Follow-up Study of the Dietary Intake, Anthropometric Measurements, and Blood Pressure in Children Born to Women in the Manawatu Pregnancy Study.

A Thesis Presented in Partial Fulfillment of the Requirements for the Degree of Master of Science in Nutritional Science at Massey University

ENTESAR AL-SHAMI

2001

PART I: ETHICS IN HUMAN RESEARCH

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GENERAL INTRODUCTION

When the proposal of the pilot study presented in this thesis was finally formulated, one of the first and important requirements was to obtain approval from accredited ethics committees. This proved to be a long and demanding process, but at the same time an interesting and useful experience. It was also somehow different from what was previously experienced in Kuwait, the researcher's home country. That was how the idea of presenting this thesis in two parts came into being.

In the first part, the development of ethics codes and ethics committees was reviewed, a comparison of the process to obtain an ethical approval in New Zealand and in Kuwait was made, and the proposals presented to Massey University Human Ethics Committee (MUHEC) and to Manawatu-Whanganui Committee (MWEC) were outlined.

Bioethics is a young discipline; the term "medical ethics" was first used at the beginning of the 19th century. However, codes of ethics of human research were only introduced towards the end of the first half of the 20th century. Hectic debates over these codes took place during the second half of the 20th century. On one side, there were growing concerns for the rights and safety of research participants, physically, psychologically and culturally, and on the other there were fears that scientific merits and benefits might be eroded by the limitations that research bioethics may enforce. These debates have

resulted in amendments and changes in ethics codes, changes that probably will continue to develop during the 21st century.

One of the difficult issues raised was research with children and other vulnerable groups. Biomedical research is an important and sociably desirable undertaking; most of the research that involves children cannot be performed on adults, yet research with children must proceed only when the rights and welfare of the participants are carefully observed, including their participation in the decision to take part when they are able to.

In the Pilot Study, which comprises the second part of this thesis, thirty mothers and their children were investigated. All participants were residents of Palmerston North City. The mothers participating in this Pilot Study had earlier been participants in a study that took place in the Manawatu area in the early nineties and which was completed in 1996. The children were those with whom the mothers were pregnant at the time of the earlier study. The Pilot Study was considered to be a follow-up upon that earlier study.

The Pilot Study aimed at investigating the relationship of atopic diseases, particularly bronchial asthma and early childhood diet and growth. The prevalence and severity of asthma has been increasing over the past few decades, particularly in urban industrialized areas. This increase is thought to be due to changing environmental factors. Smoking, particularly maternal smoking, and pollution are thought to be major contributing factors. Nutritional and dietary factors have lately received greater attention. Certain foods may

provoke asthma due to their "allergenic" properties; however, dietary deficiency of certain nutrients, specifically antioxidants, is thought to play an important role in the pathogenesis of asthma. This hypothesis was investigated in the Pilot Study.

The factors that may influence blood pressure in children were also investigated. Although the prevalence of hypertension is far lower in children than in adults, essential hypertension appears to have its onset during the first two decades of life. The identification of an at-risk-population before they develop hypertension may have profound benefits, since even small decrements in blood pressure may have substantial effects on hypertension-related morbidity and mortality. Birth weight has been linked to the development of hypertension; defining both systolic and diastolic blood pressure of the participant children and relating them to birthweight was an important part of the study.

Familial factors are recognized to influence not only the development of hypertension but also the level of blood pressure in an individual; maternal blood pressure in particular is thought to be closely related to that of her offspring. This relationship between maternal blood pressure and that of her child was also investigated.

The importance of defining these relationships is to identify children who are at risk for developing hypertension in their early life and thus planning intervention and follow-up strategies before the onset of the disease.

PART I: ETHICS IN HUMAN RESEARCH

1.0 Objectives

- To briefly outline the development of codes of ethics for human research from a historical perspective.

- To compare the approach of New Zealand and Kuwait institutions to ethics in human research.

- To develop a research proposal that meets the requirements of the Massey University and Manawatu-Whanganui ethics committees.

2.0 The Development of Codes of Ethics for Human Research

Research is the tool by which medical progress and improvement of the health of population are achieved. The basic principles of research are honesty, meticulousness and objective interpretation of the data (1).

Ethical issues arise when the conduct of research involves the interests and rights of others. People, who act, as 'participants' in medical or scientific research, regardless of the long-term prospects of the research, may be subjected to immediate or impending threats to safety, comfort, or convenience (2).

Social research involving interviewing or observation, especially where records are kept, may impinge on the confidentiality, privacy, convenience, comfort or safety of others.

While issues of safety, confidentiality, right of the subjects to refrain from participation or withdraw at any time remain fundamental, emerging issues of cultural sensitivities, gender and socioeconomic differences are acquiring importance as ethical issues to be observed when planning to perform a research.

2.1 Historical Context

The development of codes of ethical principles related to research involving humans is a relatively recent phenomenon. In decades to come, historians may argue that the most notable achievements in medical research in the closing years of the last millennium lay not just in improvements in, say, prophylaxis or therapy, but also in the increasing recognition and application of the ethical principles that underpin such endeavors (3).

In ancient times during the Greek, Roman and Egyptian civilizations, the concept of informed consent to medical treatment or experimentation was not known. However, it can be argued that one of the major 'current' ethical concepts was included in the Hippocratic corpus, "do no harm". This injunction might have been in reaction to tendencies to subject patients to treatments when there was no chance of recovering.

In those early days Eastern and Western cultures shared similar ethical precepts, contrary to the modern view that medical ethics is culture-specific (4). With time social trends changed and mankind as a whole became more focused on his rights, the concept of consent, one of the major elements of modern ethics, became

increasingly fundamental in the relationship between physician and patient and between researcher and participant.

One of the earliest examples of the growing emphasis on the right to self-determination in modern history was in the eighteenth century in England when a man brought a lawsuit against two doctors who experimented while treating his fractured leg with unsuccessful results. The man sued the physicians for malpractice; not only for using an investigational device, but for doing so without his consent (5).

The term "medical ethics" was introduced in 1803 by Thomas Percival, a British physician, Percival wrote mainly about decorum but discussed the conduct of physicians in the broad context of the whole society (4).

In the United States, at the beginning of the twentieth century, a landmark case was tried before Justice Benjamin Cardozo. In this case, a woman had consented to an abdominal examination under anesthesia, but had not consented to any operation. In spite of this, doctor removed a tumor and the patient sued. Justice Cardozo's opinion expressed what has become one of the basic elements in the whole concept of informed consent development, that an individual has the right of bodily self-determination (5).

One of the earliest contributions to modern medical ethics was that of Richard Cabot (1868-1939), an American physician who helped to establish the discipline of medical social work and whose major contribution to ethics was the recognition that

the physician's moral duty was to master scientific medicine and to apply this knowledge to the care of patients (4).

Despite the expression of these important principles in the early part of the twentieth century, abuses of human research participants continued to occur. The most horrendous were the experiments conducted by Nazi doctors in Germany on concentration camp prisoners during the Second World War.

2.1.1 The Nuremberg Code

During the 1947 trial of 23 Nazi doctors who performed the experiments in Germany, the Nuremberg Code came into being (6). This document, developed by the presiding judges at that trial, contained ten basic principles to safeguard the fundamental dignity of subjects involved in research. These principles included the concepts that voluntary consent to participate in research by a legally competent individual is essential, that the research itself should be conducted by competent investigators with skill and care, and that the benefits to the participant should exceed the risks (7).

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Despite the emergence of these codes, incidents of unethical practice continued to occur in health research. This fact prompted the emergence of a number of other codes developed over the years, the most important of which is probably the Declaration of Helsinki.

2.1.2 The Declaration of Helsinki

In 1964 the 18th World Medical Association (WMA) General Assembly in Helsinki, Finland adopted a number of ethical principles for medical research involving human subjects, this became known as the Declaration of Helsinki. This declaration provided a global document that bound physicians to the principles of the Nuremberg Code, which acknowledged that people who participate in clinical trials have basic rights that must be respected (8).

The WMA in its Declaration stressed that the standards drafted were to guide physicians all over the world, and that did not relieve doctors from criminal, civil and ethical responsibilities under the laws of their own countries. The Declaration was backed by several other documents, notably guidance from the Council for International Organizations of Medical Sciences (9).

2.2 Development of Ethical Principles in Research in Various Countries

2.2.1 Statement on Human Experimentation in Australia

The Statement on Human Experimentation was published by the Australian National Health and Medical Research Council (NHMRC) in 1966. The Statement was a set of applied ethical standards about medical research involving human subjects; it closely followed the Declaration of Helsinki (ratified by Australia in 1964).

Supplementary Notes were developed providing guidance on ethical issues in relation to distinct kinds of research or categories of research subjects and participants.

The original Statement on Human Experimentation has undergone several revisions in the light of international ethical and scientific developments. During 1996-98 the Australian Research Council (ARC) also endorsed a code of ethics for human research, parts of which have been incorporated into the present document.

A review of the Statement on Human Experimentation and Supplementary Notes (1992) was recommended and has been conducted. A National Statement on Ethical Conduct in Research Involving Humans was the outcome of that review and the deliberations of the Working Party (10).

2.2.2 Belmont Report in the United States

Even in countries like the United States, a number of violations of research ethics occurred during and after the Second World War. These violations included injecting hospital patients with radioactive substances to learn the effects on the body.

In another major example, the Tuskegee Institute conducted a 40-year study on black men with syphilis during which treatment was withheld (5). The study was not stopped until 1972, when a non-medical assistant leaked the details of the experiment to a reporter from the Associated Press. The subsequent Senate hearing resulted in the National Research Act, 1974, which contained specific provision for institutional review boards', i.e. ethical committees (11).

The Department of Health, Education and Welfare constructed regulations for the protection of human research participants. The Act established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

In 1979 the Commission issued the Belmont Report. This report identified three basic ethical principles. The first was respect for persons. Individuals should be treated as autonomous agents and persons with diminished autonomy were entitled to protection. The second was beneficence, maximizing possible benefits and minimizing possible harms. The third principle was justice, addressing the resolution of the question: who ought to receive the benefits of the research and bear its burdens. The report gave an introductory discussion of the boundaries between medical practice and research (12).

In July 1981 the regulations governing the requirements for informed consent became effective. The regulations instructed researchers of the general requirements for informed consent, as well as the basic elements the consent forms must contain. These consent forms, along with the research plans and protocols were to be reviewed by committees called Institutional Review Boards. These Boards were charged with the obligation to protect human participants involved in biomedical research.

2.2.3 Royal College of Physicians Guidelines in the United Kingdom

The Royal College of Physicians of London published its report Research on Healthy Volunteers, in 1986 where the healthy volunteer was described and the possible risks and the safeguards required for the subject and investigator were outlined. In 1990 the College published its document 'Research involving Patients'; the publication considered the patient who willingly participates in research to have the status of a volunteer.

However, a balance should be struck between the benefits, which may flow from properly conducted research on the one hand, and the risk of infringing the autonomy, of or causing harm to the individual patient on the other. Concerning children the College stated that as a vulnerable population group children needed added protection, especially regarding risk/benefit assessment and consent (13,14).

2.2.4 Health Research Council Act in New Zealand

In New Zealand in 1990, a Health Research Council (HRC) Act established the Health Research Council Ethics Committee (HRCEC). The Act probably was influenced by an outraged nation following the public exposure in the mid-'80s of a 22-year secret research program which was later identified as "The Unfortunate Experiment," in which women diagnosed with precancerous cervical lesions were intentionally left untreated by a senior specialist at Auckland's National Women's Hospital. The national screening program for cervical cancer followed the inquiry into this incident in 1991.

The functions of HRCEC was to consider and make recommendations to the Council on ethical issues in relation to health research, especially those emerging through the development of new areas of health research. To provide and review ethical guidelines for the Council, to make an independent ethical assessment of proposals of health research and to give, in relation to ethics committees established by other bodies, advice on the membership of those committees, the procedures to be adopted, and the standards to be observed, by those committees and to provide independent comment on ethical problems that may arise in any aspect of health research (15).

The Committee required the applicants to consult the Declaration of Helsinki as revised in 1989 by the World Medical Association, as a general statement of the principles applying to medical research on human subjects and to also consult the detailed interpretation of these principles as set down in the guidelines of the Council for International Organisations of Medical Sciences 1993.

A review of the national ethical review system in 1993 resulted in structural changes to the national system for ethical review. A National Advisory Committee on Health and Disability Service Ethics (NACHDSE) was established in July 1994 (NACHDSE was disestablished in 1999). The areas of operational responsibility of the NACHDSE included development of health and disability ethics guidelines, treatment ethics guidelines, sharing in revision of the standards that guide Ethics Committees, and development of standard national ethical approval systems (15).

2.3 Amendments to the Declaration of Helsinki

While the Nuremberg Code has remained unmodified for the past half-century, the Declaration of Helsinki has been amended several times. The principles, which were developed and applied in the mid-1970 served well at the time, however, both long-term trends and recent changes have resulted in a clash of the various principles in research ethics. Most notable among these trends is the growth of research conducted by for-profit organizations and the emphasis on market principles. Efficiency in all aspects of the research is required by such organizations. The ethics committees of such organizations pay less careful ethical deliberation than would university-sponsored institutional review boards (16). Another trend is internationalization of research. In many countries of the world, ethical principles such as informed consent and distributive justice are largely ignored.

A revision of the Declaration of Helsinki was submitted in 1989 by the World Medical Associations to produce a general statement of the principles applying to medical research on human subjects. The Council for International Organisations of Medical Sciences (1993) made detailed interpretation of these principles.

The Declaration of Helsinki has ignited discussions since it was first adopted; these discussions were not put off by its further amendments. As an important example the United States Food and Drug Administration (FDA) have been critical of the declaration as they were trying to give scientists greater freedom than the declaration allows. The FDA mandates many human experiments as part of the approval process for new therapies, including placebo groups. The Declaration of Helsinki explicitly forbids the use of a placebo group if an accepted treatment exists (17).

On the other hand, there are arguments that the Declaration should be strengthened, that is advocating more precautionary measures to safeguard research participants; among these measures is: unequivocal declaration of placebo comparisons to be unethical; allowing no discretion to investigators; and emphasizing that while informed consent is essential, it is not in itself enough and other principles in the declaration must be applied; but probably most importantly, that ethical standards must be applied on global basis (17). However, justification of the use of control groups in clinical trials receives strong argument as being responsive to the participant right to self-determination and in consideration of efficiency (18).

The distinction in the Declaration between therapeutic and non-therapeutic research is thought to be a source of errors (18). Policy-making agencies in the United States and Canada rejected such distinction in the 1970s, instead the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research required that each component of a research protocol be evaluated separately (18).

Thus it seems inevitable that the current ethical principles must be subjected to review, a process that probably should continue as long as changes in the field of research take place.

2.4 Children and Research

Children are a uniquely vulnerable population; children cannot give fully informed consent, yet they stand to benefit from medical and behavioral research that often cannot be conducted with adults. Parental consent may or may not correspond to what the child would choose if he or she were able to evaluate the request for participation (19).

However, autonomy is the same for everybody. The claims of children and young people are not necessary inferior to those of adults simply because they have less experience. Children's autonomy should be valued separately from their rationality. Children often do not perceive that they have a choice and therefore their rational decision-making capacities may well be underused. If children are given choices, they will be more likely to use these capacities (20, 21).

2.5 Ethics Committees

A body independent of the research team is required to examine the research design and the system for protecting participants' interests with a view to adjudication on their ethical acceptability and their accountability. This body is termed the Ethics Committee.

It is generally understood that research involving human beings that has a potential for infringing basic ethical principles must be reviewed by a human research ethics committee (10).

Ethics committees are needed to maintain ethical standards by submitting human research to independent review, with the possibility of adding more safeguards concerning information to subjects, consent, confidentiality and the degree of risk; to allow some degree of interpreting ethical codes to permit research on groups for whom informed consent may not always be possible, and to provide interpretations of existing ethical codes to innovative situations (22).

The approval of the ethics committee(s) is needed for the following reasons:

- To protect the rights and welfare of human subjects from any physical and mental discomfort, harm and danger from research procedures and intrusion of privacy.
- To protect the rights of researcher to conduct legitimate investigation and to protect the reputation of the institution conducting and sponsoring the research.
- To minimize the potential for claims of negligence made against the researcher and the institution.
- Many funding bodies require ethical approval of a project before funds are released.
- Many journals require a letter of approval from an ethics committee as a precondition for publication (23).

The ethics committee when investigating the ethical conduct of a researcher should achieve a balance between the rights and needs of three parties- potential research participants, society, and the researchers.

Research ethics committees' members, researchers and the public can have different views. Such differences are potential sources of disagreement and misunderstanding.

Kent in his 1997 study "The views of members of Local Research Ethics Committees (LRECs), researchers and the public towards the roles and functions of LRECs" stated that general practice patients believe that the main function of LRECs is to ensure that research participants come to no harm. LREC members were more concerned with the protection of participants' rights. There was also some disagreement between members and researchers with regard to the consideration of proposals on the grounds of scientific merit. He concluded that LREC members need to be aware of potential differences in views, and that they ought to make their priorities clear, and that membership of an LREC should reflect the views of both researchers and participants, e.g. Manawatu/Whanganui HEC. (24).

In their comment on the system of institutional ethics committees (IECs) in Australia, Jamorzik *et. al.*, were of the opinion that IECs may be a cause of delay or even prevention of identification of avoidable threats to health originating either inside or outside the medical system. They presented a case study to prove that this system may impede the identification of suboptimal practice and waste in the healthcare system (25).

However, probably a majority of those who are involved in the research process have a positive attitude towards the work of ethics committees. In 1983 Allen and Waters showed a high level of agreement on the need for research ethics committees but also a feeling that there can be a room for improvement, particularly by training committee members (26).

3.0 A Comparison of the Approach in New Zealand and Kuwait Institutions to Ethics in Human Research

3.1 Application of Ethical Principles in New Zealand

As a general guide, research originating in a tertiary institution will be reviewed by an ethics committee of the institution, if that committee is accredited by the HRCEC to review HRC funding applications. If the committee is not accredited then the research proposal must be reviewed by another accredited committee. This may be an ethics committee of the relevant health authority. Research involving a health sector agency would be expected to obtain approval from a regional health ethics committee.

3.2 Application of Ethical Principles in Kuwait

The methods of implementation of ethical principles while conducting research are different in Kuwait. The concept of Ethics Committees that are responsible for approving and monitoring research projects is not yet well developed, although there are efforts now to apply Western-style committees for the benefit of research and to be responsible for ensuring the safety and rights of participants.

However, this is not to say that the ethical principles are not applied. The weight of observing the implementation of these principles falls on institutions through which the research is conducted, on funding authorities and on governmental agents and

particularly the Ministry of Health. Managerial decisions are needed for any research that involves human participants; these decisions in turn depend on discussions with the researcher, peer review, and consulting expert referees.

The major principles are closely observed; procedures of safety and methods of minimizing risk are of utmost importance. Participants must give an informed consent before their participation in research procedures; however, written consent is only required if the project involves invasive procedures or collection of information that is considered confidential in nature, including the information that is gathered in the context of doctor-patient relationship.

Kuwait University is one of the main agents through which research is conducted and funded. The Research Administration subjects all projects done through the University and/or funded by the University to standard review and evaluation procedures. The Research Administration maintains a well-developed system of research review, which includes a panel of referees and specialized committees, to ensure that the proposed research is scientifically sound, and would lead to the advancement of knowledge.

The Research Administration has developed a package 'Research Support Application Form & Instructions' for researchers, who have to specify and organize all relevant information necessary for the submission and approval of the research project.

While preparing the 'Research Support Application', the Principal Investigator must clearly state the project objectives, and the intended plan of research, to convince the technical reviewers and other readers about the significance of the research, including competence in pursuing the research. In addition, the researcher's ability in planning the research budget and resource requirements also enhances the project's chances of approval. The principles of the Helsinki Declaration are well observed during this process of scrutiny (27).

The Kuwait Foundation for the Advancement of Sciences (KFAS) is another major agency in Kuwait that sponsors and funds scientific research. It aims at supporting and promoting research in all disciplines through partnership with local and international scientific communities in the context of increased globalization and international co-operation for sustained development.

The Research Projects Directorate (RPD) is responsible for approving projects for research grant programs. The grant-award process commences from the time the researcher submits a proposal to KFAS through a Kuwaiti organization. The proposal should explain objectives, methodology, expected final output, amounts of funds required, references and include the investigators' *Curriculum Vitae*. The RPD conducts an initial review to ascertain whether the project conforms to the Foundation's mission and regulations. In human-related research adherence to ethical principles of research is ascertained. Specialized reviewers, in tandem with the RPD Advisory Committee, conduct a review. The peer reviewers are a group of leading professionals from within and outside the State of Kuwait.

The objective of the peer review process is to rate the scientific merit of the proposed research and to ascertain that other aspects, particularly the ethical issues conform to established standards. Following the issuance of a grant-award, RPD monitors the progress of the research project until the receipt of the final report (28).

Many of the health-related projects are conducted through local hospitals. Research conducted that way is submitted to peer review within the hospital. Many hospital departments have what is known as 'Research Committees'. The approval of such committees, Head of the Department and the Hospital Management are required for the research to proceed. Informed consent, benefits to participants and minimizing of risk are issues that must be presented to the satisfaction of the reviewers.

3.3 Differences in the Procedures of Granting an Ethical Approval Between New Zealand and Kuwait

Ethics Committees in New Zealand involve groups of individuals from diverse backgrounds. When applying for ethical approval in New Zealand, an official application has to be filed, deliberations by the Ethics Committee members follow, and a conference with the applicant(s) may be needed. Any amendments to the research protocol deemed necessary by the Committee are officially addressed to the applicant who should respond to the satisfaction of the Committee.

In Kuwait, a research project is either done through one of the institutes interested in sponsoring scientific research or in case of medical research, through one of the local hospitals or health agencies. When applying for sponsorship, an application

should be filed to the authority in question. Ethical issues are only part of such authority's concerns. For example, in the case of the KFAS, the researcher(s) must prove that the project would lead to the advancement of science and be of national interest; adherence to accepted ethical standards is required for approval of sponsorship. Failure to meet the standards would lead to rejection of sponsorship.

When the research is done through one of the local hospital or health agencies, ethical review is done by colleagues and/or health management personnel with legal advice provided by legal staff of the hospital concerned. Discussions are more informal and may take place in private offices or even in hospital corridors.

Ethical principles must be considered when applying for approval of research protocols in both countries. However, a greater emphasis on the rights and convenience of participants is observed in the case of New Zealand. At least this was the experience observed when carrying out this study. On the other hand, colleagues reviewing a research proposal can be very critical of the scientific merits and value of the research, a finding that is regularly experienced when attempting a research in Kuwait.

In summary, the major differences between ethical review in New Zealand and Kuwait are: the process is more formal in New Zealand. In New Zealand research there is greater emphasis on the research participants, while in Kuwait the emphasis is more on the expected benefits of the research.

4.0 Development of a Research Proposal to Ethics Committees in New Zealand

To perform the current research, approval was needed from both the Massey University Human Ethics Committee MUHEC and the Manawatu-Whanganui Ethics Committee MWEC; both committees are accredited with the HRCEC. Approval of the MUHEC was needed since the research was to be conducted through the University. The MWEC approval was considered essential as the project involved blood pressure measurement and hence the research was considered to be clinical in nature. The proposal submitted by the researcher to the Ethics Committees is included in Appendix One.

During discussions with the members of the MUHEC some cultural concerns were raised. As the principle researcher was Kuwaiti, the members of the MUHEC were worried that cultural misunderstandings might take place during the course of the research and particularly when interacting with the participants. Despite the fact that the researcher had been living in New Zealand and specifically in Palmerston North for more than 2 years prior to the start of the research which made her acquainted to the ways and habits of the New Zealand community and besides her good command of the English language; the members of the committee felt that steps should be taken to lessen any possible misunderstandings.

What was agreed upon during discussions was that the Research Student's Supervisor would first introduce the researcher in a letter of introduction, and a photograph of the researcher showing her in her head dress would be attached to the Information Sheet (the head dress is part of Moslem women's custom) and finally

that a New Zealand born assistant would accompany the researcher on all her home visits (Appendix One).

The assistant was a valuable asset and a great help in conducting the research being herself a capable and charming lady. However, not on a single occasion was any ethnic tension or cultural misunderstanding felt. On the contrary many of the ladies participating in the study had read about Kuwait before the visit, and this was often a good start to the procedures involved in the study.

It was fortunate that none of the fears of the committee were realized, however, the wisdom of the committee in advising the steps that were taken is not questioned, and certainly these steps were helpful in achieving the goals of the study.

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APPENDIX ONE

APPLICATION TO THE MASSEY UNIVERSITY HUMAN ETHICS COMMITTEE

1.0 DESCRIPTION

1.1 Justification:

A study, which involved one hundred and ninety seven women in the Manawatu area to assess the effect of maternal nutritional status on infant growth, was completed in 1996. The participants were followed from month 4 of pregnancy to month 12 after birth.

Their dietary intake was assessed from 16 day weighed diet records. Their energy expenditure was assessed from 12-one-day-activity diaries. Height, weight and 7 skinfolds were measured at month 4 and month 7 of pregnancy. Babies birthweight and head circumference were measured. Socioeconomic, cultural and lifestyle details were determined by pre-tested questionnaire. The results showed that social, medical and lifestyle factors accounted for 17 % of total variance in the birthweight, anthropometric measures for 16.6%, diet for 12.6% and activity levels for 4.3% of total variance in birthweight. (1)

The proposed project is a follow up on the above study. We are targeting the same women and their children (the ones the participants were pregnant with in the original study). As the incidence of bronchial asthma in children is increasing in New Zealand over the past 30 years, we are focusing on the possible relationships between maternal diet during pregnancy, type of diet of the children, head circumference at birth and the occurrence of atopic (allergic) diseases. The attempts to establish an association between birthweight and asthma yielded conflicting

results (2, 3, 4); more work is needed in this area. Large head circumference at birth may be associated with childhood asthma. Large head at birth was found to be associated with a risk of elevated IgE (the immunoglobulin that is usually raised in allergic diseases) (5); however, an association with clinical asthma is not firmly established.

The relationship between some types of food and the occurrence of allergic diseases has been long well known (6, 7). Some young children are prone to hypertension; early identification allows early intervention and better outcome. In this study we are trying to find out the relationship between maternal blood pressure and that of the child, and whether the latter is affected by other factors such as the type of diet, level of activity, and birth weight. Hypertension was found to be associated with low birth weight in men with a high growth potential (8). Blood pressure, both systolic and diastolic, in children was found to increase with lower birth weight, suggesting that birth weight in relation to gestation age may be a contributor in the multifactorial cause of essential hypertension (9).

1.2 Objectives

Objective 1- to find out if there is a relationship between atopic diseases and early childhood diet and growth.

Objective 2- to find out the relationship between birthweight and blood pressure in childhood.

Objective 3- to find out if there is a relationship between blood pressure of the mother and that of her child.

1.3 Procedures for Recruiting Participants and Obtaining Informed Consent

Distant interaction:

As this is a follow-up study, the participants in the original study, who are still residing in the Manawatu area, will be contacted. Initially, the participant will receive a letter from Mrs. Patsy Watson to tell them about this study and to identify the researcher to them. In the second step the researcher will send the participants an information sheet to explain the purpose of the study, and the information and measurements to be obtained. This information sheet is for the participants to keep. The potential participant will then be given time to consider the implications of granting consenting.

Face-to-face interaction:

One week later, the participants will be contacted on the phone to discuss the study further and to answer any questions they may have at this stage. If the participant is willing to participate in the follow-up study, a consent form will be mailed to her. This will be collected during an arranged visit. The consent involves both the mother and the child. No consent should be required of the children as they are five years or younger. If the subject is not willing to participate, she will be thanked for her time and there will be no pressure on her. The phone call will work to a script.

1.4 Procedure in which Research Participants will be involved

The participants are the mothers and their children.

Procedures in which the mothers will be involved are listed below:

- Body weight measurement (3 times with estimation of the mean).
- Blood pressure measurement (3 times with estimation of the mean).

- A questionnaire which concentrates on the child's general health, level of activity, and the occurrence of atopic diseases.
- 24-hour dietary-record-recall of the child.

Procedures in which the child will be involved are listed below:

- Body weight measurement (3 times with estimation of the mean).
- Height measurement (3 times with estimation of the mean).
- Head circumference measurement (3 times with estimation of the mean).
- Upper arm circumference measurement (3 times with estimation of the mean).
- Blood pressure measurement (3 times with estimation of the mean).

1.5 Procedure for handling information and material produced in the course of the research including raw data and final research report(s)

- The information will be gathered as hard copy, no audio or video records are used.
- Code numbers will be used to designate the data collected. The names of the participants (mothers and children) will not appear during processing of the data.
- A separate list connecting code numbers to subject's name and address will be kept under lock and key, only supervisors will have the access to the list and will be destroyed after 5 years.
- The data collected will be coded, entered and statistically analyzed. Any publication will contain no reference to the participants in person.
- Each subject will receive a report of their individual result.

2.0 ETHICAL CONCERNS

2.1 Access to Participants

- As Mrs. Watson had secured the data from the participants in the original study, she will make the initial contact with them. This will be done through mailing an introductory letter to the potential participants in connection with this follow-up study. However, in this follow-up study we will only target those who are still residing in the Manawatu area.
- An information sheet is then to be mailed.
- A phone call will be made to discuss the sheet details and answer any questions.
- An informed consent form is to be mailed to those who agree to take part in the follow-up study.
- A further phone call will be made to respond to any other queries and to arrange for the home visits.
- The consent form will be collected during the home visit.

2.2 Informed Consent

An informed consent form (attached) will be delivered to all the participants. The form, explains in simple language the rights of the participant, including the right to decline participation in all or any part of the study at any time. The form allows for languages other than English if more convenient to the participant. Assurance of confidentiality is clearly stated. The form should be signed by the participant, consenting for her and for her child to participate, in the presence of a witness who should also sign the form. The consent form includes the names of the researcher and supervisors involved in the research.

2.3 Anonymity and Confidentiality

These are guaranteed throughout the study. Only Entesar Al-Shami (MSc student), Mrs. Patsy Watson (supervisor), Mrs. Heather McClean (second supervisor) and the assistant will have access to the names of the participants stored in separate places. Handling of the data will be through coding. No audio or videotapes are used. A Confidentiality Form will be signed by the researcher, supervisors and assistant.

2.4. Potential Harm to Participants

While the procedures, questionnaire, anthropometric measurements, and blood pressure measurement, carry absolutely no potential harm in themselves, the participants is given the right to decline any particular aspect she may feel uneasy about. Children may occasionally feel uncomfortable when checking their blood pressure; this is, however, a minor discomfort that should be alleviated with good explanation and tactful application of the procedure. A suitable size sphygmomanometer cuff will be used.

Visits are to be arranged with the participant at home, or another satisfactory location if preferred so as to be as convenient as possible and to allow maximum benefit.

2.5. Potential Harm to Researcher(s)

The research does not include handling of dangerous materials. Steps to minimize risk to the researchers during home visits are to be taken. The researcher will carry a cellphone at all times. The researcher will be accompanied by an assistant at all the visits. If either the researcher, or the assistant, or both feel unsafe during the visit they are free to leave the premises.

2.6. Potential Harm to the University

The strict anonymity and confidentiality and the professional attitude during collection and handling of the data should avoid the University any embarrassment or harm.

2.7. Participant's Right to Decline to Take Part

The participants have a total right to decline participation, to withdraw completely from the study at any time, or to decline a particular activity or question. These rights are clearly stated in the Consent Form and will be expressed verbally during the phone calls and the home visits. The participants also have the right to have answers to any questions they may ask and to receive information about the outcome of the activity in an appropriate form.

2.8. Uses of the Information

The information will be statistically analyzed to find out relationship between atopic diseases, maternal diet during pregnancy and early childhood diet and growth, and the relationship between the mother's blood pressure and her child's blood pressure. The results will be published in scientific journals and presented at scientific conferences.

2.9. Conflict of Interest/Conflict of Roles

The aim of the study is not to offer medical or health advice, such advice should be left to the concerned medical or health professional. However, if the data collected reveal a matter of health concern either in the mother or her child or both, the

researcher will suggest at the time and in the follow-up notes the subject contact her general practitioner.

2.10. Other Ethical Concerns

There is a possibility of encountering other health problems or unwise lifestyle choices. The line of action in such circumstances is to advise the subject to seek professional advice. Should the researcher find issues of child neglect among potential participants, the issue will be discussed with the supervisors, and if necessary they would consult with the chairperson of the MUAHEC.

3.0 LEGAL CONCERNS

3.1Legislation

3.1.1 Intellectual Property Legislation e.g. Copyright Act 1994

Any scientific material used will be appropriately reference. The data collected will belong to Massey University.

3.1.2 Human Rights Act 1993

The questions and procedures involved in the study were carefully designed to contain no verbal or physical abuse, and to contain no insulting or degradatory remarks or actions against any religious, ethnic, or social group.

3.1.3 Privacy Act 1993

- The information required is to be directly collected from the person in question, this includes collecting information of the young child from the mother. If the child is in foster care and the guardian is other than the mother,

the guardian's consent is required, and the mother will be contacted to obtain her consent.

- Confidentiality includes those who choose to withdraw from the study at any stage.
- Information collected will be used only in the research purposes identified to the participants.
- Any publication will contain none of the participant's names nor any information that may identify them.
- Massey University, as the agency responsible, is clearly identified.
- The right of the participant to decline participating in full or in part without prejudice or loss of any benefit is clearly stated.
- The information will be collected during a home visit that is arranged and agreed upon with the participant. No video or audio records are to be used.

3.1.4 Health and Safety in Employment Act 1992

No potential health hazards are recognized at this stage, however, if any should appear in the future, they will be dealt with appropriately.

3.1.5 Accident Rehabilitation Compensation Insurance Act 1992

The assistant will be covered by ACC in car and HIH out of car.

3.1.6 Employment Contracts Act 1991

Employees contracted to help in the research will be appropriately treated and in accordance with the Act.

3.2 Other Legal Issues

Not applicable

4.0 CULTURAL CONCERNS

The researcher is a Kuwaiti pediatrician, and she will be accompanied at all the visits with a local New Zealand born assistant, who has excellent interpersonal skills. The supervisor will identify the researcher in her introductory letter and a photo of the researcher will be supplied to participants. Subjects will be advised in writing that they may have whanau present if they wish.

5. 0 OTHER ETHICAL BODIES RELEVANT TO THIS RESEARCH

5.1. Ethics Committees

Manawatu-Whanganui Ethics Committee (MWEC)

5.2. Professional Codes

Not applicable

6.0 OTHER RELEVANT ISSUES

If either mother or child has died or is suffering from serious illness, the family will be excluded from the study for reasons of sensitivity. A card will be sent to the family. A list of supportive organizations will be made available for the family.

REFERENCES

1. Watson, P.E., (1996). Maternal nutrition and infant outcome, Report to Ministry of Health.

2. Shaheen, S.O., Sterne, J.A., Montgomery, S.M., (1999). Birth weight, body mass index and asthma in young adults, Thorax, **54** (5): 396-402.

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4. Shaheen, S.O, Sterne, J.A., Montgomery, S.M., (1998). Asthma in adult life -- is there an association with birth weight? Scandinavian Journal of Primary Health Care, **54** (5): 117-120.

5. Gregory, A., Doull, I., Pearce, N., (1999). The relationship between anthropometric measurements at birth: asthma and atopy in childhood, Clinical and Experimental Allergy, **29** (3): 330-333.

6. Monerer-Vautrin, D.A., Kanny, G., Th'evenin, F.,(1996). Asthma caused by food allergy, Review Medicine Interene, **17** (7): 551-557.

7. Ranc'e, F., Kanny, G., Dutau, G., (1999). Food allergens in children, Archives of Pediatrics, **6** (1): 61S-66S.

8. Koupilova, I., Leon, D.A., Lithel, H.O., (1997). Size at birth any hypertension in longitudinally followed 50-70-year-old men, Blood Pressure, **6**(4): 223-228.

9. Yiu, V., Buka, S., Zurakowski, D., (1999). Relationship between birth weight and blood pressure in childhood, American Journal of Kidney Diseases, **33**(2): 253-260.

Form EA 06/99

NATIONAL APPLICATION FORM FOR ETHICAL APPROVAL OF A RESEARCH PROJECT

PART I : BASIC INFORMATION

Protocol number and date received (for office use only)

1. Full project title

Follow-up Study of the Dietary Intake, Anthropometric Measurements, and Blood Pressure in Children Born to Women in the Manawatu Pregnancy Study.

2. Short project title (lay title)

Follow--up of the Children Born to Women in the Manawatu Pregnancy Study.

3. Lead Principal Investigator's name and position

Dr. Entesar Al-Shami, Masterate Student - Massey University

4. Add[redacted]or

293[redacted]	Work ph	
	Home ph	(06[redacted]
	Fax	(06[redacted]
	E-mail	eas[redacted]

5. Lead investigator's qualifications and experience in past 5 years (relevant to proposed research)

M.B.,B.Ch. (Kuwait University) 1984.
D.C.H (Dublin College University) 1986.
Diploma in Nutrition (WHO) 1996.

Paediatrician 1985-1994 Kuwait
Nutritionist 1994-1998 Kuwait
Masterate Student 1998-Current Massey University

6. Co-investigators' name(s) and position(s)

A
B
C
D

7. Address of co-investigator A

	Work ph	
	Home ph	
	Fax	
	E-mail	

8. Address of co-investigator B

	Work ph	
	Home ph	
	Fax	
	E-mail	

9. Address of co-investigator C

	Work ph	
	Home ph	
	Fax	
	E-mail	

10. Address of co-investigator D

	Work ph	
	Home ph	
	Fax	
	E-mail	

11. Where this is supervised work

11.1 Supervisor's name	Mrs. Patsy Watson
Position	Senior Lecturer, Institute of Food, Nutrition and Human Health, Massey U
Day time phone number	(06)-356-9099 Ext. 9627

11.2 Signature of supervisor (where relevant)
Declaration: I take responsibility for all ethical aspects of the project

12. List any other New Zealand Ethics Committees to which this project has been submitted and attach their letters of approval where available

Massey University Human Ethics Committee

13. I wish the protocol to be heard in a closed meeting [ ] Yes [*] No
(If yes the reason should be given in a covering letter)

14. I request a fast track procedure [*] Yes [ ] No

15. Proposed starting date (dd/mm/yy)	01/09/99
16. Proposed finishing date (dd/mm/yy)	01/12/99
17. Duration of project (mm/yy)	03/00
18. Proposed final report date (mm/yy)	01/07/00

PALMERSTON NORTH CAMPUS
Institute of Food, Nutrition and Human Health

Follow-up Study of the Dietary Intake, Anthropometric Measurements, and Blood Pressure in Children Born to Women in the Manawatu Pregnancy Study.

Dear.....

My name is Entesar Al-Shami, I am married with four children, aged 8 years to 9 months. I originally came from Kuwait, and currently I am doing my Master degree in Nutrition at Massey University, with Mrs. Patsy Watson and Mrs. Heather McClean as my supervisors.

In my research I will be looking into children's diet, growth and factors that may affect them. The research findings may help to clarify issues such as the relation between birth weight and growth, maternal weight and child's weight, mother and child's blood pressure and the causes and effects of allergic diseases.

WE NEED YOUR HELP AGAIN !

As you remember you were one of the volunteers in Mrs. Patsy Watson's study "Individual Dietary Intake, Energy Expenditure, and Body Composition of Pregnant Women" in the earlier part of 1990. You provided us with very valuable information for health education of pregnant women.

This study is a follow-up on that earlier study, to further investigates the effects of nutrition during pregnancy on you and on your child. However, in this study we will be mainly concentrating on your child.

- **We will measure your weight now and compare it with your weight during pregnancy and that of one year after delivery.**
- **We will study your child's growth and its relationship to birth weight and maternal diet during pregnancy.**
- **We will check your child's blood pressure and see if it relates to your blood pressure and to your child's birthweight and growth.**
- **We will be asking questions about signs of allergic diseases that could have affected your child, as these could have an effect on the child's growth and diet.**

This study depends mainly on your participation, such participation will be greatly valued and appreciated, not only by us but by those who could benefit from the results.

Our study will be done in one meeting of around 2 hours, the meeting could be at your home or at any other place you think more convenient, and you are welcome to have whanau. In the meeting we will cover four main parts:

PART 1 DIETARY INTAKE:

What we will do?

When you receive this letter you will find a child's 24-hour diet record sheets. We would like you to record everything your child consumed in the day before our visit.

Why this is important?

Analyzing the diet of children will help us in looking at the relationship between diet and allergic diseases.

PART 2 BODY MEASUREMENTS:

What we will do?

We will measure your body weight, and we will measure your child's

- body weight
- height
- head circumference
- upper arm circumference

Why this is important?

Measuring your body weight now and comparing it to your body weight during pregnancy and one year after delivery will provide us with valuable information about the degree of weight gain/loss during a critical period in women's life.

The four measurements of your child will enable us to form a clear picture of his/her growth.

PART 3 BLOOD PRESSURE MEASUREMENT

What we will do?

We will measure your and your child's blood pressure.

Why this is important?

These measurements will allow us to relate your blood pressure to that of your child and will also inform you of your own blood pressure.

PART 4 QUESTIONNAIRES:

What we will do?

Questions will be asked about your child's health, activity and about the presence of allergic diseases.

Why this is important?

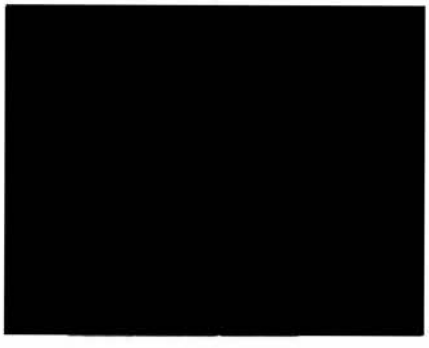
These questions are designed to give an idea about your child's general health, level of activity and to detect the presence of allergic diseases. These findings help us to study relationships between diet, growth, activity and health in general.

Anything you tell us is anonymous and will remain confidential. Your name or your child's name will not appear on any data form. If you do not want to answer a particular question, just say so at the time.

I will phone you within a week to talk further.

Regards

Entesar Al-Shami



Entesar Al-Shami / Patsy Watson / Heather McClean
Institute of Food, Nutrition, and Human Health
Massey University
Private Bag 11222
Palmerston North

Telephone: (06) [redacted]

Facsimile: (06) [redacted]

PALMERSTON NORTH CAMPUS
Institute of Food, Nutrition and Human Health

Follow-up Study of the Dietary Intake, Anthropometric Measurements, and Blood Pressure in Children Born to Women in the Manawatu Pregnancy Study.

CONSENT FORM

THIS STUDY HAS BEEN APPROVED BY THE MASSEY UNIVERSITY HUMAN ETHICS COMMITTEE AND THE MANAWATU-WANGANUI ETHICS COMMITTEE.

If you would like to take part in this study please complete this consent form and return it to:

Entesar Al-Shami / Patsy Watson / Heather McClean
Institute of Food, Nutrition and Human Health
Massey University
Private Bag 11222
Palmerston North
Phone: Entesar Al-Shami [redacted]
Patsy Watson (06) 356-9099 Ext 9627
Heather McClean (06) 356-9099 Ext 6114

English:	I wish to have an interpreter	Yes	No
Maori:	E hiahia ana ahau ki tetahi tangata hei korero Maori ki ahau	Ae	Kao
Samoan:	Oute mana'o e iai se fa' amatala upu.	Ioe	Leai
Tongan:	'Oku fiema'u ha fakatonulea.	Io	Ikai
Cook Island:	Ka inangaro au I tetai taangata uri reo.	Ae	Kare

I,----------

full name, please print

- I have heard and understood an explanation of the research project I have been invited to take part in.
- I have been given, and I have read, a written explanation of what is asked of me.
- I have had an opportunity to ask questions and to have them answered.
- I understand that I may withdraw from the project at any time.
- I understand that my consent to take part does not alter my legal rights.

I consent to take part as a subject in this research.

SIGNED:

_____

Subject (please print)

_____

____/____/___

Signature Date

In my opinion consent was given freely and with understanding:

_____

Witness (please print)

_____

____/____/___

Signature Date

Massey University
COLLEGE OF SCIENCES

Institute of Food, Nutrition and Human Health
Private Bag 102 904,
North Shore Mail Centre,
Auckland,
New Zealand
Telephone: 64 9 443 9700
Facsimile: 64 9 443 9640

Dear .....,

You will remember that you took part in my 'Nutrition in Pregnancy Study' in the early 1990's. I really appreciated your contribution to this research. Using the very important information you and all the other subjects provided we have been able to show how diet and activity levels of the mother during pregnancy influence both growth to birth, and growth to one year in the infant.

We need your help again. We would like to visit you and your child from this earlier pregnancy. The main purpose of this visit will be to find if diet during pregnancy has any influence on the later development of asthma and allergic disease in the child.

I have moved to the Albany Campus of Massey University in Auckland so am unable to visit you myself. However, Entesar Al-Shami a student from Kuwait, will carry out this follow-up study. She is completing her Masters in Nutritional Science degree under my supervision. To ensure ease of communication, a local New Zealand born woman will accompany Entesar on all visits. Entesar will write to you shortly outlining what will be required for this study, should you choose to participate.

I do hope you will consider taking part in this very important follow-up.

Kind Regards,

Patsy Watson

Patsy Watson,
Programme Leader in Human Nutrition.

PART II. PILOT FOR A FOLLOW-UP STUDY TO INVESTIGATE THE RELATIONSHIP BETWEEN MATERNAL DIET AND THE INCIDENCE OF ATOPIC DISEASE IN THE CHILD, AND MATERNAL AND CHILD BLOOD PRESSURES.

1.0 Background

Over the past fifty years there has been an interesting shift in the expectation of what diet may provide. This is particularly true in regard to the diet of pregnant women and children. The principle goal of nutritional science is to identify and quantify nutrients necessary for optimal growth and development, promote long-term health and minimize the risk of chronic illness due to heart disease, hypertension and obesity.

"Nutrition during pregnancy", was a study that involved one hundred and ninety seven New Zealand women in the Manawatu area, which was completed in 1996. In this study participants were followed from month 4 of pregnancy to month 12 after birth (1).

The dietary intake of the mothers was assessed from 16 day weighed diet records collected during month 4 and month 7 of pregnancy. Their energy expenditure was assessed from six 24-hour activity diaries, recorded at the same time.

Height, weight and skinfolds were measured at month 4 and month 7 of pregnancy. Babies birthweight and head circumference were measured. Socioeconomic, cultural and lifestyle details were determined by pre-tested questionnaire.

The results showed that social, medical and lifestyle factors accounted for 17% of total variance in the birthweight, anthropometric measures for 16.6%, diet for 12.6% and activity levels for 4.3% of total variance in birthweight.

For birthweight 3.6% of infants were below the 3rd percentile. This figure is around the expected, but for the above 98th percentile the figure was 6.6%, which is above the expected. This might be due to high percentage of overweight and obese mothers in the sample, which was 12.6% and 7.9% respectively (1).

2.0 Objectives of the Pilot Study

To develop and pilot a research protocol to determine

- If there is a relationship between atopic diseases and early childhood diet and growth.
- If there is a relationship between birthweight and blood pressure in childhood.
- If there is a relationship between blood pressure of the mother and that of her child.

The objectives of this study were based on the data collected from the initial study; these are the mother's anthropometric measurements and the anthropometric measurements of the infants at birth, and the data expected to be collected during this pilot study. This included information collected through a questionnaire, 24hour record-recall dietary intake of the child, anthropometric measurements for both the mother and child, and blood pressure measurements for both mother and child.

3.0 Introduction

3.1 Relationship Between Atopic Diseases, Maternal Diet During Pregnancy, Early Childhood Diet and Growth

3.1.1 Atopic Diseases- Definitions

Allergy is a reproducible, specific acquired change in host reactivity mediated by an immunological mechanism and causing an untoward physiological response. The substance provoking the reaction may have been ingested, injected, inhaled, or may have come into contact with the skin or mucous membranes.

The term "**atopic disease**" implies a hereditary factor expressed as susceptibility to hay fever, asthma, and eczematoid dermatitis in the families of affected individuals. The atopic patient has a predisposition to selective synthesis of IgE antibodies to common environmental antigens. Atopic individuals may differ from non-atopic individuals in their ability to regulate IgE antibody or to dispose of allergens coming in contact with mucosal surface. They may also have defective control of mediator release or generation, or have impaired mediator inactivation process.

Asthma is a condition characterized by variation in intrathoracic airway obstruction, occurring spontaneously or as a result of treatment. It is manifested by persistent or episodic wheeze, usually accompanied by cough, in a clinical sitting where asthma is likely and other conditions have been excluded.

Hay fever is a term describing a symptom complex seen in individuals who have become sensitized to wind-born pollens of trees, grasses, and weeds. Symptoms of hay fever occur seasonally and consist of paroxysmal rhinorrhea, which is often

watery and profuse; nasal obstruction; and itching of the nose, palate, pharynx, and ears. Itching, redness, and tearing of the eyes may also occur.

Atopic dermatitis or **atopic eczema** is an inflammatory skin disorder characterized by erythema, oedema, intense itching, exudation, crusting and scaling. The skin is generally dry with tendency to thickening (2).

3.1.2 Bronchial Asthma

Asthma is thought to be a condition of disrupted immune regulation; the airway inflammation can be ascribed to abnormal immunologic response to allergen.

In asthmatics aeroallergens continue to invoke and amplify a humoral immune response characterized by the presence of T lymphocyte helper 2 Th2 (or Th2-like) subtype lymphocytes, capable of producing cytokines: interleukin IL-4, IL-5, IL-10, and IL-13 upon stimulation; this contrasts with what happens in non-asthmatics in whom the response to inhaled allergens switches to a response associated with Th1 subtype lymphocytes and a different panel of cytokines including interferon gamma. In children, the atopic disease and asthma are thought to be due to faulty Th2/Th1 switching. In addition, atopic individuals fail to develop "immune tolerance", a mechanism that may involve activation of additional subsets of T lymphocytes or some other cell(s) acting as suppressor cells. These cells may act as a catalyst for Th2-Th-1 switching or suppress both Th2 and Th1 responses. The failure of this process is likely to result from a combination of allergic genetic predisposition and persistent repetitive or high levels of allergen stimulation at a critical time of immune maturation in early life (3).

3.1.3 Incidence

Asthma is a leading cause of chronic illness in childhood, and is the most frequent admitting diagnosis in children's hospitals, accounting for a high ratio of lost school days, around 3-4% of recognized asthmatics are admitted to hospital each year (2). Asthma can lead to severe psychosocial disturbances in the family. Studies have shown that the incidence of asthma in Australia and New Zealand has doubled over the last decade (3).

Before puberty approximately twice as many boys as girls suffer from asthma; thereafter, the incidence is equal. Asthma may have its onset at any age; around one-third of patients are symptomatic by one year of age, 80-90% of asthmatic children have their first symptoms by 4-5 years of age (2). About 10-15% of schoolchildren suffer from asthma at any time; cumulative figures of up to 20-25% are reached if a single episode of reported wheeze is included within the definition (4). The majority of affected children have occasional attacks of slight to moderate severity; a minority develop severe asthma.

The prevalence and severity of asthma is steadily increasing in most of the industrialized nations of the world, presumably as a result of environmental changes (2). Ethnic differences are largely explained by differences in environmental and upbringing practices rather than by genetics, although familial factors in asthma are well recognized. Differing diagnostic criteria for asthma could account for different reported incidences of childhood asthma in some countries (4,5).

3.1.4 Etiology

Both environmental and hereditary factors are important in the pathogenesis of asthma. Identification of environmental factors may help in planning interventional strategies to decrease the incidence and/or severity of asthma.

There are several environmental factors that have been identified as triggering factors of asthma and other allergic diseases or as causes for increased severity. These are:

- **Maternal Smoking**

Maternal smoking (particularly during pregnancy); this has been documented as a cause for increased frequency of respiratory illnesses in infancy (6,7). Environmental pollution probably has a similar effect.

- **Maternal Diet During Pregnancy**

Studies to examine the effect of prenatal maternal dietary manipulations on the development of allergy and asthma in the offspring had shown that prenatal maternal dietary allergen avoidance may or may not decrease allergic skin manifestations in atopy-prone children early in life, but is unlikely to have lasting impact on atopy and the ultimate risk of asthma. On the other hand, an elimination diet during lactation may confer benefit, reducing infantile eczema in high-risk individuals (8).

- **Low Birth Weight**

Low birth weight may be related to the development of asthma in childhood or later in life (9,10). However, results are conflicting and other environmental factors are

probably more important. It was shown in a cohort study that those with a birth weight less than 2 kg compared to the modal group (3-3.5 kg) had an odds ratio of 3.13 for having a diagnosis of asthma by 26 years of age (11).

- **Large Head Circumference at Birth**

Other anthropometric factors such as large head circumference at birth may be associated with increased risk for developing asthma; large head circumference was found to be associated with increased risk of developing high total IgE concentration in childhood (12,13).

- **House Dust Mite**

Exposure to house dust mite and cat allergens in early life predisposes to allergic sensitization and to the development and persistence of asthma (3).

- **Season of Birth**

Season of birth may have a relationship to sensitization and manifestations of atopy; infants born in autumn and winter may have IgE antibodies to egg white, milk, and wheat more than children born in spring and summer (14). This constitutes an in utero priming of infant allergic responses, by means of either maternal cytokines or direct transplacental allergen stimulation.

- **Breastfeeding**

Breastfeeding probably has a protective effect against allergic diseases. Saarinen and Kajosaari, (15) followed up 150 children during their first year of life and then at ages 1, 3, 5,10, and 17 years, to determine the effect on atopic disease of

breastfeeding. They found that the prevalence of manifest atopy throughout follow-up was highest in the group who had little or no breastfeeding. Prevalence of eczema at ages 1 and 3 years was lowest in the group who had prolonged breastfeeding (> 6 months). Food allergy and respiratory allergy were highest in the group who had little or no breastfeeding. They concluded that breastfeeding is prophylactic against atopic disease, including atopic eczema, food allergy, and respiratory allergy throughout childhood and adolescence, [Provided the lactating mother's diet doesn't contain trigger foods (8)].

Formula feeding before 3 months of age as opposed to breast feeding probably predisposes to asthma by 4 years of age (16). Early neonatal intake of foreign protein may be an important factor involved in sensitization and subsequent allergic manifestations, although there are reports that early brief exposure to cow's milk in breast-fed babies does not increase the susceptibility for atopic diseases (17). Food allergy induced asthma is less common than food allergy induced atopic dermatitis or angioedema (18).

- **Food and Dietary Factors**

Oxidant processes probably contribute to the pathogenesis of asthma. Oxidative stress occurs as a result of the production of reactive oxygen species (ROS) as a normal consequence to aerobic metabolism. Oxidant species created during the inflammatory process, plus the effects of inhaled exogenous oxidants such as oxides of nitrogen, sulphur dioxide, and ozone, ensue a state of uncompensated oxidative stress (19,20,21). Uncompensated oxidative stress leads to a free radical chain reaction, producing lipid peroxidation of unsaturated fatty acids in the membrane of

the airway epithelial cells and damage to proteins, especially those with high levels of sulphur-containing amino acids, cell enzyme systems, haemoglobin, DNA, and other cell components.

(a) Vitamin C, E and β-Carotene

Dietary antioxidants such as vitamins C and E may protect against this oxidant damage. A large cross-sectional study in China has demonstrated an association between dietary intake of vitamin C and lung function (22). Another cross-sectional study from the Netherlands demonstrated an association between lung function and intakes of both vitamin C and β-carotene (23). A case- control study from Scotland demonstrated an association of the occurrence of adult-onset wheezing with reduced levels of vitamin E intake, plasma ascorbate levels and reduced α-tocopherol: triglyeride ratio (24).

Ascorbic acid treatment was shown to significantly reduce airways reactivity to methacholine in asthmatic patients (25), and it was also shown that ascorbic acid decreased both the intensity and duration of the bronchoconstriction induced by methacholine aerosol in subjects with normal respiratory function (26). On the other hand, short-term ascorbic acid administration did not alter bronchial responsiveness in asthmatic subjects (27). It was found that short-term vitamin C intake failed to protect against exercise-induced diminution in respiratory function (28), whereas Schachter and Schlesinger (29) showed a significant protective effect.

(b) Magnesium

Dietary magnesium intake is probably related to lung function and bronchial reactivity. Reduced intracellular magnesium levels were demonstrated in subjects

with asthma when compared to non-asthmatics. Magnesium induces bronchodilatation when given intravenously (30).

(c) Selenium

Glutathione peroxidases have a major role in the cellular defence against oxidant stress. A number of studies have shown blood glutathione peroxidase levels to be lower in asthmatics than in non-asthmatics. Selenium is an essential co-factor of the glutathione peroxidases and selenium supplementation has been shown to ameliorate asthma symptomatology (30).

(d) Zinc and Copper

Zinc is redox-inactive and may function as an important antioxidant by displacing redox-active iron from macromolecular binding sites. High dietary iron intake and low zinc intake may potentiate the production of ROS in airway tissue and contribute to asthma risk. Both copper and zinc are cofactors in Cu, Zn-SOD, and the cytoplasm form of superoxide dismutase, which has the important function of metabolizing superoxide anion that results from the oxidative respiratory burst of eosinophils, neutrophils and macrophages in the respiratory tract. A dietary deficiency of either of these minerals could diminish such activity adding to the risk of asthma. Copper, on the other hand, is an extremely powerful redox-active transition metal and copper excess, such as from contamination of drinking water, should be considered as a possible risk for asthma (30).

(e) Iron

Iron is highly redox-active, its release during the inflammatory process forms the highly reactive hydroxyl radical $OH^{\bullet}$. However, high dietary iron intake and high body iron stores have not been determined to contribute to asthma risk (30).

(f) Sodium

Sodium does not appear to be associated with oxidative stress; however, a number of experimental studies have shown a relation between salt intake and various measures of airway hyperactivity. The effect is sodium related. It appears that individuals with airway hyperresponsiveness have an increased sodium influx into cells that is stimulated by a serum factor (30).

(g) Fish oils

Atopy and asthma are potentially affected by fatty acids, as these are substrates for the leukotriene and prostaglandin families of inflammatory mediators. Membrane fatty acids are one of the main substrates for the oxidative processes seen in the pathogenesis of asthma (31).

An increase in the consumption of n-6 polyunsaturated fatty acids and a decrease in the n-3 polyunsaturated fatty acids found in fish have been proposed as an explanation of the increase in asthma and atopy observed in economically developed countries. It was shown that consumption of oily fish is associated with a reduced risk of asthma in childhood (31).

Fish oil has a potential anti-inflammatory effect, which stems from its active ingredient, eicosapentenoic acid (EPA), which is a competitive substrate with arachidonic acid for the generation of inflammatory mediators. However, the most profound anti-inflammatory actions of fish oil are on neutrophil function and mediator generation, while EPA does not inhibit eosinophils and mast cells in vitro (31).

In asthma eosinophils and mast cells are thought to be the predominant effecter cells with T lymphocytes, and macrophages; while the role of neutrophils is much less certain. Because of the above facts and the failure of many interventional studies to show benefit of consumption of oily fish on the course of asthma, further studies are required before claims can be made of a beneficial role of oily fish on asthma (31).

3.2 Children and Blood Pressure

The relevance of blood pressure to pediatric health care has undergone great conceptual change during the past two decades. Blood pressure in children has been given serious attention only since the mid-1960s. Blood pressure is considerably lower in children than adults; it increases steadily throughout the first two decades of life. The average systolic blood pressure at one day in full term infants is approximately 70 mmHg, and it increases to approximately 85 mmHg by one month of age. Blood pressure in premature infants is considerably lower than the full term infant and it is related more closely to weight than to age (32).

During the preschool years blood pressure begins to follow a pattern, children at a given percentile of blood-pressure distribution tend to maintain that approximate value relative to their peer group as they grow older, with correlation's ranging from 0.30 to 0.66 for systolic blood pressure and 0.12 to 0.57 for diastolic blood pressure in children and adolescence. The pattern continues from adolescence into adult life, which supports the hypothesis that essential hypertension begins in childhood (32). In the Brompton study researchers followed around 2000 children from birth until the

age of 10 years, measuring blood pressure first at the age of 4 days, then 6 weeks, 6 months, 1year, and thereafter yearly till the age of 10 years. It was found that blood pressure changes relatively little between the ages of 6 months and 10 years (34).

The first report of the American Task Force on Blood pressure control in children was published in 1977 (35). The norms for blood pressure and definitions of hypertension were revised and strengthened by the second National Heart, Lung, and Blood Institute Task Force based on the distribution of blood pressure in healthy children as well as clinical experience and consensus. These finding were published in 1987, and in 1996 a revision was published containing modified recommendations and norms. These standard normograms are necessary for interpretation of blood pressure value (36,37).

Blood pressure in children is classified according to the percentile distribution of the various levels within the population. Tables derived from epidemiological studies of 70,000 children and adolescents have been the accepted blood pressure reference standards, but they classify blood pressure only according to age. These tables have been recently revised and the effects of body size and rates of growth have been taken into account by relating blood pressure to both age and height, (see Tables 3.2a to 3.2d).

The reference standards for blood pressure in children do not distinguish between racial or ethnic groups, because the differences are not clinically relevant. Blood pressure is slightly higher in boys than in girls during the first decade of life.

Table 3.2a: Blood pressure levels for the 90th and 95th percentiles of systolic blood pressure for boys aged 1 to 10 years by percentiles of height.

Age, y	Blood Pressure Percentile*	Systolic Blood Pressure by Percentile of Height, mm Hg~						
		5%	10%	25%	50%	75%	90%	95%
1	90th	94	95	97	98	100	102	102
	95th	98	99	101	102	104	106	106
2	90th	98	99	100	102	104	105	106
	95th	101	102	104	106	108	109	110
3	90th	100	101	103	105	107	108	109
	95th	104	105	107	109	111	112	113
4	90th	102	103	105	107	109	110	111
	95th	106	107	109	111	113	114	115
5	90th	104	105	106	108	110	112	112
	95th	108	109	110	112	114	115	116
6	90th	105	106	108	110	111	113	114
	95th	109	110	112	114	115	117	117
7	90th	106	107	109	111	113	114	115
	95th	110	111	113	115	116	118	119
8	90th	107	108	110	112	114	115	116
	95th	111	112	114	116	118	119	120
9	90th	109	110	112	113	115	117	117
	95th	113	114	116	117	119	121	121
10	90th	110	112	113	115	117	118	119
	95th	114	115	117	119	121	122	123

**Blood pressure percentile was determined by a single measurement.*

~ Height percentile was determined by standard growth curves.

Data are adapted from Task Force on High Blood Pressure in Children and Adolescents (37)

Table 3.2b: Blood pressure levels for the 90th and 95th percentiles of diastolic blood pressure for boys aged 1 to 10 years by percentiles of height.

Age, y	Blood Pressure Percentile*	Diastolic Blood Pressure by Percentile of Height, mmHg~						
		5%	10%	25%	50%	75%	90%	95%
1	90th	50	51	52	53	54	54	55
	95th	55	55	56	57	58	59	59
2	90th	55	55	56	57	58	59	59
	95th	59	59	60	61	62	63	63
3	90th	59	59	60	61	62	63	63
	95th	63	63	64	65	66	67	67
4	90th	62	62	63	64	65	66	66
	95th	66	67	67	68	69	70	71
5	90th	65	65	66	67	68	69	69
	95th	69	70	70	71	72	73	74
6	90th	67	68	69	70	70	71	72
	95th	72	72	73	74	75	76	76
7	90th	69	70	71	72	72	73	74
	95th	74	74	75	76	77	78	78
8	90th	71	71	72	73	74	75	75
	95th	75	76	76	77	78	79	80
9	90th	72	73	73	74	75	76	77
	95th	76	77	78	79	80	80	81
10	90th	73	74	74	75	76	77	78
	95th	77	78	79	80	80	81	82

**Blood pressure percentile was determined by a single measurement.*

~ Height percentile was determined by standard growth curves.

-Data are adapted from Task Force on High Blood Pressure in Children and Adolescents (37).

Table 3.2c: Blood pressure levels for the 90th and 95th percentiles of systolic blood pressure for girls aged 1 to 10 years by percentiles of height.

Age, y	Blood Pressure Percentile*	Systolic Blood Pressure by Percentile of Height, mmHg~						
		5%	10%	25%	50%	75%	90%	95%
1	90th	97	98	99	100	102	103	104
	95th	101	102	103	104	105	107	107
2	90th	99	99	100	102	103	104	105
	95th	102	103	104	105	107	108	109
3	90th	100	100	102	103	104	105	106
	95th	104	104	105	107	108	109	110
4	90th	101	102	103	104	106	107	108
	95th	105	106	107	108	109	111	111
5	90th	103	103	104	106	107	108	109
	95th	107	107	108	110	111	112	113
6	90th	104	105	106	107	109	110	111
	95th	108	109	110	111	112	114	114
7	90th	106	107	108	109	110	112	112
	95th	110	110	112	113	114	115	116
8	90th	108	109	110	111	112	113	114
	95th	112	112	113	115	116	117	118
9	90th	110	110	112	113	114	115	116
	95th	114	114	115	117	118	119	120
10	90th	112	112	114	115	116	117	118
	95th	116	116	117	119	120	121	122

**Blood pressure percentile was determined by a single measurement.*
~ Height percentile was determined by standard growth curves.
Data are adapted from Task Force on High Blood Pressure in Children and Adolescents (37).

Table 3.2d: Blood pressure levels for the 90th and 95th percentiles of diastolic blood pressure for girls aged 1 to 10 years by percentiles of height.

Age, y	Blood Pressure Percentile*	Diastolic Blood Pressure by Percentile of Height, mmHg~						
		5%	10%	25%	50%	75%	90%	95%
1	90th	53	53	53	54	55	56	56
	95th	57	57	57	58	59	60	60
2	90th	57	57	58	58	59	60	61
	95th	61	61	62	62	63	64	65
3	90th	61	61	61	62	63	63	64
	95th	65	65	65	66	67	67	68
4	90th	63	63	64	65	65	66	67
	95th	67	67	68	69	69	70	71
5	90th	65	66	66	67	68	68	69
	95th	69	70	70	71	72	72	73
6	90th	67	67	68	69	69	70	71
	95th	71	71	72	73	73	74	75
7	90th	69	69	69	70	71	72	72
	95th	73	73	73	74	75	76	76
8	90th	70	70	71	71	72	73	74
	95th	74	74	75	75	76	77	78
9	90th	71	72	72	73	74	74	75
	95th	75	76	76	77	78	78	79
10	90th	73	73	73	74	75	76	76
	95th	77	77	77	78	79	80	80

**Blood pressure percentile was determined by a single measurement.*
~ Height percentile was determined by standard growth curves.
-Data are adapted from Task Force on High Blood Pressure in Children and Adolescents (37).

Measurement of blood pressure is now firmly established as an important component of the routine pediatric physical examination. It has been suggested that all children above the age of 3 years should have their blood pressure measured at least yearly (4). This practice has shown mild elevations in blood pressure during childhood to be more common than previously recognized (4). Normal blood pressure during the first decades of life is defined as systolic and diastolic blood pressure below the 90th percentile for age and sex. Most children and adolescents with blood pressure levels at or just greater than the 95th percentile for their age and sex are overweight and have family histories of hypertension.

3.2.1 Hypertension in Children

Essential hypertension (with no identifiable cause) occurs commonly in adults and if untreated, is a major risk factor for myocardial infarction, stroke, and renal failure. It is estimated that 43 million (24%) of adult Americans suffer from hypertension. The prevalence of hypertension increases with age ranging from 15% of young adults to 60 % of individuals older than 65 year of age. High blood pressure is an important causative factor of decrease in life expectation (38). In New Zealand it was found that after adjustment for age and gender almost 20% of Maori, 16% of Pacific Islands and 11% of European people were classified as hypertensive (39).

Initially the orientation of physicians with regard to blood pressure measurement in children and adolescents was toward identification and treatment of secondary forms of hypertension, such as renal disorders, coarctation of the aorta, endocrine disorders, or secondary to medications, (see Table 3.2e). Essential hypertension

(primary) in children and adolescents is now recognized to occur at least as frequently as secondary hypertension (40, 41, 42).

Table 3.2e: Causes of hypertension in children and adolescents (32).

AGE GROUP	CAUSE MOST COMMON	CAUSE LESS COMMON
1 to 10 yr	Renal disease Coarctation of aorta	Renal artery stenosis Hypercalcemia Neurofibromatosis Neurogenic tumours Pheochromatosis Mineralocorticoid Hyperthyrodism
11 yr to adolescence	Renal disease Essential hypertension	

The practical criteria for definition of clinical hypertension in children should be based on a set of critical basal blood pressure values as related to body weight and body dimensions rather than to age. However, there are difficulties in defining hypertension in children since blood pressure rises with age and exhibits considerable variability in an individual.

High-normal blood pressure is defined as average systolic or diastolic blood pressure greater than or equal to the 90th percentile but less than the 95th percentile. Hypertension is defined as average systolic or diastolic blood pressure greater than or equal to the 95th percentile for age and sex measured on at least three separate occasions, a single reading cannot be considered to indicate hypertension unless it is very high and once it is diagnosed further evaluation and treatment should be implemented. On this basis the prevalence of systemic hypertension in the pediatric age group is between 1% and 3% worldwide (4). Children and young adolescents with blood pressure greater than the 90th percentile for age are threefold more likely to become adults with hypertension than are children with blood pressure at the 50th percentile.

3.2.2 Familial Factors in Hypertension

Both genes and environment contribute to blood pressure, however, because genotype and environment interact to produce the blood pressure phenotype, no partition of variation can actually separate the cause of variation. Families share both genes and environment, and similarity may result from either (43).

Familial influence on blood pressure can be identified early in infancy. Children from families with hypertension tend to have higher blood pressure than children from normotensive families. The correlation in blood pressure between parents and adopted children is significantly lower than between parents and their biological children (32). Children's blood pressure has been related to mother's blood pressure more than to father's blood pressure (41). This has been ascribed to X linked genes. Another possibility is that higher blood pressure in a mother reflects her own fetal experience, which in turn influences the intrauterine environment she provides for her child (41). There is also a greater correlation with low blood pressure between mothers and their children than fathers and their children, suggesting a direct prenatal influence (44). It has also been shown that there is an association between the blood pressure of the children and paternal hypertension. Documentation of paternal blood pressure when fathers were younger is needed in order to assess whether recognising fathers with high normal blood pressures (before they are diagnosed to have hypertension) can identify their offspring at risk of hypertension (44).

Siblings of children with high blood pressure have significantly higher blood pressure than siblings of children with low blood pressure (41).

The possibility that birth weight is a feature of the inherited predisposition to high blood pressure was examined in a cross sectional study of 452. They found that low birth weight is a feature of the inherited predisposition to hypertension this may be due to higher maternal blood pressure during pregnancy (45).

Normotensive children of hypertensive parents may show abnormal physiological responses that are similar to those of their parents. When subjected to stress or competitive tasks, the offspring of hypertensive adults, as a group, respond with greater increases in heart rate and blood pressure than do children of normotensive parents (46).

3.2.3 Relationship between Blood Pressure and Birthweight

Babies who are small at birth tend to have raised blood pressure during adult life. Association between lower birthweight and subsequent higher blood pressure levels have now been shown in three big studies of adults, Barker *et al.*, (47); Hales *et al.*, (48); Low *et al.*, (49); and are consistently found in children under 10 years of age. This relation is less consistently found in adolescence, presumably because the tracking of blood pressure is perturbed by the adolescent growth spurt.

In a study of 50 year old men and women in Preston, England, with raised systolic and diastolic blood pressure a link was found not only to low birth weight but, more strongly, to high placental weight and a lower birthweight. Mean systolic pressure fell by 11mm Hg as birth weight increased from less than 2475 g to more than 3375 g and rose by 15 mm Hg as placental weight increased from less than 450g to more

than 675 g (47,41). These associations, which were highly significant, were independent of their gestational age, current body mass index, and alcohol intake.

Law *et al.*, in their 1991 study (49) measured the blood pressures of 405 children, aged 4 year, and related them to measurements at birth. The opposing relations of systolic pressure to birth weight and placental weight that were demonstrated in 50-year-old men and women in Preston were also present in 4-year-old children, though weaker. Systolic pressure at age 4 was inversely related to birth weight. This was independent of gestational age and implies an association with reduced fetal growth.

The timing of initiation of high blood pressure and the occurrence of amplification were examined by bringing together data from four studies of children and adults in Britain (34, 50, 47,48). In this 1993 study Law et al., (41) found that at all ages beyond infancy, people who had lower birth weight had higher systolic pressure. Though small babies tend to become small children and small adults, systolic pressure is also higher in people who are heavy in childhood and adult life. Thus the highest systolic pressures are found in people who had low birth weight but become heaviest. This group of people has been shown to have a higher prevalence of non-insulin dependent diabetes.

These studies strengthen the suggestion of Folkow (51) that there are two components in the etiology of essential hypertension, an initiating process that raises the blood pressure through persisting changes in vascular structure, and an amplifying process that progressively magnifies the difference throughout life.

Persistent elevation of blood pressure seems to be associated with interference with growth at any stage of gestation, thus two groups of babies may develop high blood pressure in later life. One is thin at birth as indicated by Ponderal index (Weight / Height^3); the other is short in relation to its head size and has above average placental weight (33). Rabbia *et al.*, (52) evaluate the relation of birthweight to blood pressure in adolescence, controlling for factors related to blood pressure, to extrauterine environment, and to maternal risk of fetal distress. The data show that at least in early adolescence, the inverse association between birthweight and blood pressure may be evident only when there are maternal diseases or environmental conditions leading to severe placental hyperperfusion.

The processes underlying the association between poor maternal nutrition and higher blood pressure in the offspring are at present a matter for speculation. In humans little is known about how nutrient intakes in early pregnancy relate to placental and fetal size. Whereas nutrient intakes in late pregnancy have been reported to have inconsistent effects on fetal size, their relation to placental size is largely unknown. Godfrey *et al.,* (53) examined how the nutrient intakes in pregnancy of a group of mothers delivered at term are related to placental and fetal size at birth. It was found that placental and fetal sizes at birth are associated with the mother's intakes of carbohydrate and protein. High carbohydrate intakes in early pregnancy were associated with low placental and birth weights. In late pregnancy low intakes of dairy protein in relation to carbohydrate were also associated with low placental weight. Such an effect could have long-term consequences for the offspring's risk of cardiovascular disease.

A study in Jamaica found that children of mothers who were thin in early pregnancy, having low skinfold thickness, had raised blood pressures at age 10 to 12 years of age, the relation was independent of the child's sex and current weight (54). Support of this hypothesis comes from experimental evidence in which offspring of undernourished pregnant animals show permanent changes including raised blood pressure (42,55).

3.2.4 Diet and Blood Pressure

In adults great efforts have been made to recognize the role diet plays in determining blood pressure so that guiding dietary recommendations can be set as a preventive measure against hypertension. It is equally important to investigate this relationship in children and the effect that it may have on the long-term development of hypertension.

There have been repeated calls for significant reduction in the amount of salt in children's diet in an effort to reduce the risk of hypertension later in life. However, there is no credible evidence demonstrating that such reduction affects the development of hypertension in adult years (56). Salt intake should be matched to sodium requirements, and there is clearly no need for the high levels of sodium intake found in some children's diets. Nevertheless, the homeostatic mechanism that controls sodium levels in the blood is efficient in children permitting wide range of sodium intakes without any significant consequences on blood pressure or long-term health (56).

Some studies indicate that dietary calcium, fibre, and fat may be important determinants of blood pressure levels in children (57, 58). An inverse relationship between calcium and blood pressure has been observed in virtually all population groups studied and across racial groups, even after accounting for age, body mass index, alcohol and other possible confounding factors (59). Calcium plays a role in physiological regulation of both normal and high blood pressure. Studies on children have yielded conflicting results; some support an inverse relationship (58). For example, dietary calcium intake was inversely related to blood pressure in black and white adolescent girls and with systolic blood pressure in black girls, however, other studies do not support this relationship (58,59).

3.2.5 Body Size and Blood Pressure

Body size is the major determinant for blood pressure among children. A direct relation between weight and blood pressure has been documented as early as five years of age and is more prominent in the second decade. An obese child with moderate hypertension should be encouraged to lose weight and the blood pressure measurements subsequently repeated before undergoing investigation and possible treatment (60).

Height is independently related to blood pressure at all ages. Studies showed that body height and body mass, rather than age, is the determining factor of evolution of blood pressure in children as they grow. Larger children (heavier and taller) have higher blood pressure than smaller ones and if levels between the 90^{th} and 95^{th} percentiles are found height should be considered. After controlling for these variables there is no association between age and blood pressure in the decade of

life from five through 14 years of age. Also sex and race do not have the same impact on blood pressure in children as in adults (61,62).

3.2.6 Treatment of Hypertension in Children and Adolescents

Both nonpharmacologic and pharmacologic approaches to treatment are useful in managing children with elevated blood pressure.

The nonpharmacologic therapy is used when hypertension is borderline and it is therefore advisable to avoid labeling the child as hypertensive, instead the term 'high normal blood pressure' is used. These patients are advised to reduce weight, which may lead to a decrease in both systolic and diastolic pressure; to increase their physical activity as blood pressure is directly related to the degree of physical fitness, which effect occurs gradually over a period of months. Combining physical activity with weight reduction enhances the beneficial effect on blood pressure. Reduction in sodium intake also is important, as it reduces the blood pressure 5-10mmHg, which is similar to the effect of weight reduction. Nonpharmacologic therapy should be introduced not only in the care of patients with hypertension but also in children with high-normal blood pressure (90^{th} to 95^{th} percentile blood pressure distribution) and to complement drug therapy for patients with severe hypertension (2).

The pharmacologic therapy should be used for those who undoubtedly have high levels of blood pressure or suffer from symptoms or signs caused by hypertension.

4.0 Methods

4.1 Subjects

As this pilot study was a follow-up five years later of a previous study, the same participants and their children were selected. It was decided that only participants who were residing in Palmerston North City during the initial study would be contacted for the pilot. The procedure of contacting the participant was done in several steps. Initially, the participant received a letter from the principle investigator of the original study telling them about this pilot study. Then, the researcher sent the participants an information sheet to explain the purpose of the study, and the information and measurements to be obtained from them (Appendix One). One week later the researcher contacted the participants on the phone and the study was further discussed. The place and time of visit was also arranged, which in all cases was at the participants home. An assistant accompanied the researcher at all visits.

Eighty subjects were residents of Palmerston North City, representing 40% of the original sample. Only 50 subjects could be contacted; failure of contact with the others was due to relocation within New Zealand, leaving the country, or other causes. Of the 50 subjects contacted, 30 agreed to participate in the follow-up study. The study consisted of four main parts

4.2 Anthropometry

Measurements were made of weight, height, and head circumference for the children. Upper arm circumference was used instead of skinfold thickness for its practicability in the field survey.

The weight of the mother and her child was measured to the nearest 0.1 kg on portable digital electronic scales, calibrated twice per week at the Nutrition Laboratory of Massey University. Since the measurements were done in the

participants' residence, care was taken to put the scales on a sturdy, flat surface each time. First, mother's weight was measured twice and then child's weight was measured twice. Mean weights for mother and for child were used in analyses. No adjustments were made for clothing.

The height of the child was measured in Frankfurt plane using a portable stadiometer, which was placed against a hard flat wall; the child was barefoot, his/her hair was unbraided not to interfere with the measurement. Measurements were approximated to the nearest millimeter. Children's height was measured twice and the mean taken. Mothers' height was measured in the original study.

Arm circumference was measured using a non-stretchable fiberglass tape measure. The midpoint of the child's left upper arm was calculated as follows: first locating the tip of the child's shoulder, bending the child's elbow to make a right angle, and measuring the distant in between them, this number was then divided by two to estimate the midpoint. The measurements were taken to the nearest 0.1millimeter.

All the measurements were done by two people, the researcher and an assistant. The researcher was the measurer who held the child and took the measurements. The assistant helped hold the child and record the measurements on the measurement sheet.

4.3 Blood pressure

Blood pressure was measured using a standard mercury sphygmomanometer and auscultation for both the mother and her child. This method was decided to be more accurate because current blood-pressure standards are based on these measurements; whereas no standards for automated devices are available (37).

Two cuffs were used: an adult size for the mother, and an 8 cm cuff for the child, to completely encircle the upper arm and ensure uniform compression. The cuff covered about two thirds of the distance between the shoulder and elbow. The right arm was used, as it is preferable for consistency and comparison with standard tables.

Blood pressure was measured in a relaxed environment to avoid a falsely high reading caused by anxiety. Blood pressure was measured in the second half of the visit. The children were told about the steps of measurement and what blood pressure meant in simple language. Again the blood pressure of the mother was measured first to assure the child it would not be a painful procedure.

Systolic pressure was indicated by the appearance of the 1st Korotkoff sound, and phase 5 Korotkoff sound was used to determine diastolic pressure. Two readings were taken with a 15-minute interval, the mean was calculated. Both readings were measured in the same position. Blood pressure was not measured while the child or mother was watching TV, or eating because such situations are considered to be stressful (46).

4.4 Assessment of Dietary Intake

In this study the twenty-four-hour record-recall method was used to assess dietary intake. The forms for the 24-hour-record-recall were posted to the participants prior to the planned home visit (Appendix Two). The mother was asked to record everything her child ate or drank for the entire day before the researcher's visit, from midnight to midnight. The mother was asked to include the cooking methods and brand names (if possible), and to record the amount eaten. Quantities of foods consumed were to be estimated in household measures.

The mother was also asked to include any vitamin and mineral supplements given to the child. All participants had experience in dietary recording gained from participation in the first study. During the visit, dietary records were discussed, to ensure that all details were included and the quantities eaten were discussed as well as, the exact brands of food and the methods of preparation.

4.5 Questionnaire

The questionnaire was designed to address three issues: the first part concentrated on the occurrence of atopic symptoms, including asthma. The second part discussed feeding of the child during the first two years of life including questions on breastfeeding. The third part was about the general health and activity of the child (Appendix Two). The questionnaire was administered in an interview between the participant and the researcher during the home visit. The researcher explained and clarified the questions, gave examples, and showed pictures of conditions that were the topic to some of the questions e.g. eczema (Appendix Two).

4.6 Analysis of results

The results are expressed as means and standard deviations. All the results presented are based on the mean of two readings. Because most variables were skewed, non-parametric tests were used for comparisons. There is a probability that with increased numbers in samples some variables might change into normal distribution. In the future parametric tests might be used for comparison when appropriate. The data was analyzed using the statistical package for the social sciences (SPSS). Correlation coefficients were used to investigate relations among the numerical variables. The total number of the children in the pilot study was 30,

15 were boys and 15 girls. However, the data obtained were analyzed as one sample due to its small number. Analysis of the first part of the questionnaire showed that 16.7% (5 children of the sample) suffered from asthma at the time of the survey, while about 23.3% had experienced wheezing attacks at some stage of their lives.

Feedback was sent to the participants, which included the anthropometric measurements, and blood pressure measurements.

5.0 Results

5.1 Anthropometric Measurement

Table 5.1a shows the characteristics of the 30 children on whom data were collected. The mean age of the children in the sample was 5.8 (SD .6) years, their mean weight was 21.7 (SD 2.7) kg, and their mean height was 115 (SD 5.6) cm.

Table 5.1a: Anthropometric description of the children in the study (n=30).

Character	Minimum	Maximum	Mean	SD
Age (yr)	5	6.8	5.8	0.6
Weight (kg)	16.9	27.4	21.7	2.7
Height (cm)	106.9	127.9	115	5.6
Head Circumference (cm)	49.5	55	52.4	1.3
Arm Circumference (cm)	16.45	22.5	18.5	1.1

SD= Standard Deviation

The mothers mean weight before pregnancy was 61kg, 6 weeks after delivery it was 68kg (data obtained from the initial study). In the pilot study the mean weight of the mothers was 69 kg. One of the mothers was pregnant at the time of the pilot study. 50% of the participants became pregnant after the initial study, 27% had more than one pregnancy.

5.2 Dietary Intake of the Children in the Sample

Feeding in the First Years of Life

- Non-asthmatic children: All children were breastfed. Exclusive breastfeeding for more than 4 months was practiced for 64% of children. Breastfeeding was discontinued between 6-12months for 48% of the children, while 36% stopped after age of one year. Standard or follow-on formula was used for 44% of the infants who were breastfed. Formula was stopped in the first year of life for 78% of the children. Cow's milk was started in the first year of life for 64% of the infants. 6.7% of the children had never been given cow's milk, because their mothers thought it could cause an allergy.

- Asthmatic children: All the asthmatic children were breastfed, with 60% of the asthmatic children being exclusively breastfed for more than 4 months, almost the same as non-asthmatic. Breastfeeding was stopped between 6-12 months of age in 60% of the asthmatic children, while 20% stopped after age of one year. Standard formula or follow-on formula was used for 40% of the asthmatic children. Formula was stopped before the age of one year for 50% of infants. Cow's milk was introduced after the age of one year for 60% of the asthmatic children.

24-hour dietary intake

The analysis of the 24-hour record recall dietary intake of the children revealed that almost all the children in the sample had two main meals and three to four snacks in the day.

Table (5.2a) demonstrates the major nutrient intake of all children in the study. Mean energy intake was 6642.2 (SD 1343.8) kJ, which is 98% of the recommended dietary intake (RDI), mean intake of protein was 48.7 (SD 9.5) g which is 270% of the RDI.

Table 5.2a: The mean intake of macronutrients of children in the study (n=30).

Nutrient	Minimum	Maximum	Mean	SD
Energy (kJ)	4215	9028	6642.2	1343.8
(% of RDI)	(56%)	(130 %)	(98%)	
Protein (g)	29.2	68.2	48.7	9.5
(% of RDI)	(162%)	(379%)	(270%)	
Fat (g)	26.1	90.3	55.3	9.5
Carbohydrates (g)	131.2	325.6	225.9	52.5

kJ = Kilojoule g= grams RDI= recommended dietary intake (Australian).

Table (5.2b) demonstrates the intake of some micronutrients for all the children in the study, and the percentage of RDI for their age group (5-7 years) that this represents. Almost all of the micronutrient intakes are above 70% of RDI except selenium.

Table 5.2b: Intake of selected micronutrients of children in the study (n=30)

	Mean	% of RDI	SE	SD
Vitamin A (μg)	708.5	142%	105	575
Vitamin C (mg)	94.1	209%	14	77
Vitamin E (mg)	6.3	90%	0.6	3.2
Zinc (mg)	6.8	75%	0.3	1.6
Selenium (μg)	23.6	47%	1.7	9
Magnesium (mg)	200	111%	7.5	201
Sodium (mg)	2197.5	95%	102.2	560
Iron (mg)	8.7	108%	0.5	2.9

5.3 Asthma

Relationship Between Head Circumference at Birth, Birthweight and Asthma

The Mann-Whitney "U" test was used to account for the skewed data. The Mann-Whitney is non-parametric test that is performed by combining two data sets, comparing them to each other, then sorting them in ascending orders, assigning to each of them a mean rank. Adding up of the mean ranks gives the sum of rank. If the two sets of data have the same distribution then the sum of ranks would be close to each other.

Table 5.3a shows the relationship between asthma and birthweight and head circumference at birth. No difference in these measurements at birth was found between asthmatics and non-asthmatics.

The mean head circumference at birth of asthmatic children in the study was 35.6 cm, while the mean head circumference at birth of non-asthmatic children was 36 cm. However at the time of the study the mean head circumference of the asthmatic children was 52.6 cm, and the non-asthmatic children it was 52.3 cm.

Table 5.3a:The mean ranks of head circumference at birth, birthweight in asthmatic and non-asthmatic children.

	Asthma	Number	Mean Rank	Sum of Ranks
HC	**Yes**	5	10.9	54.5
	No	22	14.7	323.5
	Total	27*		
BW	**Yes**	5	15.2	76
	No	25	15.6	389
	Total	30		

**Head circumference at birth was not recorded for three children. HC= Head circumference, BW= Birthweight*

In table (5.3b) a different non-parametric test was used to test the relationship between birthweight, and head circumference and asthma. This table demonstrates that the relationship is not significant (p= .933) and (p=.314) respectively.

Table 5.3b: Test of significance of the relationship between head circumference at birth, birthweight and asthma.

	Head Circumference at Birth	Child's Birthweight
Mann-Whitney U	39.5	61
Wilcoxon W	54.5	76
Z	-1.007	-.083
Asymp. Sig. (2-tailed)	p=.314	p=.933
Exact sig. [2* (1-tailed) sig.]	.344	.957

Asthma and Children's Diet

Table (5.3c) shows the intake of energy and major nutrient intake in asthmatic and non-asthmatic children. The energy intake of asthmatic children was 83% of that of non-asthmatic children. The protein intake of asthmatic children was 79% of that of non-asthmatic children. For fat the intake of asthmatic children was also 82% of that of non-asthmatic children and carbohydrate intake of the asthmatic children was 86% of that of non-asthmatic children.

Table 5.3c: Major nutrient intake in asthmatic and non-asthmatic children

NUTRIENT	ASTHMATIC	NON-ASTHMATIC
Energy (kJ)	5713	6828
Protein (g)	39.9	50.4
Fat (g)	46.7	56.9
Carbohydrates (g)	198.3	231.5

kJ =kilo joule g = gram RDA= recommended dietary Intake

Table (5.3d) demonstrates the mean rank of some micronutrients intake in asthmatic and non-asthmatic. The intake of vitamins A, C, and E and magnesium is lower in asthmatic compared to non-asthmatic children in variable degrees.

Table 5.3d: Mean ranks of the intake of some micronutrients in asthmatic and non-asthmatic children

Nutrient	Asthmatic (n=5)		Non-asthmatic (n=25)	
	Mean Rank	Sum of Ranks	Mean Rank	Sum of Ranks
Iron (mg)	16.10	80.50	15.38	384.50
Selenium (μg)	14.20	71.00	15.76	394.00
Magnesium (mg)	8.40	42.00	16.92	423.00
Copper (mg)	8.90	44.50	16.82	420.50
Zinc (mg)	14.00	70.00	15.80	395.00
Sodium (mg)	10.40	52.00	16.52	413.00
Vitamin A (μg)	5.80	29.00	17.44	436.00
Vitamin C (mg)	7.80	39.00	17.04	426.00
Vitamin E (mg)	6.40	32.00	17.32	433.00

Table (5.3e) shows the intake of micronutrients in asthmatics, tested in various non-parametric tests. Vitamins A and E intake was low compared to the intake of non-asthmatics with high statistical significance (p= .007) and (p= .011) respectively. For Vitamin C, and magnesium, the intake was also low compared to the intake of non-asthmatics but with less tendency to become significant (p= .032) and (p= .048) respectively.

Table 5.3e: Tests of significant of intake of selected micronutrients in asthmatic children.

	Mann-Whitney U	**Wilcoxon W**	**Z**	**Asym. Sig. (2-tailed)**	**Exact Sig. 2*(1-tailed)**
Vitamin A	14.0	29.0	-2.699	P= 0.007	0.005
Vitamin C	24.0	39.0	-2.142	P= 0.032	0.031
Vitamin E	17.0	32.0	-2.532	P= 0.011	0.009
Iron	59.5	384.5	- 0.167	P= 0.867	0.872
Magnesium	27.0	42.0	-1.976	P= 0.048	0.049
Selenium	56.0	71.0	- 0.362	P= 0 .718	0.746
Copper	29.5	44.5	-1.838	P=0.066	0.065
Zinc	55.0	70.0	- 0.417	P= 0.676	0.706
Sodium	37.0	52.0	-1.419	P= 0.156	0.169

Asthma and Growth

Tables (5.3f) and (5.3g) show the mean and mean rank of the measurements in asthmatic and non-asthmatic children. There is no significant difference in the anthropometric measurements of the two groups.

Table 5.3f: Mean of anthropometric measurements of asthmatic and non-asthmatic children

	Asthmatic	**Non-asthmatic**
Weight (kg)	20.5	21.9
Height (cm)	112.3	115.6
Head Circumference (cm)	52.6	52.3
Arm Circumference (cm)	18.0	18.6

Table 5.3g: Mean rank of current weight and height in asthmatic and non-asthmatic children

	Asthma	**Number**	**Mean Rank**	**Sum of Ranks**
Current Body Weight/ kg	**Yes**	5	11.1	55.5
	No	25	16.4	409.5
	Total	30		
Current Height /cm	**Yes**	5	10.9	54.5
	No	25	16.4	410.5
	Total	30		

Table (5.3h) demonstrates that there is no significant difference in current weight and height of asthmatic and non-asthmatic children (p= .221) and (p=.200) respectively.

Table 5.3h: Test of significant of relationship between asthma and body weight and height

	Current Weight (kg)	Current Height (cm)
Mann-Whitney U	40.5	39.5
Wilcoxon W	55.5	54.5
Z	-1.225	-1.28
Asymp. Sig. (2-tailed	p =.221	p =.2
Exact Sig. [2* (1-tailed sig.)]	0.229	0.208

5.4 Blood Pressure

Characteristics of blood pressure of the population in the sample

Table (5.4a) shows the characteristics of blood pressure of both mothers and their children. According to tables 3.2a to 3.2d, the blood pressure of all children involved in the study were within normal range for their age. For the mothers, mean blood pressure was within normal range as well, (average blood pressure for normal adults is 120/ 80 mmHg).

Table 5.4a: The characteristic of blood pressure of the population in the study.

	Mother's Blood Pressure		Child's Blood Pressure	
	Systolic mmHg	Diastolic mmHg	Systolic mmHg	Diastolic mmHg
Mean	109.9	75.5	89.8	64.1
SE	1.9	1.5	1.7	1.1
SD	10.6	7.9	9.5	6.2
Range	47.5	32.5	40	25
Minimum	90	60	70	55
Maximum	137.5	92.5	110	80

Relationship Between Mother's and Child's Blood Pressure

The correlation coefficient was used to investigate the relationship between mother's and child's blood pressure, both systolic table (5.4b) and diastolic table (5.4c). It was found that no significant relationship could be established between systolic blood pressure of the mothers and that of their children. (p= .581).

Table 5.4b: Correlation between mother's and child's systolic blood pressure

			Child's SBP	Mother's SBP
Spearman's rho	**Child's SBP**	**Correlation Coefficient**	1.000	0.105
		Sig. (2- tailed)		p=.581
	Mother's SBP	**Correlation Coefficient**	0.105	1.000
		Sig. (2- tailed)	0.581	

SBP= Systolic Blood Pressure.

In the same time the correlation between mother's and child's diastolic blood pressure showed a tendency to significance (p=.08). This means that blood pressures of the mother and child go in the same direction; i.e. if the diastolic blood pressure of the mother increases, the child's diastolic blood pressure increases as well.

Table 5.4c: Correlation between mother's and child's diastolic blood pressure

			Child's DBP	Mother's DBP
Spearman's rho	**Child's DBP**	**Correlation Coefficient**	1.000	.325
		Sig. (2- tailed)	.	p=.08
	Mother's DBP	**Correlation Coefficient**	.325	1.000
		Sig. (2- tailed)	p=.080	.

DBP= Diastolic Blood Pressure.

Relationship between the Child's Birthweight and Blood Pressure

Table (5.4d) shows the correlation coefficient between child's birthweight and systolic blood pressure. The relationship shows a tendency towards significance (p=.082). This means there is an inverse relationship between systolic blood pressure and birthweight.

Table 5.4d: Correlation between child's birthweight and systolic blood pressure

			Child's SBP	Child's BW
Spearman's rho	**Child's SBP**	**Correlation Coefficient**	1.000	.322
		Sig. (2-tailed)	.	.082
	Child's BW	**Correlation Coefficient**	.322	1.000
		Sig. (2- tailed)	.082	.

SBP= systolic blood pressure, BW = birthweight

Table (5.4e), gives the correlation coefficient between mother's diastolic blood pressure and child's diastolic blood pressure. The relationship is not significant (p= .865).

Table 5.4e: Correlation between child's birthweight and diastolic blood pressure

			Child's DBP	Child's BW
Spearman's rho	**Child's DBP**	**Correlation Coefficient**	1.000	.077
		Sig. (2-tailed)	.	.685
	Child's BW	**Correlation Coefficient**	.077	1.000
		Sig. (2- tailed)	.685	.

DBP= diastolic blood pressure BW= Birthweight

6.0 Discussion of results

In this pilot study, the sample consisted of 30 children and their mothers. Of the children, 15 were boys and 15 were girls. The mean age of the children at the time of the study was 5.8 years.

Anthropometric measurements

Anthropometric measurements during the growing period of childhood are among the most useful criteria for assessing the health and nutritional status of children (63). The usual measurements are those made to assess:

- Body mass as judged by weight.
- Linear dimensions, especially height.
- Body composition and reserves of calories and protein, as judged by subcutaneous fat and muscle.

This classification gives the current nutritional status of the individual and indicates whether malnutrition, when present, is chronic (63,64,65).

In this study, weight, height, head circumference, and upper arm circumference, were used to assess the growth of the children. Comparing the anthropometric measurements of the children involved in the study with reference standards growth curves (66), growth of the children was found to be within normal ranges for their age.

Dietary intake

In this pilot study, the analysis of children's diet was based on a single 24-hour-dietary-record-recall for each child. Comparing the mean intake of major nutrients with the recommended dietary intake (RDI), it was found that the mean intake of energy was within about 98% of RDI for their age group, but for protein it was almost 3 times RDI (270%), and mean fat intake was 55.3 g per day, which is almost double the recommended amount, of 30 grams per day.

A point of interest noted during the dietary survey was the strict avoidance of cow's milk products in 6.7% of the children. This was due to the mothers' belief that cow's milk is a cause of allergy. Most of these children were prohibited from ingesting cow's milk from birth and had not experienced cow's milk protein allergy.

Objective one: To find if there is a relationship between atopic diseases and early childhood diet and growth.

Asthma is recognized to affect growth. The delay in growth is more in those with severe asthma, but may occur regardless of the severity. In addition treatment of asthma, particularly the use of steroids, may have its effect on growth as well (9). However, in this pilot study the difference in growth between asthmatic and non-asthmatic children was not significant. Mean weight for asthmatic children was 20.5 kg, for non-asthmatics 21.9 kg. Mean height for asthmatics was 112.3 cm and for non-asthmatics 115.6 cm. This may be explained by a good control of asthma or that the asthma was not severe. On the other hand the number of asthmatic children in this pilot study sample may have been too few to show reliable relationship between growth and asthma.

No difference in head circumference at birth between asthmatic and non-asthmatic children was found; these results do not support the suggested relationship between head circumference at birth and the future development of asthma, again this could be due to the small number of asthmatic children in the sample of this pilot study (12,13).

After analyzing the diet of the children in the first two years of life, no difference between asthmatics and non-asthmatics could be found. However, it was noted that none of the children for whom cow's milk was excluded from their diet in the first year of life developed asthma; the significance of this observation is not clear. Prospective studies have found that breastfeeding has a transient beneficial effect on the incidence of eczema, food allergy, atopic sensitization and wheezing illnesses in the first three years of life. However, there is little evidence for a persistent protective effect of breastfeeding on the incidence of childhood asthma. It is concluded that breastfeeding is probably prophylactic against atopic disease food allergy throughout childhood and adolescence (28).

Analyses of the diet of asthmatic and non-asthmatic children revealed no significant difference in their intake of protein, carbohydrates, and fat. However the intake of Vitamin A and E were significantly lower in asthmatic than non-asthmatic. For Vitamin C and magnesium the intake also was lower in asthmatic with tendency toward significance.

Objective Two: To find the relationship between birthweight and blood pressure in childhood.

Many of the studies investigating the relationship between birthweight and hypertension are retrospective, where the occurrence of cardiovascular disease including hypertension was related to weight at birth (32,33,37,38). This observation was also demonstrated in children although it is weaker (38). This hypothesis is intriguing and of great, concern for public health because it implies that interventions to prevent the onset of adult vascular disease should begin in prenatal life. The findings of the current pilot study support this relationship as an inverse relationship between child's systolic pressure and birthweight ($p=0.82$). This could not however be found for diastolic blood pressure.

Objective three: To find a relationship between mother and child blood pressure.

Early studies showed that the first-degree relatives of hypertensive subjects are more likely to have hypertension than are first-degree relatives of normotensive individuals. Similarity of blood pressure within families is not restricted to hypertensives and is seen equally in low or middle levels of blood pressure. This observation implies that familial factors operate at all levels of blood pressure (36).

A direct relation between mothers' diastolic blood pressure and that of their children with tendency to be significant was found in the current pilot study. This conforms to other studies. On the other hand, a relationship between mothers' systolic pressure and that of their children was not found in this study.

7.0 SUGGESTIONS ARISING FROM THE PILOT STUDY FOR THE MAIN FOLLOW-UP STUDY

Suggestions for the dietary method

Dietary methods designed to characterise usual intakes of individuals are the most difficult to validate, because the 'truth' is never known with absolute certainty, even if the actual food intake is monitored from weighed observation (67). Quantitative methods such as recalls or records are designed to measure actual or usual nutrient intake at an individual or group level, depending on the number of measurement days, and/or the size of the study group (66). A single 24-hour record or recall should not be used to assess dietary status or to relate nutrient intake to a clinical outcome i.e. asthma incidence.

Assessing the diet of children is more challenging than assessing the diet of adults. Children tend to have diets that are highly variable from day to day, and their food habits can change rapidly. They are less able to recall, estimate, and cooperate in the usual dietary assessment procedures; so much information by necessity has to be obtained by surrogate reporters.

In the main study, the same dietary method may be used but with increased number of days. Three to five 24-record-recall-dietary intakes should be used to account for variation in eating patterns between weekdays and weekends. Nonconsecutive days are preferable, because eating behaviors on consecutive days are correlated. This method may provide more accurate information on individual dietary intakes.

Suggestion for the questionnaire

- The following foods are particularly associated with allergic reactions: egg white, peanut, cow's milk, cod, kiwifruit, shrimp, chicken, peanut oil and hazel nut (75). Some 20-60% of people with asthma report food as a trigger factor. The presence of these foods and the relation to the asthma symptoms was not explored in this pilot study. However, in the main study it may be useful to estimate the effect of these incriminated foods in the study sample.
- The questionnaire may have to be designed to estimate the severity of asthma including the use of steroids.

The following are some of the suggested questions to be added to the questionnaire:

1- In the past 12 months, how often, on average, has your child's sleep been disturbed due to wheezing?

A- Never woken with wheezing

B- Less than one night per week

C- One or more nights per week

2- How many attacks of wheezing has your child had in the last 12 months?

A- None

B- 1 to 3

C- 4 to 12

D- More than 12

3- In the past 12 months how much did wheezing interfere with your child's daily activity?

A- Not at all
B- A little
C- A moderate amount
D- A lot

4- Has your child used any inhaled medicines (such as a nebuliser or puffer / aerosol with spacing device)?

A- No
B- Yes
C- Can't remember/ don't know

5- Has your child used any of the following medicines?

A- Ventodisk / Ventolin / Salbutamol
B- Bricanyl / Terbutaline Sulphate
C- Atrovent / Ipatropium
D- Becodisk / Becotide / Becloforte / Beclomethasone
E- Pulmicort / Budesonide
F- Intal / Vicrom / Sodium Cromoglycate
G- Tilade / Nedocromil
H- Flixotide / Fluticasone / Cutivate
I- Serevent / Salmeterol
J- Predinisone
K- Zasten / Ketotifen
L- Can't remember / Don't know

6- Is your child currently taking any of the medications listed in question 5?

A- No

B- Yes

C- Can't remember /don't know

7- Has had an allergic reactions to any type of food? (Allergic reactions, means, swelling, difficulty in breathing, severe vomiting occurring within one hour).

A- No

B- Yes

What foods: _____

_____

_____

C- Can't remember / don't know

Suggestions for blood pressure measurement

- Although the children's blood pressure is more closely related to the mother's than the father's blood pressure; in the main study blood pressure of both parents and of siblings should be measured to explore the interrelationships of blood pressure in the family.
- Blood pressure should probably be measured more than once on different days.

8.0 Summary

This pilot study which, involved 30 mothers and their children, showed that the growth of the children was within the normal range for their age, and that 16.7% of the children had asthma at the time of the study. There was no difference in the anthropometric measurements at birth between the asthmatic and non-asthmatic children nor was their a difference at the time of the pilot study.

When the diet of asthmatic and non asthmatic children was compared, there was no difference in the intake of major nutrients, however, the intake of vitamin A and E was significantly lower in asthmatic than the non asthmatic, while the intake of Vitamin C and magnesium were also lower in asthmatic but to a lesser extent.

A direct relationship between mother's diastolic blood pressure and that of her child has been found, but could not be found for systolic blood pressure. These findings support the suggestion of the similarity of blood pressure within the family (36).

A weak inverse relationship between the child's birthweight and their systolic blood pressure was found, while no relationship was found between the children's birthweight and diastolic blood pressure.

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APPENDIX TWO

PALMERSTON NORTH CAMPUS
Institute of Food, Nutrition and Human Health

Follow-up Study of the Dietary Intake, Anthropometric Measurements, and Blood Pressure in Children Born to Women in the Manawatu Pregnancy Study.

Dear.....

Thank you very much indeed for taking part in this study. Your assistance and co-operation in the data collection is greatly appreciated, as without your help the study would have failed.

We have included your child's blood pressure readings, weight and height as well as your blood pressure readings and body weight.

The 24-hour diet record of your child was quite helpful in trying to find out if a certain type of food is related to allergic diseases. However, we can not comment on your child's overall diet using one-day record as children's diet can change from day to day, like for example your child could have a party or could have been feeling unwell on the day of recording.

If you have any questions about these results please don't hesitate to call us.

Mrs. Entesar Al-Shami [redacted]59
Mrs. Patsy Watson **(06) 356-9099 Ext. 9627**
Mrs. Heather McClean **(06) 356-9099 Ext. 6114**

Thank you for your help.

Best wishes
Entesar Al-Shami

PALMERSTON NORTH CAMPUS
Institute of Food, Nutrition and Human Health

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MEASUREMENTS

Date: _____

Measurer: _____

Code No: _____

MEASUREMENTS OF THE MOTHER

Weight: _____(Kg)

_____(Kg)

_____(Kg)

Mean:_____(Kg)

Blood Pressure: _____(mm Hg)

_____(mm Hg)

_____(mm Hg)

Mean:_____(mm Hg)

MEASUREMENTS OF THE CHILD

Weight: _____(Kg)

_____(Kg) Mean: _____(Kg)

_____(Kg)

Height:_____(cm)

_____(cm) Mean: _____(cm)

_____(cm)

Head circumference:_____(cm)

_____(cm) Mean:_____(cm)

_____(cm)

Upper arm circumference:_____(cm)

_____(cm) Mean:_____(cm)

_____(cm)

Blood pressure: _____(mmHg)

_____(mmHg) Mean_____(mmHg)

_____(mmHg)

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CHILD'S 24 HOUR DIET RECORD

Date:..... Code No:.....

Interviewer name:.....

Phone: Mrs. Entesar Al-Shami : [redacted]

PROCEDURE FOR THE MOTHER

Please write down on the attached sheets, everything your child eats or drinks all the day before our visit, from midnight to midnight. Include everything your child had to eat and drink at home and away- even snacks and sweets. Include what your child has at school or kindergarten, or at friend's houses.

Use a new line for each item of food or drink.

Eating time column: write down the time your child eats/ drinks, e.g. 8 am, 10 am etc.

Amount or volume consumed column: Write down how much of this food your child actually ate or drank?

Food/beverage name column: Write down the name of the food and how this food was prepared?

Now, please read what you have written down and try to remember anything else your child ate or drank on that day that you haven't already written, even if you are not sure of the amount (s).

We will go through the list once more during our visit.

Eating Time	Food and Beverage Name, Brand, Description, Preparation (i.e. Boiling, Frying, Microwave, etc.), include recipe if necessary	Amount or Volume Consumed

DON'T FORGET SNACKS

AND SWEETS

FIZZY DRINKS TOO!

INCLUDE FRUITS

AND DON'T FORGET THE LUNCH BOX

PALMERSTON NORTH CAMPUS
Institute of Food, Nutrition and Human Health

Follow-up Study of the Dietary Intake, Anthropometric Measurements, and Blood Pressure in Children Born to Women in the Manawatu Pregnancy Study.

Date:.....
No:.....

Code

Interviewer name:.....

QUESTIONS ON WHEEZING

1) Has your child had wheezing or whistling in the chest in the last 12 months?

Q1

Yes=1
No= 2
Don't know=9 ☐

2) Has your child **ever** had wheezing or whistling in the chest at any time in the past?

Q2

Yes=1
No= 2
Don't know=9 ☐

3) Has your child **ever** had asthma?

Q3

Yes=1
No= 2
Don't know=9 ☐

4) In the last months, has wheezing ever been severe enough to limit your child's speech to only one or two words at a time between breaths?

Q4

Yes=1
No= 2
Don't know=9 ☐

5) In the last 12 months has your child's chest sounded wheezy during or after exercise?

Q5

Yes=1
No= 2
Don't know=9

QUESTIONS ON RHINITIS

All questions are about problems which occur when your child DOES NOT have a cold or the 'flu.

6) Has your child **ever** had a problem with sneezing or a runny or blocked nose, when he/she DID NOT have a cold or the 'flu?

Q6

Yes=1
No= 2
Don't know=9

7) In the past 12 months, has your child has a problem with sneezing or a runny or blocked nose, when he/she DID NOT have a cold or the 'flu?

Q7

Yes=1
No= 2
Don't know=9

8) In the past 12 months, has this nose problem been accompanied by itchy watery eyes?

Q8

Yes=1
No= 2
Don't know=9

9) Has your child **ever** had hay fever?

Q9

Yes=1
No= 2
Don't know=9

10) In the last years has your child ever had any itchy skin condition?- by itchy we mean scratching or rubbing the skin.

Q10

Yes=1
No= 2
Don't know=9

11) How old was your child when this skin condition began?

Q11

Yes=1
No= 2
Don't know=9

12) Has the skin condition **ever** affected the skin creases in the past?- by skin creases we mean front of elbows, behind the knees, front of ankles, around the neck, or around the eyes.

Q12

Yes=1
No= 2
Don't know=9

13) In the last year has your child suffered from any of the following skin complaints?

a) eczema

Q13

a)

Yes=1
No= 2
Don't know=9

b) warts

b)

Yes=1
No= 2
Don't know=9

c) psoriasis (a disease of the skin, with thickened red blotches with a scaly surface, most often on the scalp, back, and arms)

c)

Yes=1
No= 2
Don't know=9

d) scabies

d)

Yes=1
No= 2
Don't know=9

e) nits/head lice

e)

Yes=1
No= 2
Don't know=9

QUESTIONS ON FEEDING

14) Did you breastfeed your child at any time?

Q14

Yes=1
No= 2
Don't know=9

IF MOTHER DID BREASTFEED HER CHILD AT ANY TIME

15) Can you remember for how long your child was exclusively breastfed (i.e. not given formula milk)?

Q15

Not at all= 1
<4 months=2
>4 months=3
Don't know=9

16) Can you remember how old your child was when he/she stopped having breast milk, even at bedtime?

Q16

<6 months= 1
6-12 months= 2
>12 months= 3
Don't know=9

17) Can you remember what kind of milk other than breast milk you gave your child?

Q17

Standard infant formula=1
Standard follow-on formula= 2
Cow's milk= 3
Soy formula= 4
Goat's milk=5
Don't know=9

18) Can you remember how old your child was when he/she stopped having any infant formula or follow-on formula even at bedtime?

Q18

_____ months

19) How old your child was when he/she started taking cow's milk?

Q19

_____ months

20) Can you remember the first few solid foods your child had?

QUESTIONS ON LEVEL OF ACTIVITY

21) How do you describe your child's level of activity?

Q21

Not active=1
Mildly active=2
Moderately active=3
Very active=4
Don't know= 9

22) How many hours per day does your child watch television?

Q22

< 2 hours= 1
2-4 hours= 2
> 4 hours= 3
Don't know= 9

QUESTIONS ON GENERAL HEALTH

23) Has your child had any serious health problems since birth? (like pneumonia, urinary tract (kidney) infection, meningitis.....)

Q 23

Yes=1
No= 2
Don't know=9

If the answer is "YES" please state.

---

24) Has your child been **ever** hospitalized since birth?

Q24

Yes=1
No= 2
Don't know=9

If "YES", what was the problem.

QUESTIONS ON OTHER PREGNANCIES

25) Are you pregnant now?

Q25

Yes=1
No= 2
Don't know=9

26) Have you had any other pregnancies since your child (mention child by name) was born?

Q26

Yes=1
No= 2
Don't know=9

If "YES" how many?

Q27

One pregnancy=1
Two pregnancies=2
Three pregnancies=3
More than three=4