groups of fifteen. In order to achieve this, the medication and placebo were both prepared in granule form and dispensed by an independent dispenser. One group received Homoeopathic Oscillococcinum and the other group placebo. Each participant had a full case history taken to determine the onset and course of the clinical picture as well as to record the past medical history and general health of the patient. Subsequently, a questionnaire formed part of a means to obtain the required data. Section A, an evaluation of the patients symptoms, and section B, an evaluation of the presenting signs. This questionnaire was completed again on Day 3 of the treatment. Coincidentally the oral temperature of each patient was taken for three days. Thereafter each patient kept a symptoms diary for 120 days and received a medicated or placebo booster dose at monthly intervals in accordance with the numerical order assigned by the dispenser.

This study did not attempt to explain how Homoeopathy works on a biological level in the treatment of Influenza Type Syndromes. It also did not try to isolate a virus or demonstrate
antibodies via serological testing methods or any other techniques. Thus only the effectiveness of the Homoeopathic medication was evaluated.

In this study it was shown that according to Section A of the questionnaire, the improvement in the treatment group is statistically more significant than that in the placebo group. With reference to Section A of the questionnaire it also became evident that there was a greater improvement in the treatment group than in the placebo group. Furthermore, the treatment group showed a faster termination of their fever as opposed to the persisting fever of the placebo group's patients. Further results confirmed that over the 120 day follow-up treatment period, the treatment group had fewer and less frequently recurring symptoms than the placebo group.

Thus it has been established that Homoeopathic Oscillococcinum is more effective in the curative and preventative treatment of Influenza Type Syndromes, than treatment with placebo.
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CHAPTER ONE

1. THE PROBLEM AND ITS SETTING

1.1 INTRODUCTION

According to Jouanny (1991) influenza presents clinically as an infectious, a nervous and sometimes a haemorrhage syndrome. These Influenza Type Syndromes are the result of filterable pass virus (Jouanny 1991) which characteristically have antigenic variation (Cliff et al., 1985) from one year to the next or from one seasonal epidemic to the next.

The conventional scope for treating Influenza Type Syndromes is mainly preventative, with limited success rate, requiring early detection of the antigenic constitution of a new strain (Edwards 1991). The estimated effectiveness of influenza vaccines range from 40% to 90% (Carrat and Valeron 1995:419) depending on population subgroups, influenza virus, influenza vaccines, and antigenic similarities between wild and vaccine strains. It is thus evident that the success of vaccination against Influenza Type Syndrome is tentative. General allopathic influenza management is suppressive (Edwards 1991), yielding limited benefits. Homoeopathic medicines however stimulate the body’s own defences rather than directly attacking specific pathogens.

It was proposed that Homoeopathic Oscillococcinum could be used for the short and long term treatment of Influenza Type Syndrome. Homoeopathy uses the Law of Similars in its mode of treatment. This means that a medicinal substance which can produce a certain change in the body (its pathogenesis) was used to treat that clinically presenting syndrome. In this case a substance
capable of producing the symptoms and signs of influenza was administered in an infinitesimal dose stimulating the immune system to heal the body.

After a thorough investigation into the subject, sufficient literature had not become available concerning the effectiveness of Oscillococcinum in treating Influenza Type Syndrome with reference to the permanency of the results yielded. Resultingly, it was imperative to have had follow-up consultations in this study to test whether or not lasting results would be obtained through the treatment.

In summary, this study postulates that treating Influenza Type Syndromes with Homoeopathic Oscillococcinum will yield an improvement in the clinical manifestations after three days. Furthermore it hypothesises that follow-up consultations, over a 120 day period at monthly intervals, would demonstrate that recurring episodes of influenza symptoms following the initial treatment would be minimal, thus demonstrating the hypothesised curative and preventative properties of Homoeopathic Oscillococcinum. A time span of 120 days from the time of onset of the Influenza Type Syndromes has been chosen to test the patency of Homoeopathic Oscillococcinum during seasonal changes (Cliff et al., 1986) and the effects of season and climate on the occurrence of Influenza Type Syndromes. Other variables such as antigenic variation, immune phenotype, host genotype, crowding and infection density (Kilbourne 1987:264 - 268) can not be controlled effectively.
1.2 THE PROBLEM

1.2.1 THE PROBLEM STATEMENT

This study proposed to determine the efficacy of Homoeopathic OSCILLOCOCCINUM in the treatment of Influenza Type Syndromes with reference to changes in the clinical manifestations of the patient over a 120 day period incorporating follow-up consultations to monitor the permanency of the results obtained after the initial three day treatment, in order to determine the efficacy of Homoeopathy in the treatment of Influenza Type Syndromes.

1.2.2 HYPOTHESES

1.2.2.1 The First Hypothesis

It was postulated that the use of Homoeopathic OSCILLOCOCCINUM in the treatment of Influenza Type Syndromes would improve the clinical manifestations which the patients presented with at the outset of this study.

1.2.2.2 The Second Hypothesis

It was postulated that the use of placebo in the treatment of Influenza Type Syndromes would not improve the clinical manifestations which the patients presented with at the outset of this study.

1.2.2.3 The Third Hypothesis

It was postulated that the data obtained in this study would demonstrate that the Homoeopathic treatment of Influenza Type Syndromes would be more effective than treatment with placebo.
1.2.3 DELIMITATIONS

1. This study did not accept any subjects undergoing another form of treatment for their Influenza Type Syndromes.

2. This study delimited itself from any other form of treatment except Homoeopathy.

3. This study delimited itself from the explanation of how Homoeopathy works on a biochemical level in the treatment of Influenza Type Syndromes.

4. This study delimited itself from isolating a virus or demonstrating antibodies via methods such as serological tests or the fluorescent antibody technique (Edwards 1991).

1.2.4 ASSUMPTIONS

1. In this study only one form of treatment was allowed, therefore once this study had begun it was assumed that the patients would not take any other form of medication for their Influenza Type Syndromes.

2. Once the study commenced, the patient was required in a disciplined manner to take a prescribed amount of the Homoeopathic medicine per day, therefore it was assumed that the patients would participate unconditionally and take their medication as directed, not exposing it to any situation that might antidote it.

3. That the pathogenesis of the medicine used was correct.

4. That the questionnaire would be completed honestly by each patient.
1. *PLACEBO* is an inactive substance or preparation given to satisfy the patient's symbolic need for drug therapy, and used in controlled studies to determine the efficacy of medicinal substances (Dorland, 1989).

2. *ANTIDOTING* is the term used in Homoeopathy to describe a set of circumstances that cause the neutralisation of Homoeopathic remedies eg. exposing the remedies to direct sunlight for extended periods of time, high temperatures and strong smelling substances such as Camphor.


4. *OSCILLOCOCCINUM* is a Homoeopathic preparation of the heart and liver of a duck (Ullman, 1988).

5. *CLINICAL MANIFESTATIONS* is a medical concept which refers to any display or disclosure of characteristic signs or symptoms of an illness.
CHAPTER TWO

2 LITERATURE REVIEW

2.1 INTRODUCTION

Influenza is a specific acute illness caused by a group of myxoviruses. It occurs in epidemics, and occasionally pandemics, often explosive in nature (Edwards 1991). Influenza has a large impact on the economy and health services as worker absence slows productivity and advancement in the workplace (Ordobas et al., 1995: 14). The term Influenza Type Syndromes however has been termed because of the many cases encountered in general practice which present with a symptom complex like influenza. In order to treat this morbid state reference to exactly which influenza strain the causative organism might be is not of clinical value as antiviral allopathic medicine is still in the pipeline. According to Dorland (1989) the word “syndrome” refers to a set of symptoms occurring together; the sum of signs of any morbid state; a symptom complex. For the purpose of this particular study a clinical diagnosis based on the signs and symptoms of Influenza Type Syndromes will suffice, without further investigations to isolate a particular virus or strain as the causative agent.

2.2 AETIOLOGY

Edwards (1991) and Kilbourne (1987) specify two common types of viruses, A and B. At least four strains of Influenza A, which is responsible for pandemics, have been identified. Influenza B is usually associated with smaller and less virulent outbreaks. The immunity which follows infection is type-specific and of relatively short duration. This causes many problems in the provision of effective immunisation. Up to date immunological research has explored the characteristics of the
influenza virus - specific CD8+ T cell response in mice homozygous for disruption of the H-21Ab gene (Tripp et al., 1995: 2954 - 2959). The possibility to gain immunity against the influenza virus, however, is still being investigated. Once again it is necessary to reiterate that for the purpose of the clinical trials to be executed on Influenza Type Syndromes, the importance of establishing the specific viral strain responsible for a particular symptom picture is not imperative, as the researcher is treating a syndrome.

2.3 EPIDEMIOLOGY

Although reinfection with homotypic strains seems to occur fairly frequently (Kilbourne 1987), the survival of influenza viruses in man requires the continual evolution of antigenic mutants.

According to Laver (1980) and Cliff (1986) multiple amino acid substitutions within the antigen enables the virus to acquire epidemic potential. Incidentally the Homoeopathic Oscillococcinum, which is the drug of treatment for these clinical trials, has remarkable antiviral effects because of the numerous amino acids contained in the base substance rich in DNA and RNA (Jouanny 1991).

Other factors such as Immune Phenotype and Host Genotype, Kilbourne (1987), are also factors affecting the epidemiology. Environmental factors, like season and climate, propose an all-encompassing role in the epidemiology of influenza. It has been postulated that latent carriage of the virus in human tissue, its seasonal reactivation in altered antigenic form, and its subsequent transmission to susceptibles, produce epidemics. This provocative postulation should then explain the apparent simultaneous eruption of epidemics caused by the same viral antigenic variant in widely scattered areas of the planet. According to Carrat and Valleron (1995: 419) it is mainly the elderly people who are the main victims of influenza as far as mortality is concerned. During the winter 1989 - 90 in France, 88% of the deaths caused by influenza concerned people ≥ 75 years.
Furthermore, crowding and infection density makes for the easy communicability of this disease picture.

2.4 CLINICAL MANIFESTATIONS

The clinical expression of infection with an influenza virus is variable and is partially influenced by the nature of the ineffective virus, yet to a greater extent is modulated by the age, physiological state, as well the immunological experience of this host.

Stuart-Harris (1985) describes the typical onset of the symptom picture as rapid, and the degree of prostration and constitutional symptoms to be out of proportion to the severity of any respiratory symptoms. Characteristically also, the fever is short-lived lasting up to four days. He describes it as "an unvarying disease caused by a varying virus". However, even the typical case is diagnosed most easily in the context of the epidemic, thus making epidemicity an important diagnostic clue.

According to Stuart-Harris (1985) most patients invariably suffer from coughing, a fever and mild prostration. Edwards (1991) mentions a throbbing, non-localised headache as a common complaint, followed by myalgia and stiffness (Jouanny 1991). Sore throat prevails in 50% of patients. Other common symptoms are chilliness and nasal and conjunctival irritation. Rarely gastrointestinal symptoms such as nausea and vomiting occur.

On physical examination the Influenza Type Syndromes may show evidence of malaise, prostration and manifest facial flushing and conjunctival injection. Respiratory signs of the upper airways may include nasal obstruction, nasal discharge and pharyngeal infection (Boiron Laboratories).
Fever is constant finding, and for the purpose of this study the central diagnostic tool to gauge the prognosis of the presenting syndromes. Meyer (1988) defines fever as an increase in body temperature, which in most cases indicates organic disease. Benign fever does not exceed 41.5 degrees Celsius even though it is potentially complicating. The fever of the Influenza Type Syndromes is most probably due to pyrogens. These constitute proteins released by pathogenic organisms or by damaged body cells.

2.5 PERSPECTIVES ON TREATING INFLUENZA TYPE SYNDROMES.

Conventional drugs have the potential of relieving the symptoms which relate to bacterial infection; however allopathic medicine has little to offer in treating most viral conditions (Ullman 1989). Twentyman (1988) states that Homoeopathy aims at finding the remedy corresponding to the disease process. Homoeopathic medicines stimulate the body’s own immune system rather than directly attacking the virus.

Singh (1985) published documentation on research done on viruses that attack chicken embryos in which 80% of the Homoeopathic medicines tested inhibit the growth of viruses by 50 - 100%. The importance of this research lies in the fact that the shortfalls in conventional treatment of viral syndromes/ symptom pictures can be bridged by Homoeopathic intervention.

The natural laws and principles applied in Homoeopathy has its origins rooted back as far as twenty-five centuries ago in a well established medical school, that being of Hippocrates. During the 1700s a German medical practitioner of the time employed the principle of “Similia Similibus Curentur” (Lt. meaning like cures like), in practice yielding pathogeneses of drugs administered in infinitesimal doses. Hahnemann’s hypothesis has been proven through clinical trials, by prescribing a weak/
infinitesimal dose of a substance, which when administered to a healthy person causes symptoms similar to those exhibited by the ill patients.

Savage (1984) notes that “while the search goes on to find specific antiviral preparations which are free from side-effects, Homoeopathy can be used effectively to treat patients in four ways:

1. Prophylaxis - to generate resistance to the infection;
2. Treatment in the acute illness - to reduce the length and severity of the illness;
3. Restoration to revitalise the patient - during convalescence, and
4. Correction of the chronic sequelae - to restore the patient to his form state of health”.

This study emphasises the scope of treating the acute illness. Ullman (1989) states that an additional advantage in the case of Homoeopathic treatment of viral conditions is that prescription does not depend on a definite diagnosis, because it treats the totality of the symptoms constituting the Influenza Type Syndromes.

Boiron Laboratories of Lyon, France, suggests that Homoeopathic Oscillococcinum is most effective in treating Influenza Type Syndromes when taken within forty-eight hours of the onset of clinical manifestations.

Influenza Type Syndromes are essentially febrile states. When treated in the early stages, as is the aim of this clinical study, there are usually three remedies of choice (Jouanny 1991):

(i) Aconitum napellus
(ii) Belladonna, and
(iii) Ferrum phosphoricum
The employment of Homoeopathic Oscillococcinum, with its remarkable antiviral effect, seems ideal as a choice of remedy for the curative treatment of Influenza Type Syndromes.

General allopathic management of influenza includes a mild analgesic such as paracetamol 0.5 - 1g every 4 - 6 hours for myalgia and headaches. Pholcodine 5 - 10mg 3 - 4 times daily to suppress unproductive cough (Edwards 1991).

As far as prevention is concerned, immunity is type-specific. Thus if the antigenic constitution of a new strain can be detected early a specific vaccine may give about 70% protection (Edwards 1991).

2.6 PERSPECTIVES ON OSCILLOCOCCINUM

2.6.1 HISTORICAL OVERVIEW OF THE DRUG OF CHOICE

According to Roy (1925) the existence of an organism animated by an oscillatory movement was observed in certain culture conditions. The organism was therefore named Oscilloccocus. This research led to the development of a biotherapeutic remedy which was termed Oscillococcinum and which was subsequently used for clinical experimentation on influenza as well as affections of the ears, nose and throat (Chavanon 1963).

2.6.2 DRUG PREPARATION CRITERIA

Oscillococcinum 200K, a filtered autolysat of duck liver and heart (Ullman, 1988), is a speciality drug prepared by the Boiron Laboratories of Lyon, France. It is characterised by:-

a) Preparation criteria
b) Physical criteria

c) Chemical criteria

In addition, even though the preparation is not injectable:

d) Sterility tests

e) Inocuity tests

2.6.2.1 Preparation Criteria

The following information was supplied by Boiron and Abecassis (Boiron Laboratories):

The preparation is done in rigorous aseptic conditions in a room that is protected by ultraviolet light. All glass equipment and other necessary instruments are sterilised. In a 1000ml glass container is placed:

- 225 ml of sterile pancreatic peptic solution at 1%
- and
- 225 ml of tyndallised glucose serum at 10%.

The source, Anae Babariae, is decapitated. In sterile conditions the liver and heart are dissected out. Then 35 grams of liver and 14 grams of heart are incubated at 37 °C for 40 days in the container mentioned above.

After this time the autolysat is filtered on fretted glass porosity 3. It is this filtered solution that constitutes the substance which is lyophilised for preservation purposes. As this is the mother preparation subsequent analytical trials are done. From this rehydrated substance the 200th Korsakovian dilution is prepared. This is then used to impregnate i.e. medicate the granules.
2.6.2.2. Physical Criteria

The substance presents as a yellow, more or less dark, liquid or as a lyophilisat that is rehydrated during the control with a quantity of water equal to the quantity that was removed during lyophilisation.

Other physical criteria are:

- Refraction index at 25°C: 1.3430 + 0.0015
- Density: 1.018 + 0.01
- Determination of the pH: pH = 3.1% ± 0.3
- Spectrophotometric absorption graph in UV light.

The Oscillococcinum substance diluted $\dfrac{1}{100}$ in an isotonic saline solution at 0.9% presents a maximum absorption of between 260 and 275 mm.

$$\dfrac{1}{100}$$

The absorption value $E_{\text{1cm}}$ is 0.38% ± 0.05

2.6.2.3 Chemical Criteria

a) Dosage of total nitrogen

This principle is based on the Kjeldahl method which is discussed as follows:

Starting with a trial quantity of 2 grams in a small glass tube, the glass tube is introduced into a long necked flask. 10ml of concentrated sulphuric acid and 0.50g of catalyst (acid sulphate of potassium (100 parts) and copper sulphate (10 parts) and pure selenium (one part) is added. Heat is then applied until the liquid becomes
limpid. Then it is poured into a distillation flask with the rinsing waters and diluted with distilled water. A few glass marbles are added to aid the boiling process.

A refrigerant is adapted onto the flask with an ampoule residing in a beaker containing 25ml

\[ \text{H}_2\text{SO}_4 \text{ 0.1N with a Taschiri indicator (Methyl red and Methylene blue).} \]

50ml of NaOH is subsequently added together with phenolphthalein. Thereafter 30 minutes of distillation is allowed.

The NaOH moves the \( \text{NH}_3 \) of \( \text{SO}_4(\text{NH}_4)_2 \) formed during the mineralisation, and \( \text{NH}_3 \) partially neutralises the sulphuric acid. The beaker is then taken away from the end of the refrigerant and the ampoule is rinsed. The excess \( \text{H}_2\text{SO}_4 \) is measured with \( n \) ml NaOH 0.1 N until the colour becomes greyish.

The percentage of total nitrogen (in grams for 100g) is calculated by this formula:

\[
\frac{0.1401(25 - n)}{PE}
\]

The total quantity of nitrogen of the Oscillococcinum substance must be between 0.297g% and 0.363g% (P/P).
b) Dosage of the amine nitrogen.

The principle is based on dosage by formaline-titration. 1 gram of Oscillococcinum is weighed out in an erlen. Add 9ml of distilled water and 2 drops of phenolphthalein.

Then NaOH is added to neutralise the mixture - at that point the colour turns to pale pink. Also, 10ml of formaline is neutralised by the addition of NaOH 0,1N and drops of phenolphthalein until the colour becomes very pale pink in colour. This formaline is then added to the proceeding liquid.

The acidity, liberated by NaOH 0,1 put in the container until the colour turns red, is measured.

\[ n \text{ is the number of millilitres that was used} \]

\[ \text{Amine nitrogen (in grams for 100g)} = \frac{0,1401Xn}{P} \]

The quantity of amine nitrogen will have to be between: 0,207% and 0,253g% (P/P)

c) Percentage amine nitrogen/total nitrogen

The percentage \( \frac{\text{amine nitrogen}}{\text{total nitrogen}} \) should be between 0,7 + 0,1
d) Dosage of tyrosine

The phenolic group of the tyrosine is measured by colorimetry with the Folin reactive. The final solution in which the coloration develops must have a pH between 7.1 and 7.6. This principle is based on the chemical dosage of proteids by Loiseleur (Boiron Laboratories).

The following is required:

- Folin reagents, dissolved in a balloon...............1500 cc
- Sodium tungstate Na\textsubscript{2}WO\textsubscript{4},2H\textsubscript{2}O.................................100 g
- Sodium molybdate Na\textsubscript{2}MoO\textsubscript{4},2H\textsubscript{2}O.................................25 g
- Water.................................................................700 cc

By means of a cork, a reflux refrigerant is connected; the reagents are then boiled slowly for 10 hours. Then 150 g of Lithium sulphate, 50 cc of water and a few drops of liquid bromine is added to the mixture. It is then heated to boiling point, cooled down and filtered.

The end reactive should not have a green colour, for it is indicative of the presence of reduction products. The reactive must be stored away from dust. The calorimetric readings are taken at room temperature. The percentage of tyrosine should be between 0.45 and 0.55 g % (P/P).

e) Chromatographic analysis of the amino acids

The analysis done on a Jeolco 5 AH auto-analyser. Each testing is compared to a standard witness amino acid solution. The resins used for the separation are Aminex A4 and A5. The photometry measured are done at 440 and 570 nm and at three different sensitivities. (The sensitivity of the machinery used is less than \( \frac{9}{10} \) mole for an amino acid).
The expected results can be summarised as the following percentages:

- \[
\frac{\text{alanine}}{\text{glycine}} > 1
\]
- \[
\frac{\text{leucine}}{\text{isoleucine}} > 1
\]
- \[
\frac{\text{phenylalanine}}{\text{tyrosine}} > 2
\]

The level of Arginine is relatively constant at 4.5 mg ± 1 for 100 mg of autolysat. Boiron laboratories however are not equipped to do this analysis. It is therefore done by Professor Gras at the Biochemistry Pharmacy Laboratory, Faculty of Medicine and Pharmacy, 8 Rockefeller avenue, Lyon, France.

2.6.2.4 Sterility trial

This sterility trial is done on three different media over the course of seven days in accordance with the prescribed conditions set out in the French Pharmacopoeia (page 1618).

2.6.2.5 Innocuity trial

The research that is conducted is limited to verification on male mice. The mother preparation is administered intra-peritoneally at a very high dose of 0.3 ml/mouse.
2.6.3 CLINICAL PATHOGENESIS

There is no Hahnemannian pathogenic experimentation of this remedy. The following is a clinical pathogenesis according to studies conducted by Chavanon (1963), Hui-Bon-Hoa (1968) and clinical experience of the clinicians of Boiron Laboratories:

a) Generalities

- anxiety; paleness; cold sensitivity
- sensitivity to weather changes and temperature variations

b) Psychogenic symptoms

- anguish; non-motivated anxiety; stubborn
- finicky, fussy, cannot tolerate disorder; aversion to pollution and dirt
- fear of storms

c) Digestive system

- white tongue; bloated abdomen; cannot digest milk or eggs; putrid belching
- watery vomitus; abdominal cramps followed by putrid diarrhoea; icterus
- pain in right iliac fossa

d) Cardio-vascular system

- hypotony; fainting
e) Musculo-skeletal system

- myalgia; muscular stiffness; shivering; muscular weakness

f) Respiratory system

- nasal catarrh; sneezing; nose blockage
- pains in frontal and maxillary area
- hoarseness; loss of voice; dry cough with mucopurulent expectoration
- earache; shooting pains in ears with hearing loss

g) Uro-genital system

- dark, scant urine; difficult micturition

h) Integumentum

- ulcerative varicosities of the lower limb

I) Modalities

- aggravations by milk; eggs
- improvements by heat and rest.

2.6.4 DIFFERENTIAL DIAGNOSIS

The following remedies are differential diagnostic remedies for Oscillococcinum:

Eupatorium perfolatum; Cinnabaris; Pyrogenium; Luesinum; Luffa operculata; Galphimia glauca and Galinsoga parviflora (Boiron Laboratories).
2.7 SUMMARY

According to Jouanny (1991: 270) influenza can be observed clinically as an infectious syndrome with catarrh of the mucous membranes; a nervous syndrome with headache that predominate in encephalitic forms, and general arthralgia and muscle stiffness; sometimes a haemorrhage syndrome in the form epistaxis or purpura.

Furthermore, these Influenza Type Syndromes are the result of filterable passer viruses, (Jouanny 1991) which characteristically have antigenic variation (Cliff et al., 1986), from one year to the next or even from one season to the next. Depending on the clinical expression of infection with the influenza virus, the severity of the symptomatology varies greatly (Stuart-Harris et al., 1985), yet on average presents as an acute prostrating febrile illness attended by myalgia, cough and other respiratory affections.

For the purpose of this study Homoeopathic Oscillococcinum 200 K is clinically tested in the treatment and subsequent prevention of Influenza Type Syndromes.
CHAPTER THREE

3  MATERIALS AND METHODS

3.1  THE DATA

The data of this research consists of two kinds: Primary data and secondary data. The nature of each of these two types of data will be given briefly below.

3.1.1  THE PRIMARY DATA

1. The clinical manifestations displayed in the case history format.
2. The responses of the patients to the scaled questionnaire on clinical symptoms and signs, to determine the efficacy of treatment.
3. The readings of the oral temperatures of the patients taken over the three-day treatment period.
4. The patient’s symptom diary of 120 days subsequent to the initial treatment.

3.1.2  THE SECONDARY DATA

This consists of current documentation and reports taken from textbooks, journals, materia medicas and repertories.
3.2 THE CRITERIA GOVERNING THE ADMISSIBILITY OF THE DATA

Only the data from the questionnaires completed under personal supervision of the researcher was used. Each patient had to take a daily reading of his/her oral temperature for three consecutive days. Thereafter a diary was kept by each candidate noting any recurring symptoms of the Influenza Type Syndromes.

As the incubation period of Influenza-Type Syndromes is 24 - 48 hours, respondents were accepted providing they did not fall into one of the following categories:

1. Had been presenting with the influenza-type syndrome for longer than 48 hours.
2. Were using a form of analgesic during the treatment (Edwards et al., 1991).
3. Presented with complications of influenza eg. tracheitis, bronchitis, bronchiolitis, bronchopneumonia, toxic cardiomyopathy (Edwards et al., 1991)
4. Absence of a febrile state.

If research participants had stopped taking the treatment their results would have been forfeited.

3.3 THE RESEARCH METHODOLOGY

3.3.1 THE SAMPLE

Advertisements requesting participation in a clinical trial involving Homoeopathic treatment of influenza-type syndromes was placed in the local newspaper as well as on notice boards around the TECHNIKON campus and shopping centres.
A total number of thirty patients were recruited. Fifteen patients of which received placebo treatment, constituting the control group in this clinical trial. The other group of fifteen received Homoeopathic Oscillococcinum 200K.

3.3.2 PREPARATION AND DISPENSING OF MEDICATION

As this was a double blind trial, neither the researcher nor the research candidates had knowledge of whom had received placebo or medicated treatment. In order to achieve this, the medication and placebo were both prepared in granule form and dispensed by an independent dispenser. The boxes contained six vials of one gram each of either placebo or medicated granules. The dispenser numerically numbered each box and kept a private record of the corresponding placebos and treatments allocated.

During the initial treatment phase of three days one unit-dose was taken every twelve hours for three days running. During that time each patient took a daily reading of his/her oral temperature with an oral thermometer, thereby completing the Oral Temperature Chart (Appendix C). The oral temperatures taken on Day 1 and Day 3 were verified by the researcher. Both groups received 1 000 milligrams Vitamin C daily during the initial three day treatment of the acute phase Influenza Type Syndromes. Thereafter each participant received 100 milligrams Vitamin C daily for 120 days (that is approximately twice the RDA for adults). Four booster doses (placebo or medicated treatment) according to the dispenser’s prescription were also given to each participant at monthly intervals, aiming to discern whether or not Homoeopathic Oscillococcinum could aid in preventing recurrences of Influenza Type Syndromes.
3.3.3 MEANS OF OBTAINING THE DATA

A case history format (Appendix A) was taken during the initial consultation. Secondly, Section A of the questionnaire was completed by the patient on DAY 1 as well as on the termination of the initial treatment (DAY 3). Likewise, Section B (Appendix B) was completed by the researcher. The questionnaire (Appendix B) was based on a rating scale, with numerical correspondence with the degree of intensity of the symptoms and signs.

i.e. Severe 1
     Moderate 2
     Mild 3
     None 4

The lower the score, the more severe the signs and symptoms and vice versa. The Likert Scale was used to assess this data. Furthermore the Oral Temperature Chart (Appendix C) was completed during the first three days of treatment to record the changes in the participant’s fever during that time.

3.3.4 TREATMENT OF THE DATA

Data which did not meet the requirements listed in Criteria for Admissibility of the Data was rejected from the study. The Wilcoxon’s Signed Rank Test was used to assess the results within each group of fifteen, to determine whether or not they were statistically different. This statistical inferential test is therefore utilised to test whether both (or any one of) the placebo and treatment groups showed statistically significant improvement (Steyn et al., 1994).
The data obtained from the comparison of the two samples, the one being the treatment group and the other the placebo group, was processed by means of the Mann-Whitney U-Test. This non parametric test assesses data between the two groups to determine if they are statistically different. This is done by testing whether the median of the treatment group was statistically less than that of the placebo group.

Demographical pie charts were then drawn up to aid in the analysis of the results. All this was done with the necessary guidance of the statistician.
CHAPTER FOUR

4 INTRODUCTION

In this chapter all the results are given in the form of processed data and demographical information of the research participants displayed graphically. In the chapter, "p" stands for upper probability points; \( n \) represents the median value of a sample group.

4.2 INTRA GROUP COMPARISONS

The Wilcoxon's Signed Rank Test was used to test whether there was a statistically significant improvement in each of the two groups.

a) The comparison of the initial and subsequent Sections A (Appendix B) as rated by each research participant in the treatment group yielded the following:

\[ p = 0.000\,590\,099 \]

Since \( p = (0.000590\,099/2) < 0.05 \), the null hypothesis is rejected at a 5% level of significance. There was therefore significant improvement.

b) The comparison of the initial and subsequent Sections A (Appendix B) as rated by each research participant in the placebo group yielded the following:-
p = 0.007 630 480

Since \( p = (0.007 630 48/2) < 0.05 \), the null hypothesis is rejected at a 5% level of significance. There was therefore a statistically significant improvement.

d)  The comparison of the initial and subsequent Sections B (Appendix B) of the placebo group, as rated by the researcher, yielded the following:

\[ p = 0.051 645 900 \]

Since \( p = (0.051 645 900/2) \leq 0.05 \), the null hypothesis is accepted at a 5% level of significance.

4.3 INTER GROUP COMPARISONS

The test procedure used is the Mann-Whitney's U-Test to determine whether the treatment group recuperated better than the placebo group.

a)  The comparison of Sections A (Appendix B) of the treatment and placebo groups, as rated by the participant on Day 1 of treatment, yielded:

\[ p = 0.884 172 \]

Since \( p = (0.884 172/2) > 0.05 \), the null hypothesis is accepted at a 5% level of significance. This implies that there is not a statistical significant difference in the mean values of the two sample groups.
b) The comparison of Sections A (Appendix B) of the treatment and placebo groups, as rated by the participant, on Day 3 of treatment, yielded:

\[ p = 0.002\ 091\ 670 \]

Since \( p = (0.002\ 091\ 670/2) < 0.05 \), the null hypothesis is rejected at a 5% level of significance. This implies that there is a statistical significant difference in the mean values of the two sample groups. Here the median value of the treatment group is 51, whereas the median value of the placebo group is 42. These values are Likert Scale Ratings as described in 3.3.3 of Chapter Three.

c) The comparison of Sections B (Appendix B) of the treatment and placebo groups, as rated by the researcher on Day 1 of the initial treatment period, yielded the following:

\[ p = 0.554\ 308 \]

Since \( p = (0.554\ 308/2) > 0.05 \), the null hypothesis is accepted at a 5% level of significance. This implies that there is not a statistical significant difference in the mean values of the two sample groups.

d) The comparison of Sections B (Appendix B) of the treatment and placebo groups, as rated by the researcher on Day 3 of the initial treatment period, yielded the following:

\[ p = 0.000\ 773\ 200 \]
Since \( p = (0.000 \ 773 \ 200/2) < 0.05 \), the null hypothesis is rejected at a 5% level of significance. This implies that there is a statistical significant difference in the mean values of the two sample groups. Here the median value of the treatment group is 23, whereas the median value of the placebo group is 16. (These values are Likert Scale Ratings as described in 3.3.3 of Chapter Three).

4.4 ORAL TEMPERATURE COMPARISONS

Here follows the comparisons of the Oral Temperature Readings between the treatment and placebo groups. As these are the comparisons between the two sample groups, we once again use the Mann-Whitney’s U-Test as it is the appropriate test procedure to process the raw data.

a) The comparison of the Oral Temperature Readings (Appendix C) of the treatment and placebo groups, taken on Day 1 by the researcher, yielded the following:

\[ p = 0.002 \ 091 \ 690/2 < 0.05 \], the null hypothesis is rejected at a 5% level of significance. This implies that there is a statistical significant difference in the mean values of the two sample groups.

b) The comparison of the Oral Temperature Readings (Appendix C) of the treatment and placebo groups, taken on Day 3 by the researcher, yielded the following:

\[ p = 0.000 \ 069 \ 266 \ 4 \]
Since $p = (0.000 069 266 4/2) < 0.05$, the null hypothesis is rejected at a 5% level of significance. This implies that there is a statistical significant difference in the mean values of the two sample groups.

Furthermore, the average rank of the treatment group = 9.1 based on 15 values; and the average rank of the placebo group = 21.9 based on 15 values.

Since $n_t < n_p$

i.e. 9.1 < 21.9, the median temperature in the treatment groups is lower than that in the placebo group.

4.5 **TABLE 4 - 1** Demographical information of the participants

<table>
<thead>
<tr>
<th>Group / Gender</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment:</td>
<td>8</td>
<td>7</td>
<td>15</td>
</tr>
<tr>
<td>Placebo:</td>
<td>6</td>
<td>9</td>
<td>15</td>
</tr>
<tr>
<td>Total:</td>
<td>14</td>
<td>16</td>
<td>30</td>
</tr>
</tbody>
</table>

This table shows the demographical display of male and female participants who either received medicated treatment or placebo.
4.6 CHART 4 - 1 Demographical Sexual Ratio

Female 53.3%
Male 46.7%

This pie chart illustrates the sexual ratio of the participants in this study.

4.7 CHART 4 - 2 Demographical Racial Distribution

Indian 16.8%
Black 6.7%
Causacian 76.4%

This pie chart illustrates the racial distribution of the participants in the study.
4.8 CHART 4 - 3 Demographical Age Distribution

This pie chart illustrates the age distribution of the participants in this study.

4.9 TABLE 4 - 2 Treatment Group's Descriptive Statistics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Temperature 1</th>
<th>Temperature 2</th>
<th>Temperature 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Size</td>
<td>15 readings</td>
<td>15 readings</td>
<td>15 readings</td>
</tr>
<tr>
<td>Average</td>
<td>37.986667°C</td>
<td>37.113333°C</td>
<td>36.86°C</td>
</tr>
<tr>
<td>Median</td>
<td>37.9°C</td>
<td>37.1°C</td>
<td>37.0°C</td>
</tr>
<tr>
<td>Mode</td>
<td>37.9°C</td>
<td>37.1°C</td>
<td>37.1°C</td>
</tr>
<tr>
<td>Variance</td>
<td>0.064995°C</td>
<td>0.055524°C</td>
<td>0.069714°C</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>0.25317°C</td>
<td>0.235635°C</td>
<td>0.264035°C</td>
</tr>
<tr>
<td>Minimum</td>
<td>37.5°C</td>
<td>36.7°C</td>
<td>36.4°C</td>
</tr>
<tr>
<td>Maximum</td>
<td>38.4°C</td>
<td>37.6°C</td>
<td>37.2°C</td>
</tr>
<tr>
<td>Range</td>
<td>0.9°C</td>
<td>0.9°C</td>
<td>0.8°C</td>
</tr>
</tbody>
</table>

TABLE 2 represents the descriptive statistics of the temperature readings taken of the patients in the treatment group.
### TABLE 4-3  
**Placebo Group's Descriptive Statistics**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Temperature 1</th>
<th>Temperature 2</th>
<th>Temperature 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample size</td>
<td>15 readings</td>
<td>15 readings</td>
<td>15 readings</td>
</tr>
<tr>
<td>Average</td>
<td>38.053333°C</td>
<td>37.893333°C</td>
<td>37.06°C</td>
</tr>
<tr>
<td>Median</td>
<td>38.0°C</td>
<td>37.9°C</td>
<td>36.9°C</td>
</tr>
<tr>
<td>Mode</td>
<td>37.9°C</td>
<td>37.9°C</td>
<td>36.9°C</td>
</tr>
<tr>
<td>Variance</td>
<td>0.066952°C</td>
<td>0.143524°C</td>
<td>0.275429°C</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>0.258752°C</td>
<td>0.378845°C</td>
<td>0.524813°C</td>
</tr>
<tr>
<td>Minimum temp.</td>
<td>37.6°C</td>
<td>36.8°C</td>
<td>36.3°C</td>
</tr>
<tr>
<td>Maximum temp.</td>
<td>38.5°C</td>
<td>38.4°C</td>
<td>38.1°C</td>
</tr>
<tr>
<td>Range</td>
<td>0.9°C</td>
<td>1.6°C</td>
<td>1.8°C</td>
</tr>
</tbody>
</table>

TABLE 3 represents the descriptive statistics of the temperature readings taken of the patients in the placebo group.
CHAPTER FIVE

5 THE DISCUSSION

5.1 INTRODUCTION

In Chapter Four all the results were presented in accordance with the statistical methods which had been applied. In this chapter we deal with the interpretation and evaluation of this data. We will also discuss and assess the facts surrounding the data.

5.2 DISCUSSION

From the intra group comparisons of Section A of the questionnaire (Appendix B) it became evident that over the initial three day treatment period both the treatment group and the placebo group had an improvement which is shown statistically in 4.2 (a) and 4.2 (b) of Chapter Four. The null hypothesis was thus rejected in both these instances, implying an initial recuperation of all patients. After statistical analysis it was found that the "p-value" of the treatment group comparison was smaller than that of the placebo group signifying that the recuperation of the patients in the treatment group had a higher significance (Steyn et al., 1994). It is important to reiterate the fact that Section A (Appendix B) was an evaluation of the patient's symptom picture and was therefore rated by the participant himself.

As both groups felt better after three days of treatment it can be interpreted that the first hypothesis does not comply with these findings and should therefore be rejected. However, it should also be noted that both groups received 1000 milligrams Vitamin C during this time. We can thus argue that
it could have been the three large doses of Vitamin C which made the research patients feel better, and remembering that the improvement of the treatment group was of higher significance (as the "p-value" was smaller than that of the placebo group) it draws us to the third hypothesis. In this hypothesis it was stated that the Homoeopathic treatment of Influenza Type Syndromes would be more effective than treatment with placebo. This section of the hypothesis can thus be accepted as the improvement in the treatment group is statistically more significant than the improvement in the placebo group.

The intra group comparison of Section B of the questionnaire (Appendix B), as illustrated in 4.2 (c) and 4.2 (d) of Chapter Four, showed that over the initial three day treatment period the group had an improvement unlike the placebo group which did not show an improvement. Section B (Appendix B) was an evaluation of the presenting signs of the patient's clinical picture which required a clinical examination by the researcher each time. Section B (Appendix B) therefore represented an objective evaluation of the patient's Influenza Type Syndrome as opposed to the subjective evaluation portrayed in Section A (Appendix B). This indicates that the Homoeopathic treatment with Oscillococcinum thus had an effect on the initial three day treatment period of Influenza Type Syndromes. In the hypothesis it was stated that Homoeopathic Oscillococcinum would improve the clinical manifestations which the treatment group's patients had presented with at the outset of this study. As this is evident in the statistical analysis, this part of the hypothesis can be accepted.

From the inter group comparison of Section A and Section B of the questionnaire (Appendix B) as rated on Day 3 and shown in 4.3 of Chapter Four, it is evident that there was a statistically significant improvement between the two groups. The ratings done on Day 3 of the initial three day treatment period are the results we need to look at in order to discern whether or not there was an improvement in the clinical picture of the research patients. The inter group comparison of Section A and Section B of the questionnaire (Appendix B), as rated on Day 1 and shown in 4.3 (a) and 4.3 (c), are thus of
no value in this assessment and will therefore not be discussed. According to the Likert Scale Rating the higher the score obtained in the questionnaire, the greater the improvement in the health of the patient. This implies that, with reference to Section A rated on Day 3 of treatment, the median value of the treatment group was 51 and that of the placebo group was 42, showing there was a greater improvement in the treatment group. Likewise, with reference to Section B as rated on Day 3 of treatment, the median value of the treatment group was 23 and that of the placebo group was 16, illustrating once again that there was a greater improvement in the treatment group. It is thus further statistical confirmation whereby we accept that part of the hypothesis which stated that Homoeopathic Oscillococcinum would improve the treatment group's patient's clinical manifestations, which had presented at the outset of this study.

In 4.4 of Chapter Four we discussed measurement data, that being measured by using some kind of device (in this case the device was an oral thermometer). From the inter group comparison of the Oral Temperature Readings (Appendix C) of the treatment and placebo groups, taken on Day 3 by researcher, it is evident that there was a statistically significant difference in the improvement between the two groups. Furthermore is shown that the median temperature in the treatment group was less than that in the placebo group. This demonstrates the fact that after three days of taking Homoeopathic Oscillococcinum the treatment groups patients experienced a faster termination of their fever, as opposed to the persisting fever that the patients in the placebo group experienced during the initial three days treatment period.

Table 4 - 1 in Chapter Four shows the near 1:1 ratio of male to female participants who either received medicated treatment or placebo. Chart 4 - 1 is a graphical display of the same ratio. This is part of the demographical information gathered from this study. When viewing Chart 4 - 2 and Chart 4 - 3, it is interesting to note that the largest percentage of research participants were adult Caucasians. I would therefore speculate that his was due to the fact that advertisements were place
in the local English newspaper and therefore it would be anticipated that they would be the target
group most likely to respond. It might be possible that this group of the population are those most
informed about alternative health care in South Africa. All the research patients were local residents
of the Durban area implying that there was not a variance in the climate which the research patients
were exposed to.

The 120 day follow-up treatment period, that followed the initial three day treatment period of
Influenza Type Syndromes, was not statistically processed as it constituted a Symptoms Diary
(Appendix D) kept by each patient on a daily basis. There was thus no means of standardising the
findings in a mathematically correct manner. It was however interesting to note that during mid-July
the Influenza Type Syndromes reached "epidemic" proportions. The headlines of the Daily News of
Wednesday, July 19, 1995 read: "Warning on 'killer' flue". This was verified by the increased
number of symptoms recorded by the patients in their symptoms diaries during that time.

In hindsight another point of interest should be noted that could possibly have contributed to the vast
number of influenza cases this year: that being the influx of international travellers to the city of
Durban due to the fact that part of the World Cup Rugby Series was held there. A report on disease
outbreaks, which appeared in the Natal Mercury of October 16, 1995, stated that increases in travel
and international travel as well as lifestyle changes such as overcrowding in cities were contributing
factors to increased disease outbreaks.

Despite the above mentioned factors which impacted on the 120 day follow-up period, which had
been aimed at determining the efficacy of Homoeopathic Oscillococcinum in preventing recurring
Influenza Type Syndromes, it became evident that the patients of the treatment group experienced
better health than those of the placebo group. In the treatment group of 15 patients, eight
experienced a symptom free period of 12 - 18 days after every booster dose of Homoeopathic
Oscillococcinum; two experienced an 8 - 10 day symptom free period and as for the remaining five patients no pattern could be established.

In the placebo group of 15 patients, the symptom diaries (Appendix D) did not display a definite symptom free period following the administration of a booster dose (unmedicated). The symptoms noted appeared to be irregular in frequency. Thus by having monitored the patients for a 120 days following the initial three day treatment period, the patency of Homoeopathic Oscillococcinum both curatively and preventatively has become evident. This is further confirmation of the efficacy of Homoeopathy in the treatment of Influenza Type Syndromes.

5.3 CONCLUSION

These results have shown that significant statistical differences were found pertaining to the efficacy of Homoeopathic Oscillococcinum versus placebo in treating Influenza Type Syndromes. Furthermore, the visual survey of the patient’s symptoms diary (Appendix D) showed a difference in the two sample groups: that being the evident temporary preventative action of Homoeopathic Oscillococcinum following each booster dose, whereas no marked difference was seen in the placebo group.
CHAPTER SIX

6 CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

In Chapter Five a discussion of the results and interpretation of the data was evaluated. In Chapter Six there will be a conclusion and recommendation for further research.

Through this study it can be shown that Homoeopathic Oscilloccinum is indeed valuable in the treatment of and temporary prevention of Influenza Type Syndromes. In this case however, Homoeopathic Oscilloccinum was administered in a 200 Korsakovian potency; this leaves scope for further research into different potencies and especially Hahnemannian centissimal potencies. The fact that the two sample groups were residents of the Durban area ensured that vast climatic variations did not modify the findings of this study. The 120 day data capturing period for each patient was very successful in illustration the hypothesised curative as well as preventative scope of Homoeopathic Oscilloccinum.

With the results obtained, this study has established that Homoeopathic Oscilloccinum is beneficial in treating Influenza Type Syndromes.
6.2 RECOMMENDATIONS

In the proposal for this study, Homoeopathic Oscillococcinum was chosen for its anti-viral properties, but in hindsight, it could be recommended that the drug of choice for an epidemic (as was experienced in Durban during the winter of 1995) be incorporated into any proposal for further study on Homoeopathic treatment of Influenza Type Syndromes. The reason for this recommendation being that there was a tendency evident in the Case History Format (Appendix A) of most patients to display specific symptoms of Gelsemium sempervirens as portrayed in the Materia Medica (Jouanny 1984): 157 - 159)

It would also be beneficial to use larger sample groups. Another sample group could also be introduced if the candidate population was large enough. This sample group could then be trialed with a different potency of Homoeopathic Oscillococcinum in order to compare it with Homoeopathic Oscillococcinum 200K.

There is thus room for improvement in this study area. It is also an important area as Influenza Type Syndromes and recurrences thereof impacts on the patient’s quality of life.
LITERATURE REFERENCES


APPENDIX A

CASE HISTORY FORMAT
APPENDIX A

CASE HISTORY FORMAT

Date : ____________________________
Name : __________________________
Address : ________________________
Telephone : _____________________
Date of Birth : __________________
Place of Birth : __________________
Occupation : ____________________
Medical Aid : ____________________ No. : __________________

A. MEDICAL HISTORY

1. Childhood Illnesses

________________________________________________________________________

2. Adult Illnesses

________________________________________________________________________

3. Accidents and Injuries

________________________________________________________________________

4. Past Operations

________________________________________________________________________

5. Other Hospitalisation

________________________________________________________________________

6. Allergies

________________________________________________________________________
7 Immunisation

8 Smoking

9 Current Medications

B FAMILY HISTORY

Cancer : ________________________________
Alcoholism : __________________________
Angina : ______________________________
Arthritis : _____________________________
Diabetes : _____________________________
Drug Addition : ________________________
Epilepsy : _____________________________
Headache : ____________________________
Kidneys/Heart/Thyroid : ________________

C SOCIAL HISTORY

1 Exercise/Leisure Activities

2 Recent Travel
D  MAIN COMPLAINT

c/o: ________________________________

HMC: ________________________________

E.  SYSTEMS HISTORY

1  Generally (weight gain; energy levels; fever)

2  Integument (itching; discoloration; changes in hair or nails)
   Skin: ________________________________
   Hair: ________________________________
   Nails: ________________________________

3  Head (headache; vertigo; head injuries)

4  Eyes (vision; pain; tearing; redness; double vision; cataracts)

5  ENT
   (i) Ears (hearing; tinnitus; earache; discharge)
   (ii) Nose and Sinuses (discharge; hayfever; sneezing; burning; blocked)
   (iii) Mouth and Throat (bleeding gums; ulcers; taste; dryness; voice changes)
6 GIT (dysphagia; heartburn; abdominal pain; appetite; thirst; cravings; aversions; nausea; vomiting; distension; bowel movements)

7 Respiratory (coughed; sputum; chest pain; S O B; asthma; bronchitis; wheezing)

8 CVS (palpitations; oedema; claudication; varicose veins)

9 Genitourinary (pain on urination; frequency; colour; smell; force of stream; sexual problems; menstruation; discharge; leucorrhea)

10 Locomotor (pain in muscle; joint stiffness; cramps; backache)

11 Neurological (fainting; seizures; weakness; paralysis; numbness; tingling; tremor)

12 Haematological (bruising/bleeding)

13 Endocrine (sweating; intolerance to temperature change)

14 Quality of Sleep (lack of; interruption)
Psychological (mood; fears; ambitions; <>)

\[F\] PHYSICAL EXAMINATION

<table>
<thead>
<tr>
<th>Vital Signs</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>- T</td>
<td>:</td>
</tr>
<tr>
<td>- Height</td>
<td>:</td>
</tr>
<tr>
<td>- Weight</td>
<td>:</td>
</tr>
<tr>
<td>- Pulse Rate</td>
<td>:</td>
</tr>
<tr>
<td>- Respiratory</td>
<td>:</td>
</tr>
<tr>
<td>- Blood Pressure</td>
<td>:</td>
</tr>
</tbody>
</table>

Examination of related systems
APPENDIX B

QUESTIONNAIRE OF
CLINICAL SYMPTOMS AND SIGNS
APPENDIX B

NAME: __________________________________________

QUESTIONNAIRE

Ratings
- Severe 1
- Moderate 2
- Mild 3
- None 4

In the following questions mark the appropriate description.

SECTION A

A SYMPTOMS - Rated by the patient
Rate the severity of the following symptoms as they present now:

1 Systemic Affections

<table>
<thead>
<tr>
<th></th>
<th>Severe</th>
<th>Moderate</th>
<th>Mild</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chills</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myalgia (muscular pain)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malaise (vague discomfort)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
2  *Respiratory Affections*

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Severe</th>
<th>Moderate</th>
<th>Mild</th>
<th>None</th>
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3  *Other Affections*

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**SECTION B**

B  PHYSICAL FINDINGS - Rated by the researcher

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<td>Cervical Adenopathy</td>
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APPENDIX C

ORAL TEMPERATURE CHART
NAME: ____________________________________________

CHART OF ORAL TEMPERATURE MEASUREMENTS

Each patient is to take his/her oral temperature on day two and three of the three day treatment period, in the late afternoon (Chaney et al., 1977 and Meyer et al., 1988)

DAY 1: ________________________________

DAY 2: ________________________________

DAY 3: ________________________________

Instructions to patients concerning measuring procedure: According to Bates, 1991

1. Shake the glass thermometer down to below 35.5 degrees Celsius
2. Insert it under the tongue, and close both lips.
3. Wait 3 to 5 minutes
4. Then read the thermometer.
5. Reinsert it for a minute and read again. If the temperature is still rising, repeat this procedure until the reading remains stable.
APPENDIX D

PATIENT’S SYMPTOMS DIARY