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Evaluation of Phenylketonuria and Congenital Hypothyroidism Newborn Screening Program in Gaza Governorates

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Evaluation of Phenylketonuria and Congenital Hypothyroidism Newborn Screening Program in Gaza Governorates

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Dedication

To my parents who have been always supporting me…
To my brothers and sisters and friends for their love
I dedicated this work to
Those who gave me every opportunity of success

Niveen Talal Jadallah

Declaration

I certify that all this thesis submitted for the degree of Master is the result of my own research, except where otherwise acknowledged and that this thesis (or any part of the same) has not been submitted for a higher degree to any other university or institution.

Signed: Niveen Talal Jadallah

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Abstract

Newborn screening is a public health program that aims at the early identification of conditions in which early and timely interventions can lead to the elimination or reduction of associated mortality, morbidity, and disabilities. The evaluation of Phenylketonuria and Congenital Hypothyroidism newborn screening program in Gaza governorates which could and will aid in the improvement of health services and support controlling and preventing their deterioration.

The study design was a cross sectional, considering three different component of the newborn screening program; parents, Guthnie screening card, and health care providers. A geographically, proportional stratified sample was used to select parents (400) and a simple random sample technique was used to select cards (300) while the study involved all health care providers(107) who provided vaccination services and newborn screening test.

The findings of this study showed that the cards filled with required data represented 34.7% cards while 65.3 % had missed data in an area or another. Among cards that were completely documented 81% were from UNRWA clinic while 19% were from governmental clinics. There was a statistical significant relationship between sample collection date and governorate. The percentage was 7.1 in North, 57.1% in Gaza 62.7% in middle zone, 26.7 % in Khanyouis and 57.1% in Rafah. The suitability of blood sample for test was assessed and the results showed that the UNRWA samples were more suitable than governmental clinics; they were 87.4%, 59.4% respectively.

There was apparent knowledge deficit regarding the newborn screening tests among both the health care providers as well as the parents. Only 24% of parents knew what was done for their newborns before drawing the specimen. Health care providers who revealed to be familiar with congenital hypothyroidism test were limited (46.4%) in congruously knowledge about PKU was high (92%).

The study reflected that 38% of health care providers give health education before drawing the sample and 47% claimed to give health education during antenatal care. On the other hand, a clear gap was observed between health care provider's claims and the parent's opinion of the information they have received. The parents who showed to receive information during pregnancy were 1% for PKU and 20.5% for hypothyroidism. Parents received information before tests were 20.5% PKU and only 3% congenital hypothyroidism. This might reflect a communication gap between health care providers *and clients that require further research. Study revealed poor follow up of results and registration in such a program. The researcher observation during the visits to the health centers revealed lack of standardizations as procedures are not done in standardized way a cross department and centers.*

Health care providers directly involved in this program must be continuously trained educated and updated about issues related to the newborn screening programs and quality control and assurance in sample withdrawal and data recording. Health care providers must pay more efforts in follow up of the screening tests results, their reporting to parents, and proper registration in the child medical files. Parents, especially mothers must be well instructed during pregnancy about the advantages of conducting the newborn screening programs as soon as possible of the child birth.

ملخص الدراسة

تقييم برنامج المسح الروتيني حول كسل الغدة الدرقية الخلقي و الفينيل كيتونيوريا عند حديثي الولادة في محافظات فلسطين الجنوبية.

يعتبر برنامج المسح الروتيني للمواليد أحد برامج الصحة العامة التي تهدُف إلى الاكتشاف المبكر لبعض الأمراض التي يكون فيها التدخل العاجل ذا فائدة كبيرة للحد من الإعاقات والوفيات، وبصفةٍ عامةٍ تجنب الخطورة المصاحبة لهذه الأمراض. إن تقييم برنامج الفينيل كيتونيوريا وكسل الغدة الدرقية الخلقي للمواليد في محافظات فلسطين الجنوبية سيساعد في تحسين الخدمات الصحية، وذلك من خلال تقليل المشاكل المتعلقة بفشل هذا البرنامج أو تدهوره، مثل: قصور الدماغ أو التخلف العقلي عند الأطفال.

اعتمدت الدراسة المنهج الوصفي التحليلي المقطعي، أما عن مكونات الدراسة فتشمل:(الوالدين – مقدمي الخدمة – بطاقة جمع العينة). وقد روعي في اختيار أفراد عينة الوالدين (400) تمثيل جميع فئات المجتمع الفلسطيني وشرائحه، والتوزيع الديمغرافي في محافظات فلسطين الجنوبية؛ لذلك تم اعتماد الطريقة الطبقية النسبية المتكررة. وكذلك شملت الدراسة جميع مقدمي خدمة التطعيم والمسح الروتيني للمواليد(107) في مراكز الرعاية الأولية التابعة للحكومة ووكالة الغوث. أما بالنسبة لبطاقة جمع العينة فقد تم استخدام عينة عشوائية بسيطة لاختيار 300 بطاقة. ولقد كان معدل الاستجابة 95% بين الوالدين، و93% لمقدمي الخدمة.

وأظهرت النتائج أن 34.7% من بطاقات جمع العينات كانت كاملة البيانات اللازمة لإجراء هذا الفحص، ومن بين هذه البطاقات الكاملة كانت 81 % منها لعيادات وكالة الغوث، و 19% فقط لعيادات الحكومة، وأظهرت الدراسة أن 87% من بطاقات العينات في وكالة الغوث مناسبة للفحص أكثر منها في عيادات الحكومة والتي شكلت 59.4%.

شكلت نسبة الوالدين الذين تلقوا معلومات حول الفحص قبل سحب العينة من أطفالهم 24 %، ولقد كانت هناك علاقة ذات دلالة إحصائية بين كتابة تاريخ جمع العينة علي البطاقات ومحافظات فلسطين الجنوبية، حيث كانت 62.7% في المحافظة الوسطي، و7.1% في الشمال، و 26.7% في خانيونس، و23.5% في رفح و57.1% في غزة.

لقد كانت نسبة الأمهات الذين أخبروا بأنه قد تم إعلامهم عن هذا المسح خلال فترة المتابعة للحمل 41% لفحص الفينيل كيتنويوريا و 20.5% لمرض كسل الغدة الدرقية الخلقي، وقد أظهرت الدراسة أن 36 % من الأطفال الذين سحبت منهم العينة كانوا في الأسبوع الثاني من العمر، و 64% في الأسبوع الأول من العمر. كذلك أظهرت الدراسة أن معظم الوالدين (38%) لم يسمعوا عن الفحوصات الروتينية لحديثي الولادة وأن نسبة الذين يريدون معرفة المعلومات عن هذا الفحص لحديثي الولادة في بداية الحمل هي 87% بينما كانت نسبة الآباء الذين يريدون معرفة المعلومات عن الفحص الروتيني للمواليد قبل الولادة هي 10% .

أوضحت الدراسة أن هناك نقصاً واضحاً في المعرفة لدى مقدمي الخدمة الصحية والآباء بالنسبة للمسح الروتيني للمواليد، إذ كشفت أن 44.6 % فقط من مقدمي الخدمة لديهم معلومات عن إجراء فحص كسل الغدة الدرقية الخلقي، بينما 92% منهم لديهم المعرفة عن إجراء فحص الفينيل كيتونيوريا.

وفي تقييم أداء مقدمي الخدمة أظهرت النتائج أن 38% منهم يزودون الوالدين بمعلومات قبل سحب العينة، وحوالي 47% صرحوا أنهم أعطوا المعلومات عن الفحوصات الروتينية للمواليد في أثناء متابعة الأم للحمل.

ومن جانب آخر تبين للباحث أنه كانت هناك فجوة واضحة بين أقوال مقدمي الخدمة وآراء الوالدين حول المعلومات المقدمة لهم، وتبين له أيضا ضعف متابعة في نتائج الفحص الروتيني وتدوينها في ملف الطفل.

لاحظ الباحث في أثناء زيارته للمراكز الصحية أن الإجراءات ليست ممعيره و تختلف باختلاف الأماكن مما يدل علي غياب النظم والقوانين لهذه الإجراءات. وتبين له وجوب تدريب مقدمي خدمة هذا البرنامج بشكل دائم، وإطّلاعِهم علي كل جديد بخصوص الفحوصات الخاصة بهذا البرنامج ومراقبة الجودة وضمانها في سحب العينة وتسجيل البيانات كاملة ، ووجوب بذل جهدٍ في متابعة النتائج وإبلاغها للوالدين وتدوينها في ملف الطفل الطبي .

ويوصي الباحث أن يشتمل برنامج التثقيف الصحي على معلومات كافية عن فحوصات المسح الروتيني للمواليد، وأن يتم تثقيف الأمهات بالمعلومات الكافية- خلال فترة متابعتهن للحمل أو بعد الولادة- عن مزايا الفحص الروتيني للمواليد وأهمية إجرائه بعد ولادة الطفل مبكراً.

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Abbreviations and operation definition

AAP	American Academy of Pediatric
BIA	Bacterial Inhibition Assay
CDC	Center of Disease Control and Prevention
CES	Charities Evaluation Services
CH	Congenital Hypothyroidism
CHO	Child Health Organization
Epi-info	Epidemiological Information program
GDP	Gross Domestic Product
GNP	Gross National Product
HCP	Health care providers
IMCI	Integrated Management of Childhood Illness
IMR	Infant Mortality Rate
IOF	Israeli Occupied Forces
LBW	Low Birth Weight
MCH	Mother and Child Health
MOF	Ministry of Finance
MOH	Ministry of Health
MSP	Medical Services for Police and General Security
NERNSP	Newborn England Regional Newborn Screening Program
NGOs	Non Governmental Organizations Sector
NIS	New Israeli Sheqalim
PCBS	Palestinian Center Bureau Of Statistics
PHC	Primary Health Center
PKU	Phenylketonuria
SD	Standard Deviation
SES	Socio-economic status
SPSS	Statistical Package Of Social Science
TSH	Thyroid Stimulating Hormone
UNICEF	United Nations International Children's Emergency Fund
UNRWA	United Nation Relief And Work Agency
USD	United State Dollar
WB	West Bank
WHO	World Health Organization

Operational Definitions

- **Attitude**: favorable or unfavorable evaluative statements concerning newborn screening tests reflecting how one feels about it.
- **Blood specimen:** The completeness of the four circles of the blood in the Guthrie card and the penetration to the other side is a must in doing the PKU and Neonatal TSH test.
- **Congenital hypothyroidism** (CHT) is a condition of thyroid hormone deficiency present at birth (Wikipedia, the free encyclopedia, 2008).
- **Congenital hypothyroidism**: is inadequate thyroid hormone production in newborn infants. This can occur because of an anatomic defect in the gland, an inborn error of thyroid metabolism, or iodine deficiency (Postellon, Bourgeois, 2008).
- **Guthrie Card:** A special type of filter paper called Guthrie filter paper or Guthrie card used for the blood collection of the newborn screening test in (3/8) inch circle (Annex 4)
- **Guthrie test:** Test used for the PKU screening program is based on the inhibition of Bacillus subtitles and the ability of phenylalanine to overcome this inhibition. Four blood spots are obtained from the infant's heel, after 24 hours of protein feeding. Normal phenylalanine from the screening test is below the level of 2 mg/dl (American Academy of pediatrics, 1989).
- **Health education**: A combination of learning experiences that aim to develop not only knowledge and attitude, but also skills (i.e., life skills) which are needed to make decision and take positive actions to change behaviors and environments to promote health and safety and to prevent disease (UNCIEF, ND).

- **Knowledge**: Refers to the state or condition of understanding that fact or subject, and being able to apply it (UNCIEF, ND).
- **Newborn screening** tests look for serious developmental, genetic, and metabolic disorders so that important action can be taken during the critical time before symptoms develop (Kayton, 2007).
- **Phenylketonuria (PKU)**: A hereditary disorder of amino acid metabolism in humans, inherited as an autosomal recessive (Genetics Dictionary, 2008).
- **Phenylketonuria:** The inherited inability to metabolize (process) the essential amino acid phenylalanine due to complete or near-complete deficiency of the enzyme phenylalanine hydroxylase (Greene, 2007).
- **Practice**: Do or perform often, customarily, or habitually, style of behavior regarding the newborn screening.
- **Screening**: is a public health service in which members of a defined population, who do not necessarily perceive they are at risk of, or are already affected by a disease or its complications, are asked a question or offered a test, to identify those individuals who are more likely to be helped than harmed by further tests or treatment to reduce the risk of a disease or its complications (UK National Screening Committee, 2003).
- **Waiting time:** The time that the client waits inside the health care centers starting from registration until the moment of entering the vaccination room.

Chapter (1)

Introduction

Chapter 1: Introduction

1.1 Background

Infant phenylketonuria (PKU) and congenital hypothyroidism (CH) screening is gradually becoming a global issue as countries disadvantaged by intractable health and socioeconomic problems explore options for the early detection of congenital hypothyroidism. Screening is a public health service aimed at reducing the risks accompanying diseases rather than providing a guarantee of diagnosis and cure. Effective medical management of PKU and CH requires diagnosis as soon as possible after birth and rapid initiation of strict low protein diet and supplement of thyroxin hormone.

Screening programs have a long and distinguished history in efforts to control epidemics of infectious diseases and targeting treatment for chronic diseases. Newborn children are routinely tested for errors of inborn metabolism and other problems. Although most of these outcomes are rare, a positive test result triggers interventions that benefit both mother and child, and these efforts have been responsible for substantial improvements in health and well-being. In conditions such as phenylketonuria and hypothyroidism for instance, with a high index of brain damage or mental retardation, parental consent may be validly waived. Otherwise, parental autonomy must be respected even when in the physician's judgment it does not serve the best interests of the child (Hamamy, *et al.*, 2007). Disease screening is one of the most basic tools of modern public health and preventive medicine.

In the United Arab Emirate National Newborn Screening Programmed was introduced in 2000 for screening CH and PKU the incidences for CH and for PKU were 1:1570 (Al-Hosani, *et al.*, 2003[a]). Abu Shahla showed that in Palestine the prevalence of PKU was

6.35/100.000 while the maximum prevalence of 28.3/100 000 occurred in the rural areas (Abu Shahla, *et al*., 2004).

The screening programs like these for the 40,000 infants born each year in the Gaza governorate have heralded as successful and cost effective. The newborn screening programs efficiency and effectiveness depend on the smooth integration of sample collection, laboratory testing, follow-up, diagnosis, timely treatment and tracking of outcome (Palestine, MOH, 2004).

Newborn screening for PKU and CH is a highly visible, and important state-based public health program that began over 12 years ago in the government in Gaza Governorates while the UNRWA health program introduced the test in 2000, the new reported cases of PKU during 2005 were 25 with an incidence rate of 2.6 per 10,000 live births compared with 31 cases, with an incidence rate of 3.4 per 10,000 live births in 2004. The new reported cases of congenital hypothyroidism (TSH) during 2005 were 40 cases with an incidence rate of 4.1 per 10,000 live births compared with 38 cases with an incidence rate of 0.42 per 1000 live births in 2004 (Palestine, MOH, 2005).

1.2 Statement of the problem

Newborn screening is recognized internationally as an essential preventive pubic health program for early identification of disorders in newborns that can affect their long-term health. PKU and CH consider serious health problem. Since it was started the screening program for PKU and CH was not subjected to through evaluation in order to pen point the major defects and problem facing such an important program. To the researcher knowledge only the PKU screening program was evaluated about 10 years ago. In those studies, only patients were considered and CH was not included at that time. Therefore, there is a need for a more comprehensive evaluation of the program that will cover data from the screened newborns their families and the health care providers responsible for this screening.

1.3 Justification of the study

The importance of this study stems from the need of a high quality of services in Ministry of Health clinics. Health care providers play a vital role in running and developing the health care services in Primary Health Care. Therefore, the improvement of neonatal screening programs is very important for good healthy newborn in Palestine. One of these development and improvement method can be achieved through studying the most important problems and gaps in services provision and through strengthening the research in this field to follow up the evaluation neonatal screening program in Gaza governorate. Newborn screening is an important tool in the prevention of disease and disability in our children and thus should be a key part of a comprehensive public health system in all of our countries. During my work in central laboratory, which conduct the tests of PKU and CH, the researcher intended to review the screening methods.

The evaluation and management of the PKU and CH neonatal screening program from time to time will survive for keeping the success in improvement of health services by reducing brain damage or mental retardation of infants, continuing in strengthening, supporting of the success of prevention, controlling and prevent health services deterioration.

As reported in the last published Palestinian MOH annual report (2005), PKU incidence rate is 2.6 per 10,000 live births and CH incidence rate is 4.1 per 10,000 live births. In Gaza Strip, Palestine, one previous study carried out about evaluation Phenylketonuria screening, so we need further studies to improve the neonatal health. It is worthy to say that there are no previous studies carried out about evaluation congenital hypothyroidism screening in Gaza Strip due to the researcher knowledge.

1.4 General Objective

This study aims to evaluate the Palestinian national newborn screening for Phenylketonuria and Congenital Hypothyroidism and support program at MOH in Gaza Governorates, and to find out if the program achieves its preset goal of preventing the mental retardation as soon as possible.

1.5 Specific Objectives

- To measure the effectiveness of the newborn screening program.
- To reveal the most important problems and defects facing neonatal screening services in Gaza Governorates.
- To examine the knowledge, attitude and behavior of parents and health providers. related to Phenylketonuria and Congenital Hypothyroidisms screening program.
- Enhancement and strengthen the procedures of follow up program.
- Set up recommendations for policy makers that would improve the affect of the screening program.

1.6 Research questions

- Are there problems and defects in neonatal screening services?

- Is their public awareness of parents about screening tests?
- Are there different between the knowledge of Bacillus Calmette-Guérin (BCG) vaccine, and screening test among parents?

- Are there different between the performance of UNRWA health care providers and governmental health care providers?
- What is the knowledge, attitudes and behaviors of parents related to PKU?
- What is the knowledge, attitudes and behaviors of parents related to CH?
- What is the knowledge, attitudes and behaviors of provider health care related to PKU?
- What is the knowledge, attitudes and behaviors of provider health care related to CH?

1.7 Study Context

Gaza Strip is a small area of around 362 km^2, bordered by Egypt in the south, and Israel in the north and the east. More than 1,443,814 (37.13%) of the total Occupied Palestinian Territories (3,888,292), live in the Gaza Strip, with a population density of 3988 person / km^2 (PCBS, 2006). About two third of them are registered refugees. The population natural growth rate in Gaza Strip is 3.8%, with 44987 newborn a year, and Crud Birth Rate (CBR) of 41.7 per 1000 population (PCBS, 2006[a]).

1.8 Socio-economic context

According to the Ministry of Finance (MOF) estimation, the year 2005 showed a further steep decline in all Palestinian economic indicators in comparison with 2000, which affect all aspects of the Palestinians life specially the health care. The Gross National production (GNP) decreased from 5,275 million USD in 2000 to 4,709 million USD in 2005, and GNP per capita decreased from 1,674 USD in 2000 to 1,174 USD in 2005. According to W.B., 2005, report that states that, despite growth rates during 2003 to 2005, Palestinian incomes remain considerably lower than their pre-Intifada levels with real GDP per capita in 2005 about 31%lower than in 1999, the real growth of GDP was 6.3% and the growth of GDP per capita was 2.7%. Unemployment rate increased from 14% in 2000 to 24.5% in 2005 of the workforce. Around 43% of the Palestinian population still falls below the poverty line, with perhaps 15% living in deep poverty and not able to meet substantial needs(Palestine, MOH, 2004). The mean household monthly income decreased by 22 % since June 2007, from 1358 NIS before June 2007 to 1,058 NIS while the median income dropped by 30% from 1,000 to 700 NIS (PCBS, 2008).

1.9 Health care system

The Ministry of Health (MOH) is the main health care provider in Palestine with the other health care providers, UNRWA, Medical Services for Police and General Security (MSP), health services of national and international Non Governmental Organizations (NGOs), and private health sector for profit. The MOH is the health authority responsible for supervision, regulation, licensure and control of the whole health services. Primary health care system (PHC) is a major component of Palestinian health care system; this system has provided health care to all Palestinian people especially for children and other venerable groups. Primary health care centers in Palestine provide primary and secondary health care services as well as tertiary services. In the last five years and after the uprising of second Intifada (Al Aqsua), PHC centers in Palestine have been developed in a dynamic way to face the instability of Palestinian situation were Israeli occupied forces (IOF) tends to divide Palestinian localities into isolated geographical areas. PHC centers try to offer accessible and affordable health services for all Palestinians regardless the geographical locations (Annex2). According to MOH policy, PHC centers classified from level I to level IV. They offer different health services according to clinic level, theses services include maternal and child health, care of chronic diseases, daily care, family planning, dental, mental services and other services according to center level.

1.10 Child health

1.10.1 Integrated management of childhood illness (IMCI):

IMCI is an integrated approach to child health that focuses on the well-being of the whole child. IMCI aims to reduce death, illness, and disability, and to promote improved growth and development among children under five years of age. IMCI includes both preventive and curative elements that are implemented by families and communities as well as by health facilities. This strategy is developed by the WHO division of child health and development (WHO, CHO), with UNICEF to improve the prevention and management of childhood illness and to deal with the sick child as a whole integrity instead of single disease (WHO, 1999). In Palestine, this strategy has been implemented in year 2003 within the health system to improve the growth and the development of the children less than five years (WHO, 2008).

The strategy includes three main components:

- Improving case management skills of health-care staff
- Improving overall health systems
- Improving family and community health practices

In health facilities, the IMCI strategy promotes the accurate identification of childhood illnesses in outpatient settings, ensures appropriate combined treatment of all major illnesses, strengthens the counseling of caretakers, and speeds up the referral of severely ill children. In the home setting, it promotes appropriate care seeking behaviors, improved nutrition and preventative care, and the correct implementation of prescribed care (Palestine, MOH, 2004).

1.10.2 Child health department:

Child health indicators and their trends demonstrate the change of child health status over time. Infant mortality rates (IMR) are of the most health indices that reflect socioeconomic level and health status of a community. It helps the process of health surveillance and the evaluation of health programs. Countries set their health polices based on change of their health indices.

The Palestinian MOH devoted its efforts to the reduction of infant and child mortality through increasing the accessibility and child health services.

Infant mortality rate in Palestine scored 24 deaths per 1000 live births in 2004, reducing from 32.8 deaths/ 1000 live births in 1994. the mortality rate in Gaza Governorates (30.2 deaths/ 1000 live births) is higher as compared to West Bank Governorates (20 deaths/ 1000 live births) (PCBS, 2006[b]).

Prematurely and low birth weight accounted for 41.1% of the total deaths (MOH, 2004).

Congenital anomalies were responsible for 14.3% (MOH, 2004). Respiratory tract infections and diarrhea were responsible for 13.7% of the total infant morality in Palestine (MOH, 2004), which can be prevented by exclusive breastfeeding in the first six months and a continued breastfeeding with proper complementary food. International studies revealed that exclusive breastfeeding patterns contribute it the reduction of infant mortality due it respiratory tract infections and diarrhea (Vectoria, *et al.*, 1987).

Infectious diseases were responsible for 6.6% of the total IMR in Palestine. Equitably, MOH jointly with UNRWA have achieved universal vaccination coverage in the west bank and Gaza governorate. In a technical paper (2005), Abu Hamad cited that children under two year who have been fully immunized according to WHO recommended vaccination regimen were 95% (PCBS HHS, 2004).

1.10.3 Immunization and child health:

Palestinian system for disease prevention and control programs include the expanded program for immunization, which aimed to reduce the incidence of communicable diseases. The immunization program is the major success of Palestinian health care system where the services are available, accessible, and affordable almost in all the PHC centers in both Gaza governorate and West Bank. It is worth to mention that UNRWA plays an important role in providing immunization to refugee's children with no cost through the coordination and cooperation with MOH. The MOH and UNRWA offered two main programs of vaccination, the EPI during infancy and early childhood, and the second program is the booster doses of DT, OPV, and d.T. vaccines, in addition to, rubella for female students at 12 years. As recommended by WHO, the immunization program is conducted to cover the following infectious disease: Diphtheria, Pertussis, Tetanus, Hepatitis B, Polio, Measles and Tuberculosis as well as German measles and Mumps (Annex 3).

Chapter (2)

Literature review

Chapter Two

Literature Review

In this chapter, the researcher will review literatures dealing with evaluation newborn screening phenylketonuria (PKU) and congenital hypothyroidism (CH).

2.1Conceptual Framework

Conceptual frameworks are a type of intermediate theory that has the potential to connect to all aspects of inquiry (e.g. problem definition, purpose, literature review, methodology, data collection, and analysis). Conceptual frameworks act like maps that give coherence to empirical inquiry (Wikipedia, 2008). The framework used as the basis for measurement of the performance of the public health system as a whole or as a specific public health organization. The developed model will allow public health researcher, practitioners, and policymakers more effectively examine the relationship between the practice of public health and population outcomes; it also will contribute to the development of a science base for the public health system (Adren, *et al.*, 2001).

After the researcher study, the status of the newborn screening services in addition to the current situation of the place of study researcher were able to sketch map-showing lines of the factors interdependence that affect the of newborn screening performance of PKU and CH. Various factors related and affected by the performance of newborn screening of PKU and CH. The researcher in conceptual framework (Fig 2.1) developed all these factors. According to developed framework of PKU and CH, newborn screening tests are affected by three main parts; including factors related to parents, health care provider and administrative factors.

Parents' components can be subdivided into five components: knowledge, education, economic status, geographical area, pregnancy health education. Firstly, knowledge is the tool that measures the extent of information available about PKU and CH tests for parents. This component (knowledge) should be was measured by analyzing the percentage of parents who have information about these tests and disease complication from total samples. Secondly, to the education component, the researcher measured the relationship between parents' education level and their knowledge about importance of PKU and CH tests. The third component (economic status) is the relationship between parent's economic status and their knowledge of PKU and CH tests. To the fourth component (geographical area), identifying whether there is difference in parents awareness of the tests according to their geographical area. Finally, pregnant health education was to measure mothers' percentage who receives information about newborn screening test (PKU and CH) during pregnancy period or any other health programs.

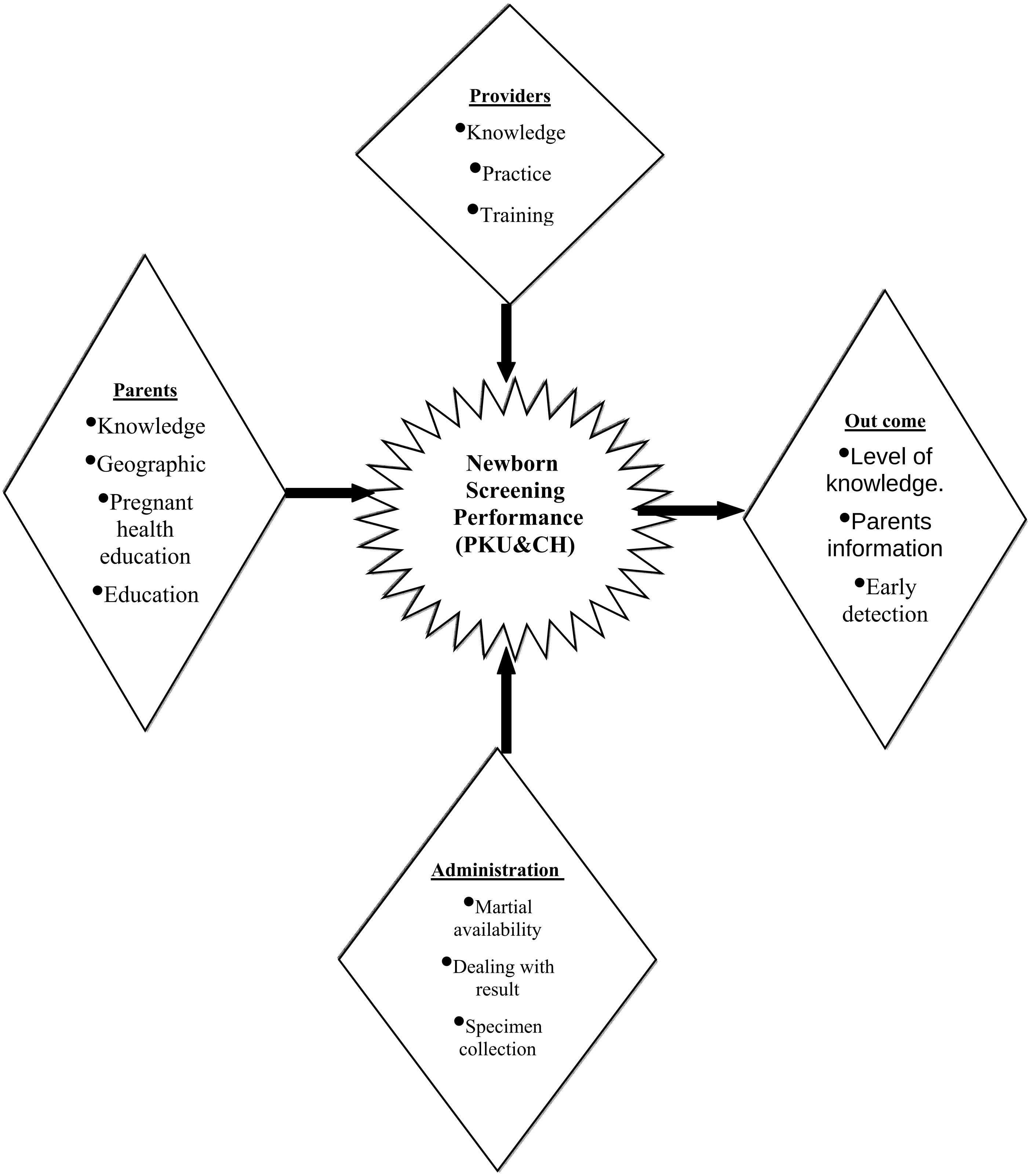
The second part, health care providers (nurse, physician, and lab technician) this part that affects performance of newborn screening tests is subdivided into three main components: knowledge, practice, and training. The first (knowledge) measured the knowledge of health care providers about PKU and CH newborn screening tests performance. Finally, training component measured the number of health care providers who received training course about PKU and CH test along time with their practice. It is important to mention here that this part HCP is being affected by the feedback of screening test results. Feedback was measured by identifying whether HCP receive the results about newborn or not.

To third part (administration) is a crucial part that affects a number of components related to administrative issues (training, supply of materials, dealing with results, patient connection).

- Collection of specimen cards and the way of sending them to central laboratory; the card includes infant full name, sex, ID. number., mother full name, date of birth, primary health care center address, collection date of specimen, name of sample collector, suitability of sample to the test and completers of four blood spots.
- Availability of materials: whether materials and equipment are available and sufficient for all over the year or not.
- Dealing with results: how are the managers dealing with the results, who is responsible for informing parents about positive results and who is responsible follow up and how?

It is important to identify whether there is much time consumed from the date of birth until getting positive results or not. All pervious parts affect directly or indirectly the out come of PKU and CH newborn screening program.

Fig 2.1 Conceptual Framework



2.2Program evaluation

Health promotion initiatives are often delivered through structured programs. A program in any group of related complementary activities intended to achieve specific outcome or results. To be successful in achieving their goals, health promotion practitioners need to make ongoing decisions about optimal use of resources, determining if the program is meeting the needs of participants, ways of improving program and demonstrating the effectiveness of a program to founders and other stakeholders. Program evaluation is "the systematic gathering, analysis and reporting of program data to assist in decision making" (Ontario Ministry of Health, 1996).

The primary focus of evaluation is to determine the effectiveness of a program in light of the attainment of pre-set priorities and goals. Evaluation helps document whether a program is accomplishing its goals or not. It identifies program weaknesses, strengths, and the areas of the program that need revision. The Joint Committee on Standards for Educational Evaluation (Canada Evaluation Society, 2006) defines evaluation as "The systematic investigation of the worth or of an object".

Evaluation is the process of determining significance or worth, usually by careful appraisal and study. Evaluation is the analysis and comparison of actual progress *vs.* prior plan, oriented toward improving plans for future implementation. It is part of a continuing management process consisting of planning, implementation, and evaluation; ideally with each following the other in a continuous cycle until successful completion of the activity. Evaluation is the process of determining the worth or value of something. This involves assigning values to the thing or person being evaluated (Marris and Braz, 2006).

An evaluation plan may have two different focuses: formative and summative. A comprehensive evaluation plan should include both types of evaluation.

Formative evaluation: is designed to collect data while a program is being developed with the intention to improve it. Formative evaluation provides ongoing feedback on how the different components of a program are working and leads to decisions regarding what needs to be enhanced, what needs to be deleted, what needs to be added. Formative evaluation includes needs assessment, program logic models, pre-testing program materials, and audience analysis (Marris and Braz, 2006).

Summative evaluation: is designed to gather conclusive data that indicates how effective the overall program is. Summative evaluation results in decisions to continue or not a program (Maricopa, 2007). Summative evaluation includes change in attitudes, knowledge or behavior, change in morbidity or mortality rates, number of people participating or served, and impact assessment. It also includes cost benefit and cost effective analysis (Marris and Braz, 2006).

Another type of evaluation is called process evaluation. It focuses on programs while underway and it examines the procedures and tasks involved. Process evaluation includes tracking quantities and description of people reached and services provided, describing how services are provided and the quality of services provided.

2.2.1Importance of evaluation:

Charities Evaluation Services (CES) approach is that monitoring and evaluation not only measure how well you are doing, but also help you to be more effective. Evaluation has two main purposes:

2.2.1.1 Learning and development:

Monitoring and evaluating your services will help you assess how well you are doing in order to help you do it better. It is about asking what has happened and why-what is and what is not working. It is about using evaluation to learn more about an organization's activities and then using what has been learnt (Maricopa, 2007). Health promotion practitioners undertake program evaluation to collect evidence on the effectiveness/impact of a program, identify ways of improvement, assess the efficiency of a program (cost benefit analysis) and test hypothesis for research purposes (Marris and Braz, 2006).

In the past, program evaluation was used mainly to determine whether a program was effective (i.e., did it work?). Today program evaluation is more often used to ensure continuous quality improvement (i.e., what needs to be changed to improve the effectiveness of a program?) (Marris and Braz, 2006).

2.3 Newborn screening

Newborn screening is a public health program aimed at the early identification of conditions for which early and timely interventions can lead to the elimination or reduction of associated mortality, morbidity, and disabilities. This screening takes place within the context of a newborn screening system, and involves the following components: screening, short-term follow-up, diagnosis, treatment/management, and evaluation. Inherent to each of these components is an education process. The newborn screening program's efficiency and effectiveness depend on the smooth integration of sample collection, laboratory testing, and follow- up, diagnosis, timely treatment, and tracking outcomes (Moyer, *et al.*, 2008). The foundation and justification of newborn screening systems rest on the principles that testing procedures are readily available; technically feasible; economically sound; and clearly beneficial to affected newborns, their families, and to society. However, although newborn screening systems have succeeded in preventing morbidity and mortality, controversies, challenges, and opportunities continue (Therrell, 1993).

2.3.1 History of newborn screening:

Newborn screening programs began in the early 1960s with the original work of Dr Robert Guthrie, who developed a screening test for PKU and a system for collection and transportation of blood samples on filter paper. By 1962, Massachusetts launched a voluntary newborn PKU screening program that demonstrated the feasibility of mass genetic screening. The American Academy of Pediatrics (AAP), acting as the professional association that develops policy for the care of children, raised concerns about the sensitivity and specificity of PKU screening tests, as well as the efficacy of early intervention for PKU (A Blueprint for the Future, 2000).

In state of America, newborn screening for PKU was not a health department role or a legislated activity. Health professionals were slow to adopt the practice of screening for PKU, and the responsibility for screening was not modified. The AAP, acting as the professional association that develops policy for the care of children , raised concerns about the sensitivity and specificity of PKU screening tests , as well as the efficiency of early intervention for PKU. The federal children's Beruca funded a collaborative study to address questions and concerns about the effectiveness of the PKU screening test (Paul, *et al.*, 1997).

The national association for retarded citizens proposed model legislation for creation of public programs to address low detection rates of mandatory PKU screening legislation. The Kennedy administration, with the guidance of the presidential advisory commission on mental retardation, was also supportive. Other advocacy groups, such as the march of Dimes Birth Defects foundation, mobilized volunteers to lobby for passage of legislation at the state level (Newborn Screening Expands, 2000).

As a response to this mandate, some states up screening laboratories or added phenylanine analysis to their state laboratory repertoire of tests. Early in the 1970s, the need to improve quality assurance through systematic proficiency testing was recognized. In an early proficiency –testing study, the centers for disease control and prevention (CDC) found marked variability among health department laboratories. As a result, the Newborn Screening Quality Assurance Program was begun at the CDC (Newborn Screening Expands, 2000).

Because of the laws mandating PKU testing, and the establishment of health department newborn screening units that occurred in the 1960s and 1970s:

- Every newborn had an opportunity to be screened for PKU when laws were properly implemented; consequently, most were screened.
- Financial barriers to screening and diagnosis were removed, but families often had to pay for the special formula, special foods, and other related treatments.
- State newborn screening programs evolved, with the goal of providing safe screening tests and appropriate follow-up to every newborn (Paul, *et al.*, 1997).

2.3.2 Phenylketonuria:

2.3.2.1 Definition of PKU:

Phenylketonuria is an inherited metabolic disease (also called an in born error of metabolic) that leads to mental retardation and other developmental disabilities if untreated in infancy with an inborn error of metabolism, the body is unable to produce proteins or enzymes needed to convert certain toxic chemicals into nontoxic products, or transport substances from one place to another (Glanze,1996).

March of Dimes, a Public Education American Center defined PKU as (a disease that effects the body processes protein). Children with PKU cannot assimilate an amino acid called phenylalanine. As a result, phenylalanine builds up in the blood stream and causes brain damage (March of Dimes, 1998).

Children's hospitals in the United States defined PKU from the view of metabolism as (a disease of body chemistry). Any individual with PKU due to the lack of the enzyme breaking down phenylalanine will have mental retardation (PKU corps, 1997).

Harvery described PKU as (heredity, in which liver cells tyrosine), as recognized by an increased blood phenylalanine level cannot convert phenylalanine to hyperphenylalaninemia (Harvery, 1986).

2.3.2.2 Discovery:

Filling discovery of PKU in Norway in 1934 was when a mother of two severely, mentally retarded children came to him, after she had asked many doctors for help without any positive results. These women were unusually persistent and would not accept the situation without a convincing explanation. She had also noticed that a peculiar smell always clung to her children.

On clinical examination, he found the children could not speak or walk, eat or drink, also unable to focus their eyes on any thing, and their stool urine habits were not like those of other babies.

Urine examinations with ferric chloride normally give a brownish color, and when ketones are present, the result is purple or burgundy. Instead, a deep green color developed in the urine samples. He had not seen this reaction before and his first task was to isolate the substance and determine that material Phenylpyruvic acid fitted all the observations; therefore he conduced that (the two mentally retarded children, excreted Phenylpyruvic acid in their urine) while normal people do not and this was the main discovery (F'lling, 1994).

Asbjrn F'lling in1934 defined PKU as an (in-born error of metabolism) and he was the first to discover that the genetic defect of phenylalanine metabolism resulted in mental retardation in its most serious manifestation (Nelson, 1982).

2.3.2.3 Inherit phenylketonuria:

This condition is inherited in an autosomal recessive pattern, which means both copies of the gene in each cell have mutations. Most often, the parents of an individual with an autosomal recessive condition each carry one copy of the mutated gene, but do not show signs and symptoms of the condition (Genetics home reference, 2008).

2.3.2.4 Causes of phenylketonuria:

PKU is a condition in which the body is unable to break down one of the protein building blocks from food. These building blocks are called amino acids and one of them is phenylalanine. In PKU the phenylalanine cannot be processed (metabolized) normally and builds up in the blood and tissues. The high phenylalanine level can prevent the brain from developing, as it should. Progressive mental retardation results if the condition is not treated in early infancy. The diet for PKU is essential in childhood to prevent damage to the growing brain (Geelhoed, *et al*., 2005).

2.3.2.5 Clinical symptoms of phenylketonuria:

Although infants with PKU usually appear normal at birth, early symptoms may include skin rash, seizures, excessive restlessness, irritable behavior, and a musty odor of the body or urine. Later signs include developmental delays, gait disturbances and mental retardation (Illinois department of public health, 1996).

2.3.2.6 Diagnosis of phenylketonuria:

Screening is the only way to detect PKU before symptoms start to develop. The test is typically performed between one and seven days after birth. Blood is obtained by pricking the heel of the newborn and analyzing it for phenylalanine concentration. Very high levels of phenylalanine indicate that there is a problem with phenylalanine hydroxylase. Blood levels above 20 mg/dl are generally associated with classical PKU. The generally accepted upper limit for normal in newborns is 2 mg/dl, with most unaffected children having levels below 1 mg/dl. Patients with high blood levels of phenylalanine are tested further to distinguish between classic PKU and related diseases.

The Guthrie Inhibition Assay is usually used to test for blood phenylalanine levels. The test uses a special strain of the bacterium *Bacillus subtilis* that requires phenylalanine for growth. The bacterium is grown on the surface of a special medium that lacks phenylalanine. Paper disks containing blood samples and testing standards are placed on top of the agar plate, and the bacteria are allowed to grow. The amount of growth around each disk is proportional to the amount of phenylalanine in the disk. A second assay detects high levels of phenylalanine metabolites in the urine. These metabolites first appear four to six weeks after birth and are detected by the addition of a few drops of a

10% ferric chloride solution to a urine sample. If the metabolites are present, a deep bluish green color develops. Color development indicates that the patient has PKU (Lohr, 2006).

Recently, tandem mass spectrometry (MS/MS) has been implemented to provide newborn screening for PKU and hyperphenylalaninemia. This new laboratory technology has replaced the fluorometric analysis previously utilized for PKU screening (Illinois department of public health, 1996).

2.3.2.7 Treatment of phenylketonuria:

Treatment involves a diet that is extremely low in phenylalanine, particularly when the child is growing and the diet must be strictly followed by parents and health care providers. This requires close supervision by a registered dietitian or doctor, and cooperation of the parent and child. Those who continue the diet into adulthood have better physical and mental health. “Diet for life” has become the standard recommended by most experts. This is especially important before conception and throughout pregnancy. A special infant formula called Lofenalac is made for infants with PKU. It can be used throughout life as a protein source that is extremely low in phenylalanine and balanced for the remaining essential amino acids (Greene, 2007).

2.3.2.8 Types of PKU:

The major types of PKU are Classical PKU, Atypical PKU, Malignant, and the Maternal PKU (Mijuskovic, *et al.,* 2006).

2.4 Congenital hypothyroidism (Cretinism)

Newborn screening for CH began in Quebec in 1974. Jean Dussault and Claude Laberge adapted newly available immunoassays for T4 and TSH and new information characterizing thyroid system ontogenesis in the fetus and newborn to the Quebec filter paper blood spot screening program for PKU Parallel programs were rapidly developed in New England and the northwest United States, leading in 1977 to recommendations for CH screening programs from the Newborn Screening Committee of the American (Fisher, 2005).

2.4.1 Definition of congenital hypothyroidism:

Congenital hypothyroidism can be defined as a lack of thyroid hormones present from birth which unless detected and treated early, is associated with irreversible neurological problems and poor growth. Some infants may develop a lack of thyroid hormones after birth and this may represent primary hypothyroidism rather than congenital hypothyroidism (Morin, *et al.*, 2002).

Congenital hypothyroidism is a condition where a newborn has decreased or absent thyroid function and thyroid hormone production. The thyroid is a gland in the lower neck that makes iodine-containing hormones that regulate growth, brain development, and metabolism. Hypothyroidism occurs when the gland is absent, abnormally developed, destroyed, or reduced in size, or the production of thyroid hormones is decreased or absent (Scheinberg, 2006).

2.4.2 History of congenital hypothyrodism:

Endemic cretinism was noted in Alpine Europe as early as the 13th century. However, it was only in 1848 that a commission, sponsored by the King of Sardinia, first formally demonstrated its link to goiter. An important landmark was the publication of a report in 1871 describing several cases of nongoitrous hypothyroidism that were clearly distinguished from the endemic form of the disease, for which the author suggested the designation of “sporadic cretinism”(Anissa, *et al*., 2006).

2.4.3 Causes of congenital hypothyroidism:

The most common cause of hypothyroidism is the body's autoimmune reaction to itself, producing antibodies against the thyroid gland. A mother's thyroid disorder treatment (such as iodine) or maternal antithyroid antibodies can affect her unborn child's thyroid function (Trotsenburg, *et al*., 2006)

2.4.4 Types of congenital hypothyroidism:

We can divide patients with congenital primary hypothyroidism into four groups, as follows:

1- Those with an absent thyroid gland in this group, the thyroid gland has failed to develop before birth. The gland is absent and will never grow. Consequently, no thyroxin is produced. This condition is called thyroid agenesis or athyrosis. It is more common in females compared to males – about twice as many girls as boys are affected. It occurs about once every 10,000 births and accounts for about 35% of the cases detected by Newborn Screening.

2- Those with an ectopic thyroid gland in these babies, the thyroid is small and malformed and does not occupy its normal position in the neck. It is often found at the base of the tongue, near the place where the gland first began to form in the embryo. An ectopic thyroid may have varying degrees of function. Sometimes it is very small and under active. On other occasions, it is able to produce a nearly normal amount of thyroid hormone. Ectopic thyroid glands also occur about twice as frequently in girls as in boys. They account for about 50% of the cases detected by Newborn Screening and so are slightly more common than the cases of thyroid agenesis.

3. Those with a malformed thyroid gland in the normal position, this condition is sometimes called thyroid hypoplasia and it only accounts for a very small percentage of the total number of cases. In thyroid hypoplasia, the gland is small, malformed and occasionally consists of only one lobe.

4. Those who have a thyroid gland which has developed normally, but which cannot produce normal amount of thyroxin. This condition is known as thyroid dyshormonogenesis and is accounts for about 15% of the cases detected by Neonatal Screening. Dyshormonogenesis can be either transient, in which case it gets better with the passage of time, or else it is permanent and lasts for life. In babies affected with dyshormonogenesis, the thyroid gland is often enlarged and may be seen or felt in the front of the neck as a goiter (Kumar, *et al*., 2006).

2.4.5 Inheritance of congenital hypothyroidism:

Approximately 85% of cases are sporadic, and 15% are hereditary. Each of the inborn errors of T_4 synthesis is autosomal recessive except thyroid hormone receptor defects, which are autosomal dominant. In the cases associated with transplacental passage of a maternal blocking antibody, future siblings are at risk of having the same problem (Schokking, *et al.,* 2000).

2.4.6 Symptoms and signs of congenital hypothyroidism:

The symptoms of congenital hypothyroidism in children are different from in adults. The following are the late symptoms of the disorder. However, each child may experience symptoms differently, and often the symptoms are not seen at all. Infants are usually clinically normal at birth due to the presence of maternal thyroid hormones.

Symptoms: feeding difficulties, somnolence, lethargy , low frequency of crying , and constipation.

Signs: Large fontanel's, Myxoedema - with coarse features and a large head and oedema of the genitalia and extremities, Nasal obstruction, Macroglossia, Low temperature (often <35°C) with cold and mottled skin on the extremities, Jaundice - prolongation of the physiological jaundice, Umbilical hernia, Hypotonia, Hoarse voice, Cardiomegaly, Bradycardia, Pericardial effusion - usually asymptomatic, Failure of fusion of distal femoral epiphyses, Growing child will have short stature, hypertelorism, depressed bridge of nose, narrow palpebral fissures and swollen eyelidsand ,refractory anaemia (Rull, 2006).

2.4.7 Diagnosis of congenital hypothyroidism:

Congenital (present at birth) hypothyroidism is usually detected during the routine newborn screening. Blood samples taken will reveal abnormal levels of T4 (a hormone of the thyroid that regulates metabolism) and thyroid-stimulating hormone, or TSH (a hormone that helps to increase the size, number, and activity of the thyroid cells; stimulates the release of hormones that affect a person's metabolism and that are essential for normal growth and development), that may indicate thyroid problems (Children's Hospital of Wisconsin,2006).

The Coat- A- count Neonatal TSH IRMA is an immunoradiometric assay, which is usually used to test of thyroid stimulating hormone (TSH). The Interscientific TSH540NM Neonatal Screening Assay for quantitative determination of TSH concentration in dried blood spot samples (Virginia, *et al*., 2007).

2.4.8 Treatment of congenital hypothyroidism:

The infant with suspected congenital hypothyroidism should be seen without delay by a physician, preferably by a pediatric endocrinologist. Blood should be obtained to confirm the diagnosis, and treatment with thyroxine should begin before the confirmatory T4 and TSH values are available. Measurements of T4 and TSH should be made 2 and 4 weeks after starting the thyroxine, 2 weeks after a dosage change, and every 1 to 2 months during the first year of life (Thyroid Foundation of America, 2004).

2.5 International of magnitude of newborn screening PKU

2.5.1 Epidemiology of PKU:

In European, Chinese, and Korean populations, the prevalence of PKU is approximately 1/10,000. Over the period 1994 to 2004, 167 children were diagnosed with PKU (Hardelid, *et at*., 2008). The birth prevalence of PKU in the United States is 1 in 20,000 newborns. If untreated, PKU results in severe mental retardation in most children as well as congenital hypothyroidism results in mental retardation (Grosse, *et al*., 2006).

The incidence of PKU in Canada is 1:15,000 births and that of CH is 1:2500 births. Newborn screening for these two diseases was embraced by the industrialized countries and is now virtually universal in North America, Eastern and Western Europe, Australia, New Zealand, Israel and Japan. It is gradually being introduced in several Middle Eastern countries, China, Central, and South America, and other areas (Hanley, 2005). In china, the incidence of phenylketonuria was 1:11 200 and the cost-benefit ratio was 1:3.7 for PKU screening (Xue Fan., 2001). PKU has a reported incidence in the U.S. of about 1 in 13,500 to 1 in 19,000 live births. For hyperphenylalaninemia, the estimate is approximately 1 in 48,000 newborns (Schuett, 2000).

The average birth prevalence of PKU in Caucasians is 1 per 10.000 (range 1 per 6000 to 1 per 16000). In Turkey, PKU was diagnosed in 1 per 4370 newborns, but in Teheran , Islamic republic of Iran, the reported incidence is 1 per 8633 neonates rather similar to that in western Europe. In Iraq 3.8% and in Egypt 1.4% of such children had PKU (EMRO, 2006).

In United States the incidence of congenital hypothyroidism, as detected through newborn screening, is approximately 1 per 4000 births. In areas of iodine deficiency, the prevalence of goiter reported to range from 5-15% of the population, with a lower incidence of hypothyroidism (Postellon, 2007).

In the United Kingdom 1 in 4,000 live births have CH and the incidence is twice as common in females (Rull, 2006)· In Bursa, Turkey, the incidence of CH was found to be 1/2354 (Sag lam, *et al*., 2007).

In the Gaza strip (1986), the test for PKU was performed using filter paper impregnated in ferric chloride to detect phenylpyruvic acid; the suspected cases were transferred to Tel-Hashomer in Tel Aviv for the testing and monitoring. With the increase of positive cases, there was a greater need to be able to carry out the required tests in our centers in the Gaza Strip. Therefore, some technicians were trained in Tel-Hashomer hospital in Israel (1994). From the beginning of 1995, the test was applied in the central laboratory in the Gaza Strip for all newborn babies who receive vaccination in the governmental clinics while the UNRWA health program introduced the test in 2000 after Abu Shahla recommended in his studies (Abu Shahla, 1999).

In the Gaza Strip, Palestine, one previous studies carried out about evaluation PKU screening, the prevalence of PKU was 6.35/100.000 while the maximum prevalence of

28.3/100 000 occurred in the rural areas. Coverage of PKU testing in the Gaza Strip is limited to about 35.3 % of the total newborns, who are delivered and received health care at the government clinics. Among those newborns delivered at the government clinics, the percentage of PKU screening is about 87.8 %. However, PKU testing is not carried out at UNRWA clinics where about two-thirds of newborn deliveries take place (Abu Shahla, *et al*., 2004).

2.5.2 Experience of countries for newborn screening test:

In the United States, the hospital routine is to do the "PKU" just before the baby is discharged. This tends to be at around 36 hours, and this timing is decimal - the baby tends to be very dehydrated, so it can take quite a long time of stabbing the baby (up to a half hour) in order to get the necessary blood samples. Nursing often is not yet well established, so it cannot always comfort the baby, and the trauma of a half-hour of torture can disrupt the beginnings of a good breastfeeding relationship (Connie, *et al*., 2006).

Davis recommended prenatal and primary care providers be more involved in educating parents about newborn screening. Professional societies and state health officials should work together to encourage parent and provider education. User-friendly patient and provider education materials, such as those he developed, could form the basis for this educational approach (Connie, *et al*., 2006).

2.5.3 Epidemiology of congenital hypothyroidism:

The introduction of neonatal screening for CH has had a dramatic effect on the prognosis of affected children. Thyroxine is essential for neurological and skeletal development and early replacement therapy is critical in optimizing outcome. The severity of CH is variable and the causes diverse, from developmental disorders of thyroid development to disorders of hormone synthesis. An understanding of the mechanisms underlying disorders of the thyroid gland, in some cases at the molecular level, can help in both guiding management and prognosis (Beardsall, *et al.*, 2004).

The incidence of CH has been found to be 4 to 5 times more common than PKU, for which screening programs were originally developed. The overall incidence of CH ranges from 1 in 3000 to 1 in 4000 newborn infants. The incidence of CH is higher in Hispanic individuals and lower in black individuals. There is a 2:1 incidence in females compared with males, and there is an increased risk in infants with Down syndrome (Susan, *et al.*, 2006).

All protocol require that providers collect dried blood spot specimens from infants soon after birth and send them to be tested at an approved screening laboratory for a panel of disorders specified by the state. The most common newborn genetic disorders are congenital hypothyroidism, with prevalence at birth of 1 in 2,500 newborns (Grosse, *et al.*, 2006).

A study in US conducted that most current newborn screening brochures should be revised to make them more readable and user-friendly for parents. About 92 % of brochures were written at a reading level that is higher than the average reading level of US adults (eighth-grade level). In most brochures, the essential information for parents was buried. Although all brochures were brief and focused on the newborn screening tests being performed, 81% needed improvement in getting to the point quickly and making it easy for parents to identify what they needed to know or to do (Connie, ***et al.*****,** 2006).

Kerruish said that blood samples are collected between 2 and 5 days of age, analyzed at central laboratories and results released within a few days. For positive results, confirmatory tests are necessary, but treatment is usually instituted within 10–14 days of birth. For PKU and CH, this usually means the baby avoids any of the squeals of the untreated conditions, such as seizures and severe developmental delay. Most countries report coverage rates of 95–100% of the population for this type of screening (Kerruish and Robertson, 2005).

In china, the incidence of the CH was 1:3 600. The cost-benefit ratio was 1:3.6 for CH screening; it is still a big challenge for nationwide screening program. To gradually increase the national coverage rate of neonatal screening, we should train more staff in neonatal screening laboratories and to apply newer techniques in neonatal screening such as tandem mass technique and also to develop Internet network system between neonatal screening laboratories (Xue Fan,2001).

In Italy, where the CH incidence is 1:3100 live births, neonatal screening for CH was established in 1977 and then progressively developed all over the country. The design was used a population-based case-control study which was carried out by using the network created in Italy for the National Register of Infants with CH. This study showed that many risk factors contribute to the etiology of CH. In particular, our results suggested a multifactorial origin of CH in which genetic and environmental factors play a role in the development of the disease (Olivieri, *et al.*, 2005).

2.6 Magnitude of newborn screening in Mediterranean area:

In the eastern Mediterranean region, newborn screening program have been carried out in Bahrain, Egypt, Islamic republic of Iran, Jordon & Sundi Arabia.

Neonatal screening for congenital hypothyroidism is routine in most industrialized countries, where it affects about 1 in 3600 to 5000 newborn. Neonatal screening has shown an in cadence of one per 3000 in Egypt, 1 per 2666 in Soudi Arabia., and 1 per 1433 in the Islamic republic of Iran. It thus seems likely that CH is at least as common throughout the eastern Mediterranean region as in industrialized countries, and neonatal screening might be appropriate.

Jordan adopt a strategic action plan for the prevention of genetic and congenital disorders for the period 2006-2010 was jointly prepared and is being implemented by the MOH, WHO and NCDEG. The overall goal would be to monitor yearly the frequencies of affected births of genetic and congenital disorders and to achieve a progressive decline in the national rates of genetic and congenital disorders. The plan includes national programs for premarital screening, newborn screening, public and professional education, establishing a national birth defects registry, and introducing new technology (Hamamy, *et al.*, 2007).

In a study in Turkey, the researcher concludes that the incidence of CH is very high in their population, which warrants a countrywide neonatal screening program. Since transient cases cannot be distinguished and untreated transient hypothyroidism may also cause mental retardation, treatment must be started as early as possible with frequent monitoring to optimize the outcome and identify the transient patients (Sag lam, *et al.*, 2007).

All babies are screened at birth (with mothers consent) using blood taken *via* a pin prick and analyzed for TSH and T4. This is part of the UK Newborn Screening Program (Foo, *et al.*, 2002).

2.7 Challenges related to newborn screening

Some challenges most directly related to newborn screening include:

- Laboratory capacity is sometimes inadequate. The methods used by some health department laboratories are in need of enhancement. In addition, public health laboratories are often under competitive pressure from commercial laboratories. Budget constraints make it more difficult for health departments to cope with the current workload, let alone with new tests that require additional equipment and personnel.
- Benefits of some screening tests have not been appropriately validated.
- State public health agencies screen for different conditions. These differences are not always based on the prevalence of the disorders in the respective states, or proof of the tests' utility and validity.
- Funding is insufficient for newborn screening quality assurance and evaluation, particularly for laboratory and database information systems.
- State policymakers possess an incomplete understanding of the conditions for which newborn screening can be conducted, and/or of testing technology.
- Informing and educating consumers is often challenging, and meaningful public and consumer involvement is not always considered.
- Adequate funding is needed for comprehensive care by multidisciplinary teams in medical homes, including resources that ensure the availability of special formula, special foods, and other treatments for all affected children and adults (Moyer, *et al.*, 2008).

2.8.1 Screening strategies:

The three main laboratory methods used for population-based screening of newborns for PKU in the United States are the Guthrie Bacterial Inhibition Assay (BIA), fluorometric analysis, and tandem mass spectrometry. The Guthrie BIA is inexpensive, relatively simple, and reliable. Fluorometric analysis and tandem mass spectrometry are quantitative, can be automated, and produce fewer false positives than BIA. Tandem mass spectrometry has the ability to simultaneously obtain tyrosine levels that can be used to assist in the interpretation of PKU levels and the identification of numerous other metabolic disorders on a single sample (NIH Consensus Statement, 2000).

2.8.2 Effectiveness:

Effective screening of newborn infants for PKU requires competence in a number of complex interrelated systems: specimen collection, specimen transport and tracking, laboratory analysis, data collection and analysis, locating and contacting families of infants with abnormal results, diagnosis, treatment, and long-term management including psychological, nursing and social services and nutritional, genetic and family counseling. Although the United States screening programs have been highly effective, there is concern that individuals with PKU could be missed. This could occur at any step in the process-in collection of specimens, laboratory procedures, or initiation of treatment and clinical follow-up. Although missing an individual with PKU through screening is considered extremely rare, there are few recent data available to accurately determine the magnitude of the problem or to define the actual cause of the missed cases. Home births and early hospital discharge may contribute to missed cases (Health Council of the Netherlands, 2005).

2.8.3 Cost Savings:

Most economic analyses of PKU screening are more than 10 years old. Methodological approaches vary widely among the studies. All published studies, however, find that PKU screening and treatment represent a net direct cost savings to society, although the analyses assume 100 % compliance, and typically exclude the costs of operating data systems and follow up components of a newborn screening program (NIH Consensus Statement, 2000).

2.8.4 Current status and scope:

Routinely test blood sports collected from for up to thirty metabolic and genetic diseases of which the four most commonly included are phenylketonuria, congenital hypothyroidism, galactosemia, and sickle cell disease. Many identified through newborn screening programs, including ensuring appropriate diagnosis, treatment, and on going evaluation. In many cases, education (professional& consumer) is also program responsibility along with counseling & provision of other ancillary services.

The panel of newborn disorders screened for varies from country to country and decisions for adding or deleting tests involve many complex social, ethical, and political issues (NNSGR, 2008).

2.8.5 The economic burden of newborn screening for PKU and CH:

The economic benefits derive the prevention of intellectual disability which otherwise insure lost throughout the life of the affected individual. Sensitivity analysis showed that the cost savings were robust, given changes in the levels of intellectual disability but varied according to the discount rate (Geelhoed, *et al.*, 2005).

2.9 Strategies for screening

2.9.1 Intervention policy:

The researcher can really appreciate the benefits of PKU and CH intervention policy if he ever seen an untreated person with PKU and CH and compare to the positive out come when children are treated early, growing up normally, attending college and becoming productive adults. The intervention policy for controlling disability can be categorized as primary, secondary, and tertiary prevention (NFDN, 2005).

2.9.1.1 Primary prevention:

This involves the prevention of the manifestation of the disability. It may be universal (i.e. prevention desirable for everyone), or be restricted to a selected population (i.e. prevention recommended for high-risk groups) or to an indicated population (i.e. prevention in individuals with an identified risk).

Primary efforts are directed toward reducing the actual occurrence of disabilities and they employ measures that prevent the conception of a disabled individual or delay the disabling process. Primary prevention efforts includes: genetic counseling, immunization programs, improved prenatal, prenatal and postnatal care, regulations and legislation, other related, means, Genetic counseling. Genetic counseling is an essential part of primary prevention strategies. It is the process of providing information on genetic (recurrence) risk, the nature, and consequence of genetic disorders and the means available for the prevention of transmission of defective genes (NFDN, 2005).

2.9.1.2 Secondary prevention:

Secondary prevention strategies aim at reducing the duration or severity of disability. These activities provide early identification of the disabling condition followed by prompt treatment and intervention to minimize the development of disability. These strategies can be applied either at the prenatal or neonatal level. At the neonatal level, screening of neonates and proper intervention in those affected has been successful in reducing disability. The best-known example of secondary intervention is that of neonatal screening for PKU, other aminoacidurias, CH, the thalassaemias and other haemoglobinopathies (El-Hazmi, 1997).

2.9.1.3 Screening test:

Screening is the presumptive identification of unrecognized disease or behavior by using tests, examinations, questionnaires and other procedures. Screening sorts the cases into positives, negatives, or normal cases, people who are positive will probably require further intervention. It is important to examine the proportion of false positives and false negatives. Dr Robert Guthrie developed a new born screening test of PKU and he work hard for more than thirty years to establish the newborn screening program in the United States and many other countries (Guthrie, 1964).

There are three principal methods used for PKU screening in the United States: the Guthrie Bacterial Inhibition Assay (BIA), automated fluorometric assay, and tandem mass spectrometry. Screening tests are most accurate if performed after 24 hours of life but before the infant is 7 days old (USPSTF, 2008).

2.9.3.2Criteria of screening:

Screening can only be justified if the following criteria are met as reported by WHO criteria for screening. The condition sought should be an important health problem for the individual, community should be an accepted treatment or useful intervention for patients with the disease, and the natural history of the disease should be adequately understood, there should be a latent or early symptomatic stage.
There should be a suitable and acceptable screening test or examination and facilities for diagnosis and treatment should be available, there should be an agreed policy on whom to treat as patients, treatment started at an early stage should be of more benefit than treatment started later. The cost should be economically balanced in relation to

possible expenditure on medical care as a whole and case finding should be a continuing process and not a finally project (Mak, 1998).

2.9.3.3 Time Table:

The newborn screening should take place shortly after birth, before the baby leaves the hospital. Early collection can affect the results for PKU and hypothyroidism screening. It can result in a false positive for primary congenital hypothyroidism due to the biological phenomenon known as "neonatal surge." More significantly, early collection could result in a false negative for PKU and other amino acid disorders.

A study in California has shown that most newborns with PKU demonstrate elevated phenylalanine by six hours of age. While California recommends that newborns be a minimum of 12 hours old at the time of collection. The newborn's physician, when reviewing the screening results, should note the baby's age at time of collection and quantitative phenylalanine level. Newborns whose specimen was collected prior to 12 hours of age must have a second specimen submitted (California department of public health, 2007).

WHO criteria stipulate that samples for TSH measurement should be collected 72 hours after birth (to avoid the physiological rise in TSH concentration which occurs immediately after birth (WHO, 1999).

2.9.3.4 Blood specimen:

The newborn screening for PKU and CH is based on blood tests, the Dried Blood Spot Specimen or 'heel prick test' (formerly known as the Guthrie test) is usually carried out around the fifth day of life. The midwife takes several drops of blood, from the baby's heel, to fill a number of small circles on a special card. This is then sent to the laboratory for testing (National society for PKU, 2003).

2.9.3.5 Card preparation:

The card established is labeled with the newborn name, the date, the time, the sex, the date of birth, and the name of mother and the time of first milk feeding (Annex 4).

2.9.3.6 Patient's care:

The sample for PKU test should always be taken prior to blood transfusion, after protein feeding, not from the intervention line, and by heel prick on dried filter paper, the site may be rubbed with a warm, wet towel to increase blood flow (Mabry, *et al.*, 1988).

The mainstay in the treatment of congenital hypothyroidism is early diagnosis and thyroid hormone replacement. One study suggested that optimal care includes diagnosis before age 13 days and normalization of thyroid hormone blood levels by age 3 weeks (Schokking, *et al.*, 2000).

2.9.3.7 Test collection:

Umbilical cord blood spots were made on standardized filter paper (Guthrie card No. 2992, Scleicher & Schuell, Dassel, Germany) immediately after birth of the babies. Both sides of each spot on the Guthrie cards were fully saturated with the cord blood (Mekonnen, *et al.*, 2003).

Neonatal screening specimens should be drawn optimally by 48 hours to 4 days of age. Testing in the first 24-48 hours may lead to false-positive TSH elevations using any screening method, but this timing is often used because it is convenient for the families and healthcare providers. The circles on the approved filter paper forms (i.e. Guthrie cards) need to be filled and saturated to be accurate. The specimens need to be dried at room temperature and should not be subjected to excessive heat (Pediatric education, 2006).

2.9.3.8 Storage instructions sample stability:

The spots were dried at room temperature and cards were sealed and kept in a deep freezer until assayed in the laboratory (Mekonnen, *et al.,* 2003).

2.9.3.9 Cases for rejection:

Causes for rejection newborn screening specimen according standard by NBS laboratory services, the specimen has to be received on non-expired forms by the laboratory by the 14th day after collection. It should have at least three adequately filled circles, complete and accurate demographic information, missing or invalid patient demographic information; specimen is too old upon receipt (received 14 or more days following collection) and no blood samples received with request form (NBS Laboratory Services, 2007).

2.9.3.10 Limitations of PKU test result:

Cases have been missed because blood phenylalanine was not increased, even after the third day of life. Identification of non-PKU forms of hyperphenylalaninemia require additional testing for tetrahydrobiopterin pathway enzyme defects. Not all individuals with increased blood phenylalanine have phenylketonuria. When the infant is tested for PKU before 24 hours of age, there is a 16% chance of missing a positive case. When tested between 24 and 48 hours of birth, there is a 2.2% chance of missing a positive, between 48 and 72 hours, 0.3% chance (National Institutes of Health, 2006).

2.9.4Tertiary prevention:

Tertiary prevention aims at limiting or reducing the effects of a disorder or disability that is already present. It involves long-term care and management of a chronic condition, e.g. rehabilitation or correction of the disability by surgical measures or by adopting strategies by which the disabled person can lead a normal or near normal life. The main aims of rehabilitation of the disabled are to increase awareness of disabilities and the needs of disabled people; to encourage their full integration in society; and to improve prevention and stimulate a more sensitive and understanding attitude. These measures also include special education program. Only 50 years ago, the majority of disabled people were left illiterate. However, during the past three or four decades, considerable efforts have been made to develop special education programs to educate blind deaf mute, deaf-mute, blind and mentally retarded patients. Special schools with specially trained teachers have provided excellent education programs, which have helped disabled people achieve goals that, in many ways, are similar to those of normal individuals (El-Hazmi, 1997).

Chapter (3)

Methodology

Chapter Three

Methodology

3.1 Introduction

The evaluation of PKU and CH neonatal screening program study is essential for highlighting the importance of giving further attention to study these diseases and carrying out more detailed investigations, which tries to answer the questions about the knowledge, attitude and practice of parents and health care providers toward PKU and CH screening in the Gaza Governorate. It also encourage and stimulate the decision makers in paying more attention and show more interest to the screening program as well as comprehend the importance of taking these tests more seriously. A high percentage of newborn screening coverage will minimize the suffering of PKU and CH patients and their families as well as preventing mental retardation and the complications attached with the disease.

3.2 Study Design

This study is descriptive, analytical, a cross- sectional study, which tries to answer the questions about the evaluation of PKU and CH neonatal screening program in the Gaza governorate. The investigator had developed a questionnaire for parents, health care providers, and checklist for card newborn screening. The advantage of analytical, a cross-sectional study is easily applied, economical, and cost effective while the disadvantage is causality, face-to-face questioner interview for parents and self-questioner for health care providers and checklist for card newborn screening.

3.3 Study Population

The study population included all health care providers (115) that work in neonatal screening programs, a sample parents (400)coming with children for BCG vaccination in Gaza governorate and checklist for newborn screening cards (300).

3.4 Study Setting

The study is carried out on governmental and UNRWA primary health care centers in Gaza governorates, Palestine including all health care providers who work in newborn screening program, parents who came with neonate to primary health care centers in the five governorates (Shohda Jabalia, Shohda Al-Rimal, Shohda Deralbalah, Shohda Khanyoins and Shohda Rafah) and five UNRWA centers (Jabalia, Soidi, ALmakhazi, Khanyoins and Rafah) in Gaza governorate.: Rafah, Khanyounis, Middle region, Gaza and North region, and all primary health care centers (32 government and 18 UNRWA)providing vaccination services and checklist for cards newborn screening test in central laboratory in Al-Rimal center.

3.5 Sampling method

Sampling involves a process of selecting a subset of population that represents the entire population in order to obtain information regarding the phenomenon of interest.

A- The investigator utilized stratified cluster sample to select parents. The sample size was 400 parents comprising those who attended the primary health care centers and who met the inclusion criteria from 10 primary health care centers (five governorates and five UNRWA) from Gaza governorate (3.1).

B- All health care providers who introduce offer vaccination services in newborn screening programs, which will be, include without sampling.

C-Random sample used to last received newborn screening cards (300) from central laboratory.

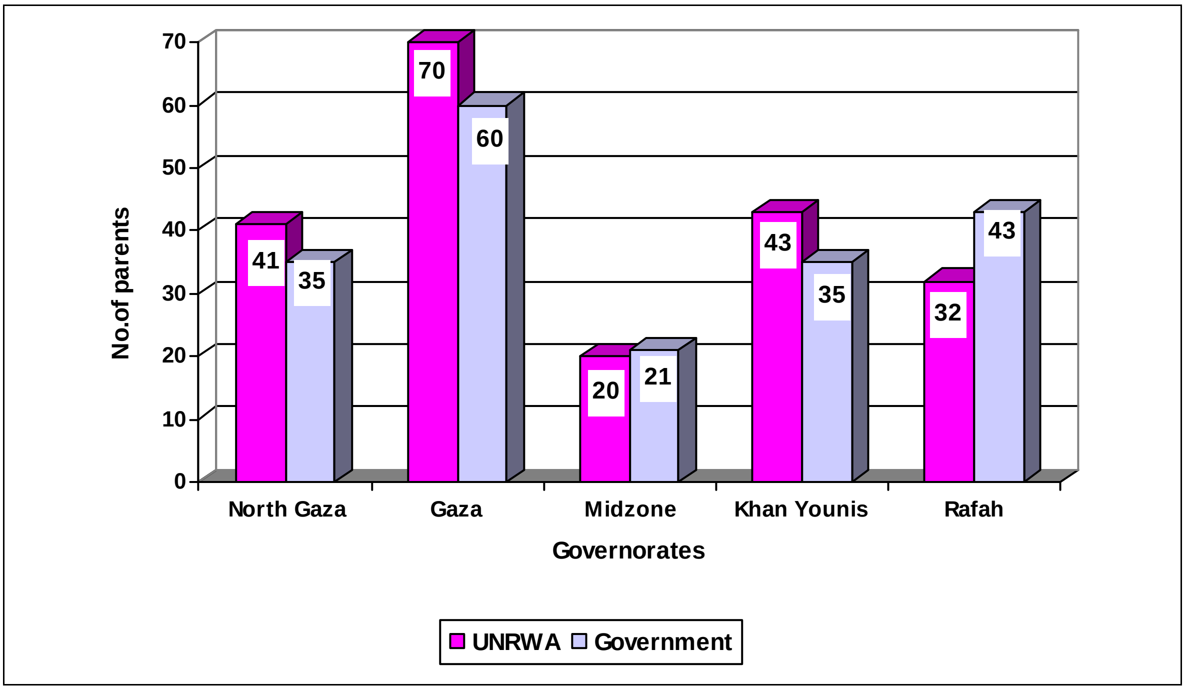
Table No. (3.1): Distribution of parents by residency in Gaza Governorate

Resid	Immunization place	Tot. Clinic Samples
NORTH GAZA	G. SHOHDA JBALIA	35
	U. JBALIA	41
	Total NORTH GAZA Samples	**76**
GAZA CITY	G. SHOHDA ALREMAL	60
	U. SOIDI	70
	Total GAZA CITY samples	**130**
MIDlIE ZONE	G. DER ALBALAH	20
	U. ALMAKHAZI	21
	Total MID ZONE Samples	**41**
KHAN YOUNIS	G. SHOHDA KHANYOINS	35
	U. KHANYOINS	43
	Total Khan Younis Samples	**78**
RAFAH	G. SHOHDA RAFAH	43
	U. RAFAH	32
	Total RAFAH samples	**75**
	Total sample	**400**

U.: UNRWA clinic

G.: Governmental clinic

Figure (3.1): Distribution of parents by residency in Gaza Governorate



3.6 Sample Size

A sample size of 400 was calculated using the parents who came with newborn to get BCG vaccination. To estimate the sample size, Epi-INFO was used to calculate the sample confidence interval 95% and estimate error (p- value) and stratified cluster proportional sample is used. The sample size was calculated by assumption that 50% of parents are familiar with the newborn screening. The sample size was calculated and 380 subjects, the researcher decided to take 400 subjects to compensate for the non-responding subjects, estimate it, and estimate it.

3.7 Eligibility Criteria

3.7.1 Criteria of inclusion:

1. The laboratory employees in neonatal screening program in central laboratories at MOH who have responsibilities in technical work at the time of study.
2. All health care providers in neonatal screening program in PHC (UNRWA and Governorates) who have responsibilities in technical work at the time of study.
3. Parents who came for vaccination BCG for the child.

3.7.2Criteria of Exclusion:

1. Any health care provider who did not has direct responsibilities in neonatal screening program such as secretaries and accountants will be excluded from the study.
2. Any parents who did not come for the BCG vaccination.

3.8 Ethical and Administrative Consideration

For ethical reasons, the author sought administration board of UNRWA and MOH association approval. A written approval was obtained (Annex 5, 6).

Written consent from explaining the purpose of the study, and reserving the right of full voluntary participation of the participants were obtained from the study subjects. The participants understood, and it was clear to them, that they had total right to stop and/or withdraw from participating in the study at any time they want, without affecting the service they are receiving (Annex 8, 9). Permission to the study from Helsinki committee was obtained, Attached Helsinki agreement for the project as a whole (Annex 7).

3.9.1 Data collection instrument:

Data was collected by indirect methods. The indirect method included a structure interview questionnaire. The interview was carried out by face-to-face interview which was conducted with parents, self-administered questioners were handed to the health care providers (nurses, physicians, and lab technician), while checklist evaluated the specimens cards. The collected information must be related to the objective of the study. This questionnaire was designed in English language (with close-ended questions) and made content validity to evaluate the PKU and hypothyroidism newborn screening program in Gaza governorates (Annex 10, 11, 12). A structural closed ended questionnaire was designed as the data collection instrument. The structured questionnaire was selected because it enables the researcher to be consistent in asking questions and data yielded was easy to analyze. Its benefit saving time and effort, less costly, require less energy in administration complete the questionnaire adequately and minimized as much as possible missing information. The questions were clear, unambiguous, and arranged in such a way that data collection was easy.

The questionnaire (1) for parents was divided into two sections:

Section **A** comprised socio-demographic data, which sought to obtain respondents age, educational status, residency, average family income.

Section **B** sought to determine the knowledge and awareness about the newborn screening test examination for PKU and CH.

The questionnaire (2) for health care providers was divided into four sections: they contain socio-demographic data, continuing education, current practice, newborn screening education, the care for newborns and performance the program.

3.9.2 Instrument validity and reliability:

After being constructed, the data collection tool (questionnaire) has been reviewed by thirteen experts to ensure its face and content validity (Annex 13). Instrument looked acceptable to experts. The instrument questions were relevant and comprehensive. It includes items that measure knowledge, attitudes, and practice of parents and health care providers. To minimize inter-observer variations and intra-observer variations the investigator completes all the process of data collection and data management by him self to strengthen reliability of the study.

3.10 Pilot study

A pilot study was conducted where twenty cases recruited to parents and five cases for health care providers. After implantations, few questions were reworded to clarify the intended meaning, and two questions were omitted. The piloting estimated the time consumed in conducting the interview, which was 10 minutes in average. The instrument questions were easily understood by participants.

3.11 Data collection

Data were collected by the researcher. First, he must introduce his self to the client, ask his permission to participate for the questionnaire, explain that it will not take a lot of time and what he must do and told her that all information that he gave will be kept confidential.

3.12 Statistical analysis

3.12.1 Data entry:

Over reviewing of the questionnaires was the first step, prior to data entry. This step followed by designing an entry model using the computer Software Statistical Package for Social Sciences (SPSS) version 13. Then the coded questionnaires entered into the computer by the researcher. Data cleaning was done through checking out a random number of the questionnaires and through exploring descriptive statistics frequencies for the variable. All suspected or missed values were checked by revising the available sheets.

3.12.2 Data analysis:

In data analysis, different statistical tests were used, through frequency of the study factors, description of the study population. Frequency statistics were performed where means and standard deviations were calculated. Tables for data frequency were constructed. Inferential statistics (Chi-square) were performed to study the relationships between variables.

3.13 Limitations of the study

- Time limitation
- Lack of scientific resources like books and journals.
- Lack of resources including budget and facilities especially during the economic siege for Gaza Strip. Additionally the cut of electricity for long period.
- Political situation. During data collection Gaza Strip exposed to infighting among different political affiliation; which affect the movement between governorates, and sometimes different areas was isolated.

Chapter (4)

Results and Discussions

Chapter Four

Results and discussions

This chapter represents the core results of the study including socio-demographic characteristics of the subjects of the study population that affecting knowledge, experience, practices and awareness of the study population towards PKU and CH newborn screening program. The data collected in this study provide information related to the effectiveness.

Then the researcher examine factors that may affect the knowledge attitude and behavior of parents and his care providers related to PKU and CH newborn screening program. The researcher also compared between UNRWA and governmental health care centers services related to the program.

4.1 Characteristics of the study population

The study population was 400 Palestinian parents living in Gaza Strip. The number of health care providers who had participated in the study was 107 working in vaccination centers and newborn screening in Primary Health Centers with high response rate, as it was 93% and the response rate of parents was 95%. The study showed obvious variations in socio-demographic characteristics of participants.

4.1.1 Distribution of the study population by governorate and health care provider:

The study was conducted to be representative to the five geographical districts of Gaza governorate with its two main sections of primary health care centers: UNRWA and governmental centers. Table (4.1) shows the total 400 subjects distributed within provinces. North Gaza represents 18% of the study population; Gaza city represented

34%, Middle zone 10%, Khan-younis 20% and Rafah 18.8% (figure 4.1). This percentage distribution for the study sample is similar to the population distribution conducted by the Palestinian Central Bureau of statistics (PCBS, 2008) and it shows 51.8% come from UNRWA health care centers while 48.2% come from governmental health care centers.

Table (4.1): Distribution of the parents by province

Variables	No	Percentage (%)
Governorate		
North Gaza	76	18
Gaza	130	34
Middle Zone	41	10
Khan Younis	78	20
Rafah	75	18
Total	400	100
Primary Health care Centers		
UNRWA	207	51.8
Government	193	48.2

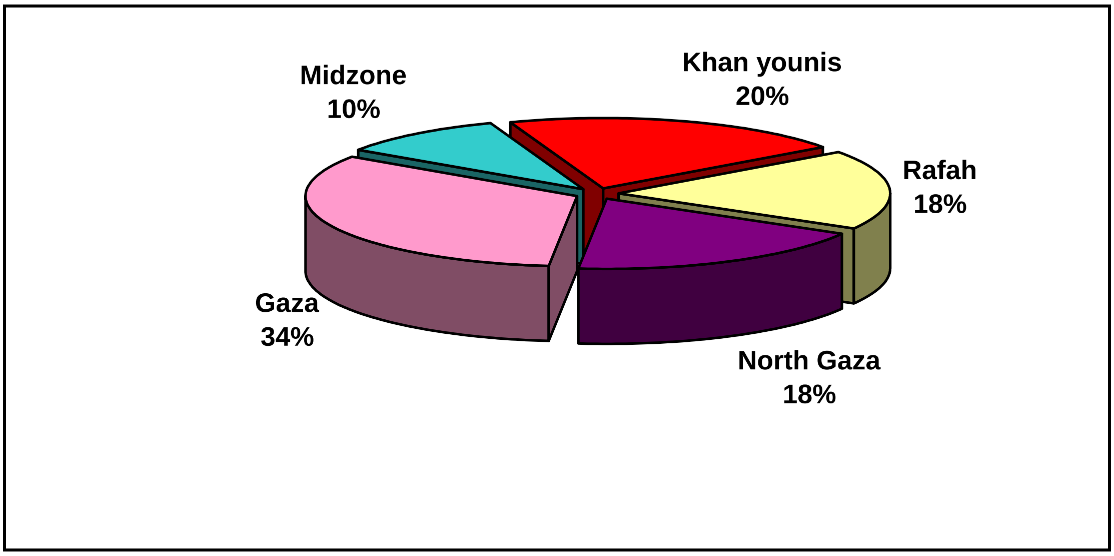


Figure 4.1: Distribution of parents by Governorate

4.1.2 Socio-demographic characteristics and socioeconomic status:

The study showed variations in socio-demographic characteristics of the participated parents and their children. Table (4.2) summarizes the main characteristics, like child gender participated in the study, educational level of parents and household member. The researcher recoded the data collected and categorized this data as demonstrated in the table below, another factor was working status of both fathers and mothers, if they are employed or not and then he examined the occupations of the employed respondents.

4.1.2.1 Education level of respondents:

Regarding the education levels of participated parents, the researcher categorized and re-coded the years of education into three groups. The first group, which is low level from 0 to 6 years of education which represented 20.5% among mothers and 11.25% among fathers. The second group which is the moderate level from 7 to 12 years, which represented the majority of the study population 57% among mothers and 51.5% among fathers, the third group which is the high level with more than 12 years of education represented 22.5% of mothers and 37.25% of fathers as shown in figure (4.2). The mean of mother's years of education was 11.6 years, the median was 12 years, and (SD) was 2.6, range from 0 to 17 years, and for fathers the mean was 12.2 years, the median 12, and (SD) was 3.4 range from 0 to 20 years.

A study conducted by Planning and research center (PRC) in the west bank in 1996 revealed that the median year of women's education was 9 years and for their husbands it was 10 years, Nearly about 63.9% of surveyed women had less than 12 years of education (Ismail and Shahin, 1996). In our study there was 57% of mothers had educational level from 7-12 years or less. About 51.5% of fathers had education level from 7-12 year.

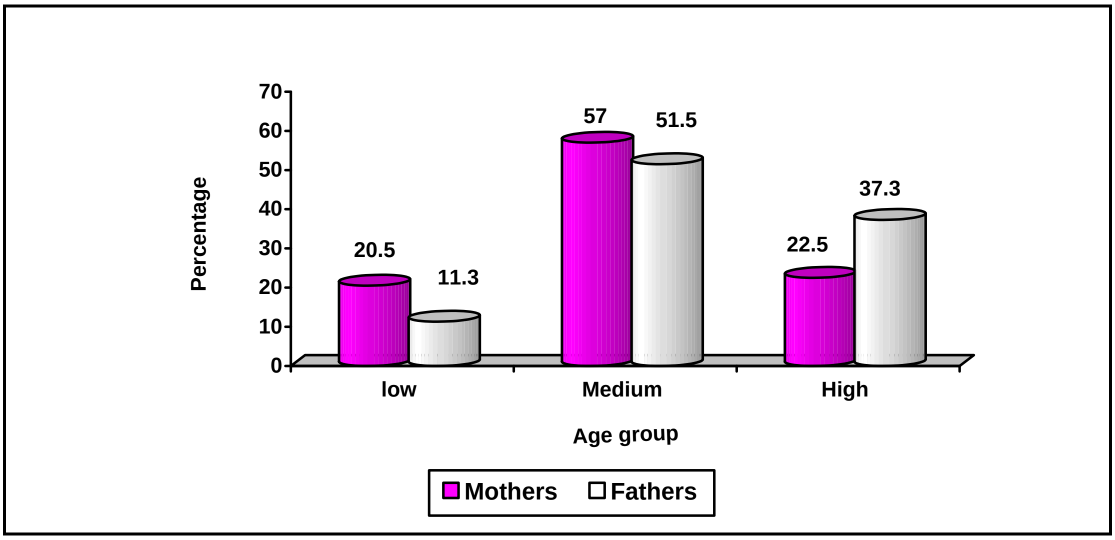


Figure 4.2: Percentage distribution of mothers and fathers by educational level

Table (4.2): Distribution of the parents by socio-demographic characteristics (n = 400)

Socio-demographic variables	No	%
Sex child		
Male	205	51.2
Female	195	48.8
Educational Mother level		
Low	82	20.5
Moderate	228	57
High	90	22.5
Educational Father level		
Low (0-6 years)	45	11.25
Moderate (7-12 years)	206	51.5
High (>12 years)	149	37.25
Average monthly income		
< 1700	221	55.3
1800-2100	76	19.0
> 2100	103	25.8
Employment status		
Employed	16	4
Unemployed	384	96
Father occupation		
Professional	68	17
Skilled	16	4
Merchant	20	5
Policeman	80	20
Unskilled	60	15
Unemployed	156	39
Mother occupation		
Jobless (HW)	384	96
Professional	16	4
House hold member		
1	101	25
2 - 5	215	53.8
6 -10	81	20.2
10+	3	1

4.1.2.2 Working status of parents:

As shown in table (4.2) there was high rate of unemployment among mothers. Congruently, 384 out of 400 mothers were unemployment and represented 96% of the participated mothers, and 16 of the mothers were workers and represented only 4%of the participated mothers. For mothers, 4% of mothers involved in the study had professional jobs as shown in (figure 4.3). The percentage of working fathers was 61%, while 39% of fathers were unemployed. Among fathers, police represented the highest percentage that was 20% of the study population, followed by professionals who represent 17%, while unskilled workers represent 15% of fathers in the study, merchants represent 5%, and skilled workers represent 4% as shown in (figure 4.4).

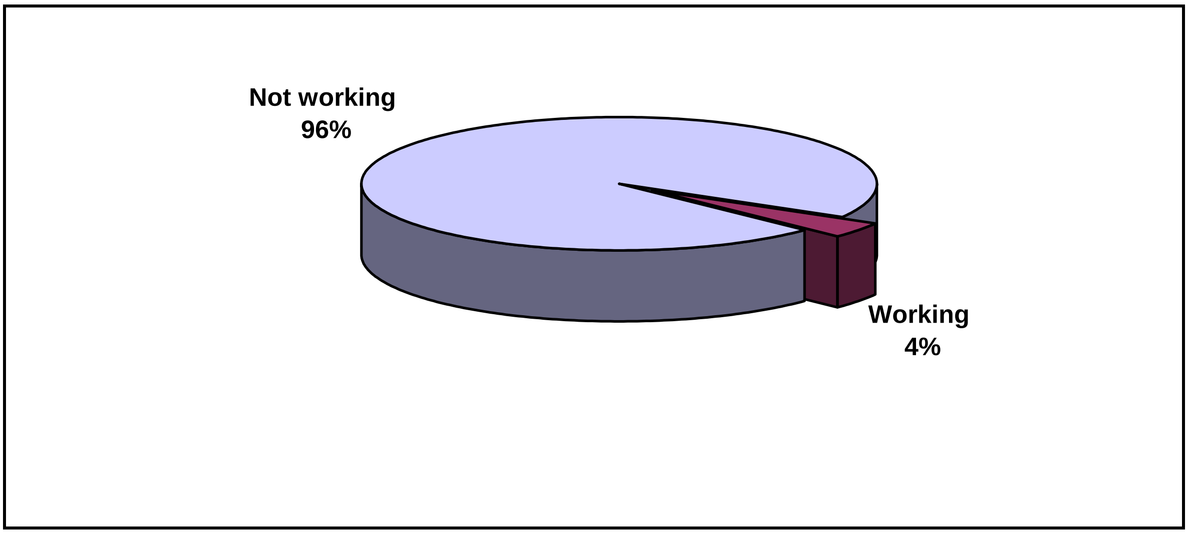


Figure 4.3: Percentage of distribution of mothers by working status.

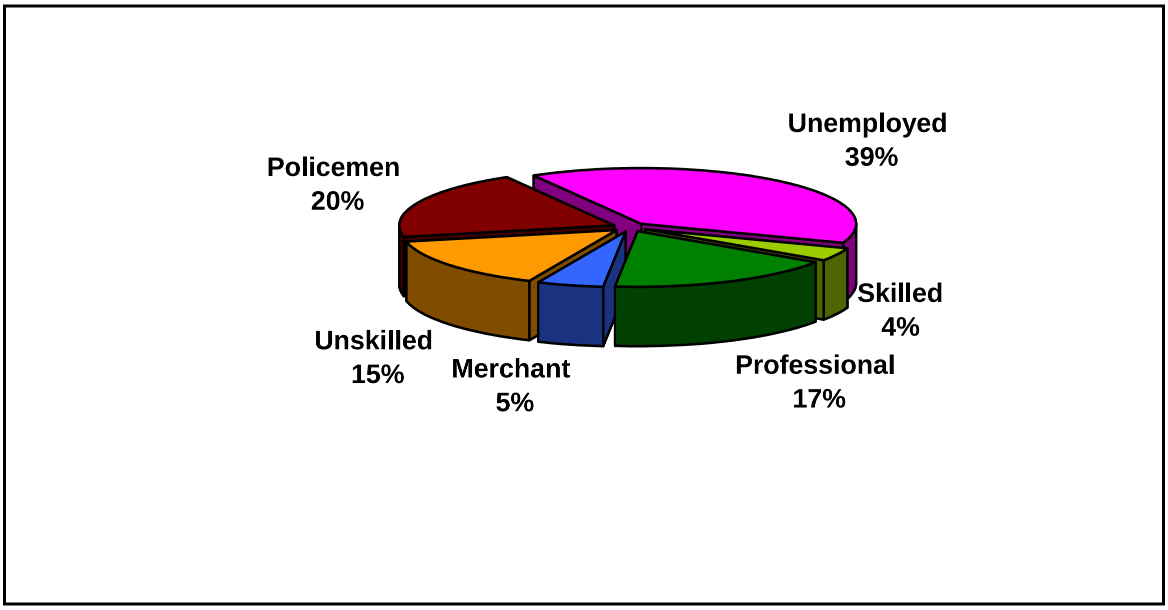


Figure 4.4: Percentage distribution of fathers by occupational groups

4.1.2.3 Financial status of the family:

Regarding financial status of the families involved in the study, the researcher classified family income according to PCBS (PCBS, 2006[a]). The finding revealed poor economic situation among the population study, unfortunately, 74.3 % of total sample was below poverty line (less than 2100 NIS), they were classified into two groups: 55.3 % was less than 1700 NIS (extreme poverty), and 19.0 % was average monthly income between 1800-2100 NIS. On the other hand, the population, which was above poverty line (more than 2100), represented only 25.8 % of total study population (figure 4.5). The mean of their monthly family income was 1563.7 NIS; the median income was 1500 NIS with (SD) 1261.3 and range from 0 to 6000 NIS.

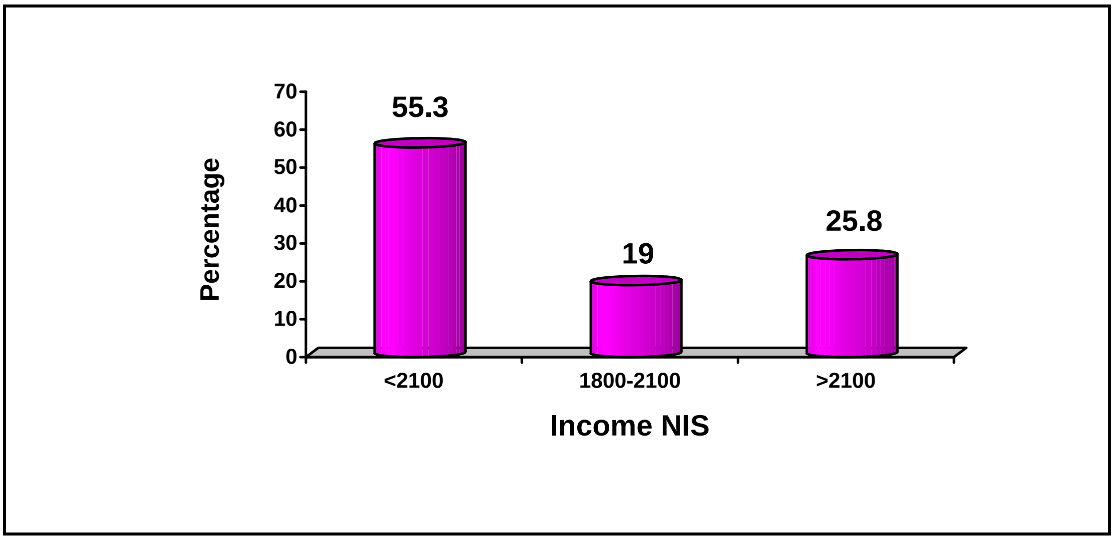


Figure 4.5: Percentage distribution of the parents according to financial status.

4.2 Characteristics of the health care providers

The study population was 115 Palestinian health care providers working in PHC centers in Gaza Strip in both UNRWA and Government. The number of providers who had participated in the study was 107 with response rate high as it was 93%.

4.2.1 Distribution of health care providers by governorate, sex, and primary health care centers:

The study was conducted to be representative to five geographical districts of Gaza Strip. Table (4.3) shows the total 107 subjects were distributed within PHC centers. North Gaza represents 12%of the study providers; Gaza city represents 42%, middle zone 15%, Khan-younis 19% and Rafah 12% (figure 4.6).

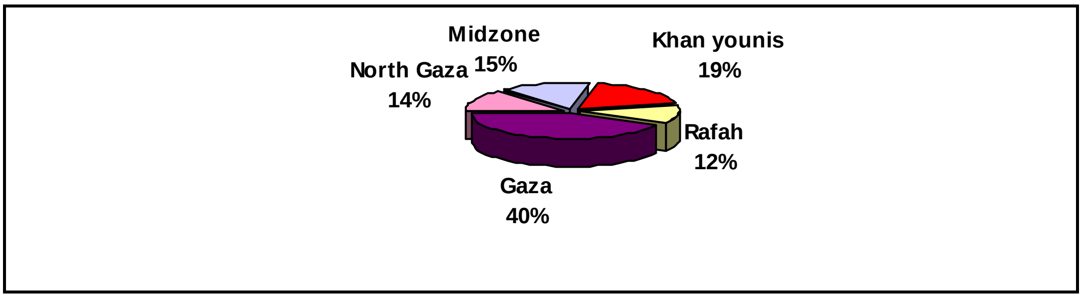


Figure 4.6: Distribution of health care providers by governorate

Table (4.3): Summary table of demographic characteristics of health care providers (n = 107)

Variables	No	Percentage (%)
Governorate		
North Gaza	13	12
Gaza city	45	42
Middle Zone	16	15
Khan Younis	20	19
Rafah	13	12
Sex		
Male	42	39
Female	65	61
UNRWA	29	27
Government	78	73
Age group		
< 25	2	2
26 - 35	32	31.4
> 35	68	66.6

About 39% of the health care provider was male while 61% of health care provider was female. In addition, 27% of health care provider worked in UNRWA while 73% worked in Government. The age of study population was divided into three main age group; (table 4.3) shows the majority of population at age group more than 35 years, which represented 66.6% of population, followed by age group (26-35) years, which represented 31.4% of population, followed by age group less than 25 years was 2%. These results were according to providers who work in newborn screening program in Gaza governorate at the time of the study.

4.2.2 Distribution of health care providers by job title:

Table (4.4) shows the distribution providers by job title. Head of departments represent 31% that is equal to nurse percentage, directors were 13% of the study population, followed by physician who represent 11%, lab technician who represent 7% while midwives represent 3% of the study population.

Table (4.4): Distribution of health care providers by Job Title

Variables	No	Percentage (%)
Job Title		
Head department	33	31
Nurse	33	31
Physician	12	11
pediatric	4	4
Director	14	13
midwife	3	3
Lab technician	8	7
Total	107	100

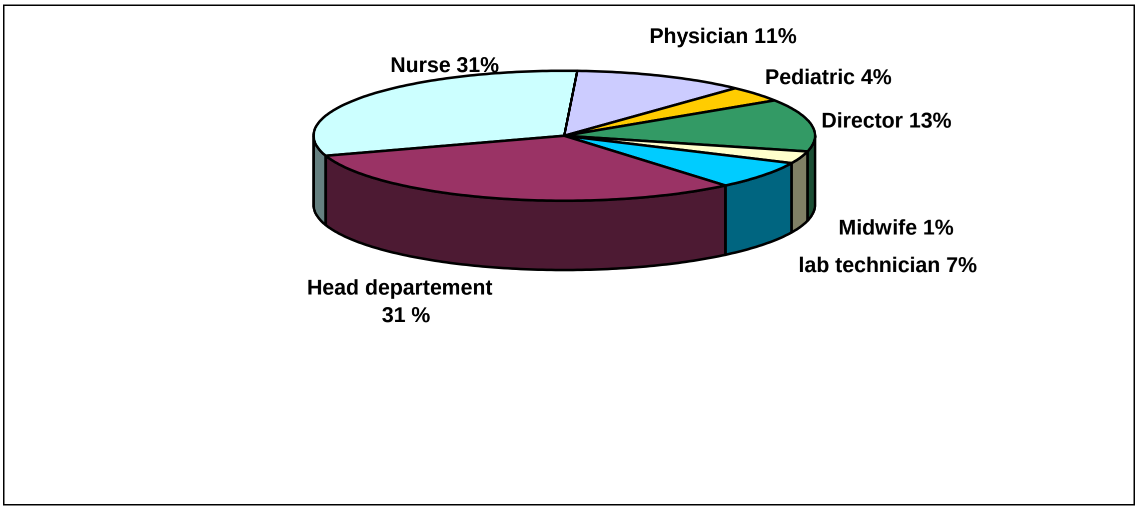


Figure 4 .7: Distribution of health care provider according job title

4.2.3 Distribution of health care providers by specification and qualification:

Table (4.5) shows the distribution of providers according specification. The majority of providers of the study population were staff nurses, which represented 44%, practical nurses represent 18%, followed by physician, that represent 24% while midwifes represent 5% of the study population and lab technicians represent 9% (figure 4.8). According the qualification, the majority of providers of the study population have BSC, which represented 54% of the study population, followed by Diploma, which represent 27%, licensed practical nurse that represented 12%, master degree, which represented 6 % and PhD, which represented (1%).

Table (4.5): Distribution of health care providers by specification and qualification

Variables	No	Percentage (%)
Specification		
Staff nurse	47	44
Practical nurse	19	18
midwife	5	5
Physician	26	24
Lab technician	10	9
Qualification		
Diploma	29	27
BSc	58	54
Licensed, practical nurse	13	12
Master degree	6	6
PhD	1	1

4.2.4 Distribution of health care providers by experience:

4.2.4.1 Experience of health care providers since graduation:

The researcher classified and categorized the experience into three groups, the first group was about 9% of the study population were 0 to 5 years, the second group was 24% of the health care providers in the study population (6 to 9 years) of experience. The third group, which was more than ten years of experience, has represented 67%, which was the high percentage in the study population.

4.2.4.2 Experience of health care providers in the newborn screening:

Regarding the experience of the health care provider in the newborn screening; the researcher categorized and re-coded the years of experience into three categories. The first was low level of experience (5 years and less) which represented the majority of the study population 52% among health care providers. The second group, which is the medium level from (6 to 10 years), which represented 25.5 %, the third level was a high level with more than ten years of experience represented by 22.5% as shown in (figure 4.9).

Table (4.6): Distribution of health care providers by experience

Variables	No	Percentage (%)
Experience since graduation (n=107)		
0-5 years	10	9
6 – 9 years	26	24
10+ years	71	67
Experience in the newborn screening (n=103)		
0 - 5 years	54	52
6 - 10 years	26	25.5
10+ years	23	22.5

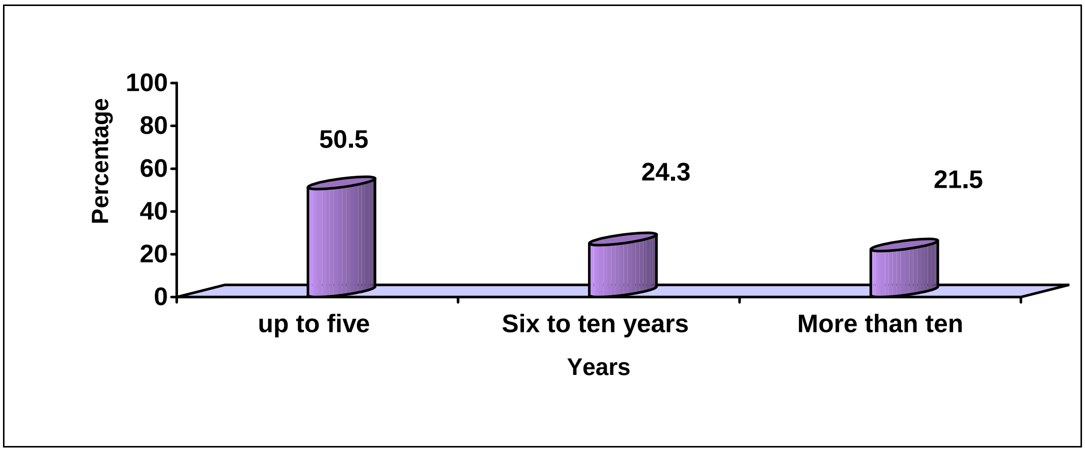


Figure (4.8): Distribution of health care providers according the newborn screening experience

4.3 Characteristics of specimen cards

The majority of specimens cards were from Gaza 28% followed by Khan younis 25 %, Middle Zone 20%, North Gaza 14%, and Rafah represented by the least score 13%. These results were according to cards that the researcher took them by random sample. The majority of cards were from UNRWA that represented by 66%, while the cards from Governmental centers that represented 34%. It is shown that the UNRWA represents 2/3 of the total cards as shown in table (4.7).

Table (4.7): Summary table of demographic characteristics of Guthrie cards (n = 300)

Variables	No	Percentage (%)
Places of residences		
North Gaza	42	14
Gaza city	84	28
Middle Zone	59	20
Khan Younis	75	25
Rafah	40	13
Primary health care centers		
UNRWA	199	66
Government	101	34

Whether the card was complete or incomplete for filling the card with all the required information, 34.7% of the cards shown to be complete while 65.3 % of the cards shown to be incomplete. Among the cards that had complete data filling, 81% were UNRWA while 19 % were governmental cards. For infant name, 91% of infant names were reported correctly while the 9% were missing one or more components of the name. About 90% of infant sex completed on the cards. The mother's names were completed in 23% of study sample. About 98% of the date of birth was completed and 94 % completed the address of primary health care centers. About 60% of cards were not written of the date specimen collection and 86 % was completed four blood spots on the card while 78% of cards are suitable for the test.

Table (4.8): Summary table of variable of the checklist Guthrie cards (n = 300)

Variable	Complete		In complete	
	No.	%	No.	%
Infant name	274	91	26	9
Infant sex	272	90	28	10
Infant I.D no.	295	98	5	2
Mother name	69	23	231	77
Date of birth	296	98	4	2
Primary Health Care	285	94	15	6
Date of specimen collection	121	40	179	60
Four circle of blood sample	259	86	41	14
Suitable for test	234	78	66	22

4.4 Challenges related to the newborn screening

Some challenges most directly related to newborn screening include:

4.4.1 Material and equipments:

Regarding availability of the material and equipment, the study shows that 30% of the providers who answered that the materials are always available for newborn screening tests. About 80% of the health providers stated that there was a shortage of PKU reagents lasted for two months and 20% stated that shortage for more than three months in CH reagents. When they are asked about the equipment of the measurement and the suitable way of the test used about 40% of the provider answered that it is suitable.

No world studies discussed the availability of the material and equipment in Palestine to ensure its continuity and it must be available in all times. These tests are done freely in the countries out sharing fees could help provision material and equipment. Political situation prevented from non-stop supply of these reagents.

Task force assumption regarding the future of newborn screening laboratory capacity is sometimes in adequate. The methods used by health department laboratories are in need of enhancement. Internationally it is recognized, that public health laboratories are often under competitive pressure. Budget constraints make it more difficult for health departments to cope with new tests that require additional equipments and personal (Newborn screening expands, 2000).

4.4.2 Child age at time specimen collection:

The researcher found that the age at the time of collection during the first week of life was 64%of study population while 36 % of the children presented after the end of the first week table (4.9).

Table (4.9): Child age at time specimen collection

Age at time of collection	No. of birth	Percentage of birth
1-7 days	256	64
Over 7 days	144	36

Regulations require all specimens to be collected between 24-48 hours of birth, or prior to discharge from delivery places. Specimens collected past day two are at increased risk of delayed diagnosis. The National PKU News (1998) recommended that testing should take place in the first week after birth if not less, to achieve detection of the PKU cases and reduce it complications including mental retardation. In this study, the results show that the average for the Gaza governorates in the different provinces for the specimen drawing is 7 days (American academy of pisietric, 1998). In a study conducted in Nebraska, 88.6% of birth samples were collected within 2 days (24 to 48 hours of age) while (0.56%) of birth was over 7 days of age at the time of collection (Nebraska annual report, 2005). The American academy of pediatrics (1982) stated that the "optimum timing for screening of full term healthy newborn babies is between 48_72 hours of age and mental retardation develops between four and six months, with psychological irritability, feeding problems, vomiting and fits during the first few weeks of life"(American academy of pediatrics,1982). A study in Gaza Strip showed that the PKU sampling takes place in between (264 _408) hours of age , which is not comply with the recommended range for PKU testing (Abu shahla,1999).

4.4.3 Unsatisfactory specimen (card):

In this study, the suitability of specimen cards for laboratory test was determent. 59.4% of specimens from governmental clinics were suitable for laboratory test while 40.6% were not. On the other hand, 87.4% of specimens from UNRWA clinics were suitable for test while 12.6% were not. The difference between UNRWA and Governmental clinics in suitability of specimen test was highly statistical significant (p-value < 0.001 table (4.11).

For comparison, in a study conducted in Nebraska about 159 of 26,228 of specimen (0.6%) were unsatisfactory (Nebraska annual report, 2005). In a study conducted in Gaza governorate, the accurate of four spots of blood was varying in accuracy with 40% to 100% (Abu shahla, 1999). Various studies reported that every unsatisfactory specimen must be repeated to ensure sufficiently reliable screening results.

4.4.4 From Birth to results (turnaround time):

In case of positive test, the result was reported at age 3 weeks in 60% of providers; at age 4 weeks in 20% of the providers and at age more than 4 weeks in 20% of the providers table (4.10).

Table (4.10): Distribution of the health care providers by turnaround time

Age at reporting	Percentage of provider
3 weeks	60
4 weeks	20
> 4 weeks	20

Regular monitoring of turnaround time of results reporting from initial specimen is an important indicator for how well the newborn screening system is functioning to be able to identify affected infants in time to prevent the effects of the disorder.

4.4.5 Specimen collection date:

In this study, the researcher studied whether the provider record the date of sample collection on the card. The date of sample collection was written on 40% of the studied cards. Among these 45.7% were from UNRWA and 29.7% from governmental clinics. Among the remaining 60% of cards that did not have any date, 54.3% were from UNRWA and 70.3 %from governmental clinics (table 4.11).

According to Newborn Screening Basics, a specimen cannot tested without a collection date and the test is delayed until the date is reported (Hitti, 2006). Moreover, the turnaround time of test cannot be determined unless the date of sample collection clearly written.

4.4.6 Mother's information:

This study shows that about 23% of cards completed the mother name while 77% incomplete the mother name but 10.9 % was complete in the government while about 28.6% complete in the UNRWA. The mothers name in Newborn Screening Basics is an important part of the baby's information, which is needed to help identifications of the baby (table 4.11).

Swati concluded that the carrier status for phenylalanine deficiency can be determined in at- risk family members with a positive family history (Kolpuru, 2007). The family history of child can't be known unless his mother name is known.

4.4.7 Infant sex:

The sex of infant is also important to the newborn screening test. Most of cards have a completed sex of baby (91%) from study sample. It is important to complete the sex of baby to help identifications of the baby (table 4.10).

4.4.8 Primary health care address:

The address of the infant's parent(s) and primary care centers are important to be clear in the newborn screening program. This is important for reporting of result as soon as possible and for obtaining confirmatory samples from the same child. Nine fifty percentage of the study sample had completed providers' information about the address (table 4.8).

4.4.9 Collector of specimen:

It is also important to write the name of the specimen collector. In our study, 95.5% did not write the name of collector specimen in the cards samples. This will make it difficult to feed back in case any problem with sample collection.

Table (4.11) illustrated the relationship between components of the checklist and primary health care providers. UNRWA performance in suitability of the sample for the test is higher than governmental centers where 87.4% of the samples were complete in UNRWA while this percentage is 59.4% in Governmental health centers. The differences between UNRWA and Governmental clinics reached a statistical significant level (P<0.001).

Governmental centers performance in completeness infant name of the specimen is greater than UNRWA where 96% of sample cards were complete in governmental health centers while this percentage is 88.9 in UNRWA. The difference between two groups demonstrated that there is a statistical significant level (P= 0.02).

Table (4.11): Relationship between component of Guthrie cards and primary health care centers

Item	Complete		Incomplete		P-value
	No	%	No	%	
Sample suitable for test					
Government	60	59.4	41	40.6	0. 0001
UNRWA	174	87.4	25	12.6	
Infant name (third)					
Government	97	96	4	4	0.02
UNRWA	177	88.9	22	11..1	
Infant sex					
Government	90	89.1	11	10.9	0.32
UNRWA	182	91.5	17	8.5	
Mother name					
Government	11	10.9	89	88.1	0.001
UNRWA	57	28.6	142	71.4	
Date of birth					
Government	97	96	4	4	0.01
UNRWA	199	100	0	0	
PHC address					
Government	89	88.1	12	11.9	0.0001
UNRWA	196	98.5	3	1.2	
Date of collection sample					
Government	30	29.7	71	70.3	0.005
UNRWA	91	45.7	108	54.3	
Collector sample written					
Government	4	4.5	190	95.5	0.5
UNRWA	9	4	97	96	
Four circle of blood					
Government	72	71.3	29	28.7	0.0001
UNRWA	187	94	12	6	

From the above findings, it is evident that infant sex completeness in both groups was approximately equal while UNRWA was 91.5 % but 89.1% was in governmental health centers. The differences between the two groups had no any statistical significant (P=0.32).

At the same time, the performance of UNRWA in completeness the writing of the mother name in cards is higher than governmental health centers where 28.6% of the samples were complete in UNRWA while the percentage is 10.9 in governmental health centers. The differences between two providers reached that there is a statistically significant level (P=0.001).

In this study it is also found that there is a statistically significant association (P<0.001) relationship between governmental and UNRWA health centers in clearness and completeness of the address of primary health care centers. About 88.1% of them were in governmental and 98.5% of them in UNRWA.

UNRWA performance in completeness of the card writing date of specimen collection is higher than government where it is 45.7% in UNRWA while 29.7 % in governmental health centers. The difference between UNRWA and government reached a statistically significant level (P=0.005).

Finally drawing the four spots of blood correctly took a percentage of 71.3 % in governmental health centers while it looks 94 % in UNRWA. The difference between the two groups of primary health care centers demonstrated that there is a statistically significant level (P< 0.001).

Table (4.12): Relationship between component of Guthrie cards and the governorates (part 1)

Item	Complete		Incomplete		P-value
	No	%	No	%	
1.Sample suitable for test					
North Gaza	34	81	8	19	0.15
Gaza city	59	70.2	25	29.8	
Middle zone	44	74.6	15	25.4	
Khan Younis	62	82.7	13	17.3	
Rafah	35	87.5	5	12.5	
2.Mother name					
North Gaza	5	11.9	37	88.1	0.0001
Gaza city	37	44	46	54.8	
Middle zone	9	15.3	50	84.7	
Khan Younis	6	8	70	92.3	
Rafah	11	27.5	29	72.5	
3.PHC address					
North Gaza	39	92.9	3	7.1	0.08
Gaza city	76	90.5	8	9.5	
Middle zone	56	94.9	3	5.1	
Khan Younis	74	98.7	1	1.3	
Rafah	40	100	0	0	
4.Date of collection sample					
North Gaza	3	7.1	39	92.9	0.0001
Gaza city	48	57.1	36	42.9	
Middle zone	37	62.7	22	37.3	
Khan Younis	20	26.7	55	73.3	
Rafah	13	32.5	27	67.5	
5.Collector sample written					
North Gaza	3	7.1	39	92.9	0.5
Gaza city	5	6	79	94	
Middle zone	2	3.4	57	96.6	
Khan Younis	3	4	72	90	
Rafah	0	0	40	100	

Table (4.12) clarifies the relationship between the component of the checklist and governorates, such as the name of child, mother name, gender, date of birth of child, suitability of test, completeness of the four circles, address of PHC centers, date of collection specimen and name of specimen collector. The researcher intended to study if they had any effect on the performance of the test or not. As is shown in table (4.12) there was strongly a statistically significant difference of mother name to governorates (P<0 .001), it was 44% in Gaza city and decrease to 8% in Khan -younis. Our study shows that the effect of the completeness of collection date on the test, there was a strongly statistically significant difference of completeness of collection date to governorates (P< 0.001), it was 62.7% in Middle Zone and decreases to 7.1% in North Gaza.

Table (4.12): Relationship between component of Guthrie cards and governorates (Part 2)

Item	Complete		Incomplete		P-value
	No	%	No	%	
6.Infant name					
North Gaza	39	92.9	3	7.1	0.43
Gaza city	75	89.3	9	10.7	
Middle zone	55	93.2	4	6.8	
Khan Younis	66	88	9	12	
Rafah	39	97.5	1	2.5	
7.Sex clear					
North Gaza	42	100	0	0	0.0001
Gaza city	67	79.8	17	20.2	
Middle zone	49	83.1	10	16.9	
Khan Younis	74	98.7	1	1.3	
Rafah	40	100	0	0	
8.Date birth					
North Gaza	41	97.6	1	2.4	0.6
Gaza city	82	97.6	2	2.4	
Middle zone	58	98.3	1	1.7	
Khan Younis	75	100	0	0	
Rafah	40	100	0	0	
9.Four circle of blood					
North Gaza	36	85.7	6	14.3	0.04
Gaza city	66	78.6	18	21.4	
Middle zone	54	91.5	5	8.5	
Khan Younis	64	85.3	11	14.7	
Rafah	39	97.5	1	2.5	

The researcher intended to study if completeness of four spots of blood affect on the test, as it shown above table (4.12) there was a statistically significant difference of completeness of four circle to governorates (P=0.04), it was highest (97.5%) in Rafah while it was lowest in Gaza city (78.5%). There is not any statistical significant difference by writing date of birth in governorates.

4.5 Knowledge about the newborn screening

4.5.1 Parents knowledge about the newborn screening:

Parents were asked about their knowledge of newborn screening test. The results showed parents who heard about newborn screening test were 17% while most of parents 83% did not hear about it. Most of parents preferred to get medical information from the physician (94%) followed by staff nurse (4%) and few of them prefer to get from media.

Parents who wanted to get the information about the newborn screening test in the early pregnancy were 87% while 10% wanted to know before delivery and 3% wanted after delivery. Parents who knew what is going to do for their child before drawing of the specimen for test was 24% but those who did not know was 76% as shown in (table 4.13). Some studies about time of counseling conducted that during pregnancy control reveals that the fetus is at risk, retrospectively after the birth of an affected child (European Genetics Foundation, 2008).

Routinely mothers came to the clinic after delivery to give their child the vaccine not concerning to the importance of newborn screening test. So the researcher advise to give the pregnant women all information about newborn screening test during the time of their antenatal care to be aware to do the test at the suitable time to protect their child of being brain damaged mentally and then mentally retarded. Besides, to notice any abnormal changes on their child.

Table (4.13): Parents knowledge about the newborn screening test

Variables	Frequency	Percentage
Heard about newborn screening		
Yes	67	17
No	333	83
Source of medical information		
Staff nurse	17	4
Physician	374	94
Media	5	1.3
Family	4	0.7
Time of getting information		
In start of pregnancy	349	87
Before delivery	40	10
After delivery	11	3
Source of information about newborn screening		
Staff nurse	24	6
Physician	374	93.5
Media	2	0.5
Before collection sample if explain about what is going to do		
Yes	96	24
No	304	76

The knowledge and awareness about newborn screening in a study in Louisiana showed that there is a limited knowledge and awareness of the parents concerning this tests and it also showed that parents wanted the information orally from the health care providers (Connie *et al*, 2006).

4.5.2 Knowledge of parents about PKU and congenital hypothyroidism:

The study revealed that the majority of parents (99%) did not receive any information about PKU during pregnancy whereas 97.5% did not receive any information about PKU before the test. About 79.5 % did not receive any information about CH during pregnancy and 96.5% did know any information about CH before the test. However, the knowledge of CH is about 20.5% of the parents who were informed about CH during pregnancy where as their knowledge of CH during pregnancy is much more than their knowledge about PKU (table 4.14).

Table (4.14): Parents knowledge about PKU and congenital hypothyroidism

Variable	PKU %		CH %	
	Yes	No	Yes	No.
Information during pregnancy	1	99	20.5	79.5
Information before test	2.5	97.5	3.5	96.5
Family history	0.5	99.5	4.5	95.5

The researcher measured the level of knowledge among parents about newborn screening test through choosing eight questions from the questioner and categorizing them. Parents were divided into two groups. The first group (lack of knowledge) who answered one question from (zero to one) was 71.3% of parents while the second group (little of knowledge) which answered 2 to 4 questions was 28.7% from parents. No parents were able to answer more than four questions as shown in table (4.15). This shows that there is little of knowledge in health education about PKU and CH test.

A study in United States showed that unaffected adolescent and adult had gaps in their knowledge about the genetic basis of PKU. These findings suggest that it must be an effective role for genetic services, providers including genetic counselors, in assisting all members of a family (Lana, *et al.*, 2003).

Table (4.15): level of knowledge among parents

Group	No	Percent (%)
Lack knowledge (0-1)	285	71.3
Little knowledge (2-4)	115	28.7
Tot al	400	100

4.5.3 Knowledge of health care providers about newborn screening:

In this study, there is about 92% of health care providers were familiar with PKU test while 8% of them did not know about this test. However, about 46.4% of health care providers know about this test whereas 50.6% of them did not know about the CH. Most of health care providers were familiar with PKU test, while less than half of them (46.4%) know about CH test. This study reflects that there is lack of health educational programs in developing health care providers. Besides, there are poor educational facilities for health staff. So it is very important and essential to improve the level of those health care providers and to expose the continuous training courses concerning PKU and CH.

4.5.4 Times of giving information about newborn screen tests:

Regarding the times given to the parents about newborn tests, table 4.16 shows that 43% of health care providers give information during antenatal care and 34.6% before sample collection, but after sample collection, we have 9% and 13.4% after results.

Table (4. 16): Times of giving information about newborn screening tests (n=107)

Item	No.	%
During antenatal care	46	43
Before sample collection	37	34.6
After sample collection	10	9
After results	14	13.4

4.6 Practice about newborn screening program

4.6.1 Vaccination parents practice:

The analysis of parents practice in screening test depends largely on knowledge and abidance by the time of vaccination. Most of parents (92%) go to clinics just for vaccination and not for making newborn screening tests. The researcher found out that 144 (36%) from 400 parents were delayed (more than 7 days according to WHO standards). Among them 59 % were delayed eight days and 41% were delayed for more than 8 days as shown in (table 4.17). Regarding the reasons for delay the researcher found out the following: 48% were given late appointment by health care providers, 30% lack of knowledge about the importance of vaccination in the first week of child's life, 7% newborn hospital admission, and 9% mother had a caesarian section.

To reach to the effectiveness of the newborn screening test program, it should be awareness and knowledge to the parents and they must be realize the importance of vaccination in the first week of their life of children's as well as to make PKU and CH tests. Providers of health services must give right times of registration for vaccination. To avoid the delay of vaccination it should be a plan of health education program about PKU and CH during antenatal care for mothers.

Table (4.17): Parents practice about vaccination

Variables	Frequency	Percentage (%)
Vaccine defaulter		
Yes	144	36
No	256	64
Period of defaulter		
8 days	85	59
> 8 days	59	41
Reasons of defaulter		
Late appointment	69	48
Lack of knowledge	44	30
Hospital admission	10	7
Newborn in low birth weight	8	6
A caesarian section	13	9
Total	**144**	**100**

4.6.2 Health services parent's satisfaction:

The researcher inquires about their satisfaction of the services provided by health care centers. Parents were asked about their satisfaction on the vaccination services, the results were 99.5% that mean the most of parents are satisfied. Regarding the accuracy of physical examination, the results were 97.2% concerning health education services the satisfied parents were 58.8 % while the percentage of satisfaction of parents of following up positive cases were 44% (table 4.18).

As mentioned above, the programs, which are provided, were highly successful and effective in both UNRWA and governmental PHC centers. Besides, there is a weakness in health education served to the child, so educated health program must be developed and must include posters, brochures, and films on PKU, and CH as there must be available to all parents in all centers, in addition to awareness and guidance programs.

Table (4.18): Parents satisfaction about the health services

Variables	Frequency	Percentage
	Vaccination services	
Yes	398	99.5
No	2	0.5
	Accuracy of physical examination	
Yes	389	97.2
No	11	2.8
	Health education	
Yes	235	58.8
No	165	41.2

4.6.3 Parents attitude about newborn screening:

Table (4.19) shows the attitude of parents about the previous results. Most of parents (96%) answered not informed with the previous results of screening, however when they are asked if they prefer to know the results when it is normal, abnormal or in all cases. Most of them (99.5%) answered (in all cases) while few of them have child with retested.

Our findings are consistent with previous research that found that parents are most interested in information that they deem relevant and practical and that emphasizes what they need to know and do (Fredrickson *et al*, 2004, 2001).

Table (4.19): Parents previous results s attitude

Variables	Frequency	Percentage
Informed about previous screening results (n=303)		
Yes	2	0.6
No	291	96.0
I don't know	10	3.4
Do you prefer to inform about screening results		
Yes, if there is abnormality	2	0.3
No	3	1
Yes, in all cases	298	98.7
Retested babies		
Yes	1	0.3
No	302	99.7

Although most parents prefer to know the results in all cases whether they are normal or abnormal, they are only informed in positive cases. The current situation, parents were informed if the cases were positive only.

4.6.4 Needs of parents to know about newborn screening:

Table (4.20) shows the needs of parents to know about newborn screening program. The researcher selected the most important items which mostly known by parents. Mainly the parents are looking to know more information on the disease were 90.5%, impact of the disease on their children were 98.5% and when they have the result of test were 81%while low proportional of parents was interested by purpose of the test 16.3% and counseling of positive cases 8%.

Table (4.20): Distribution of parents to know about newborn screening program

Variables	Frequency	Percentage
Purpose of the test		
Yes	65	16.3
No	335	83.7
Information on the disease		
Yes	362	90.5
No	38	9.5
Impact of the disease on child		
Yes	395	98.5
No	5	1.5
Time duration of results		
Yes	324	81.2
No	76	18.8
Mode of counseling for positive cases		
Yes	32	8.0
No	368	92.0

The results show that there is high proportion of parents looking to know more information about the newborn screening test, which indicated the weakness of disease related educational program. The education of program for parents is important to enforce the MOH plan to reduce infant complications that may occur as result to complications of mother regarding important time of screening test. Despite of the implementation of screening test with vaccine, the parents should have more information about vaccine importance, and they should be given more attentive for vaccine time while they neglect the screen test, this due to lack of enough information. Parent's education is essential to know the importance of early detection of abnormalities during the first month before hard complication.

4.6.5 Continuous education for health care providers:

The health care providers were asked about their continues education in service education, 84.6% of participants update their medical information about newborn screening test while 14.4% of them answered no. About 58% of participants had access to computer in their work but 42% answered no, while 12% of 58% had internet service available and 88% of them answered no. Moreover, when the providers are asked how they update their knowledge, the majority of participant (68%) answered by MOH leaflets and circulations. At the same time 46% of them, update by guideline protocol while 39 % of them update their medical information by personal research. Finally, the least of them (17%) update by postgraduate continued education programs (table 4.21).

The table reflects poor educational facilities for health staff and there is necessity to improve it and ensure continuous medical educations.

Table (4.21): Attitude of health care providers about newborn screening

Variables	No	Percentage
Update with the latest scientific development(n=107)		
Yes	87	81
No	20	19
Personal search in medical resources and net search(n= 87)		
Yes	34	39
No	53	61
Distribution of leaflets and curriculums by MOH(n= 87)		
Yes	59	68
No	28	32
Post grade continued education program(n= 87)		
Yes	15	17
No	72	83
Guideline protocol(n= 87)		
Yes	40	46
No	47	54
Access to computer in work (n=107)		
Yes	42	39
No	65	61
Internet service available (n=42)		
Yes	5	12
No	37	88

4.7 Health care providers practice

As it is shown in the table (4.22) the participants were asked about their current practice health education, about 64%of participants used lectures, while 24% of them used written material and 22% of them used media (video show). When they were asked the provider who gives the health education to parents, the majority (91%) answered staff nurse while physicians represented 8% of participant. In addition, asked if included the information about newborn screening tests during counseling with mothers, about 70% of participate answered yes while 23% of them answered no. About 47% of participates give health education on newborn screening during antenatal care, while 38% of them give the health education before sample collection and 8% of them give after results and sample collection. 88% of participated were answered if they used any educational materials, 44% of them answered yes by using education materials such as Brochure (74%), booklets (14%) and 13% using poster. As it is shown in the (table 4.22), percentage of health care provider who gets permission before drawing the specimen was about 37%, while the percentage of providers who did not was 59%.

The American Academy of Pediatrics (AAP) newborn screening Task force recommended in 1989 that each state design and implement parent education efforts regarding newborn screening (American Academy of Pediatrics, 1989).

In this study, it seems that the numbers of physicians are too much lower than staff nurses. So the physician role should be supported because there is a big gab between nurses and physicians despite this program serves all Gaza governorates. Besides, there is a little providing information about PKU and CH to the parents. The number of physician should be increased to suite the size of the services, which the program provides. There is a big difference between the answers of health care providers and answers of parents regarding the information given to mothers, health care providers answered that they provide mothers with all information needed while mothers answered they didn't received enough information.

Half of health care providers said that they provided information about newborn screening test during antenatal care while most mothers said that they did not receive any information about newborn screening test during their antenatal care period.

Regarding types of educational material, health care providers said that they used three types of educational material, which are brochures, booklets, and posters, but in fact, the researcher did not found any such types of educational material about PKU and CH in the centers. The researcher thinks that permission should be given to health care providers when they want to take the specimen from children feet. Whereas the study showed that more than 50% of health care providers didn't get such permission before taking the specimen. Although neither parents nor providers were interested in detailed information about newborn screening, there were some key points that they wanted to know. For parents, the most important information was (1) that their infant would be screened, (2) that screening would benefit the infant, (3) that the infant might need to be retested, and (4) how parents would be notified about the need for retesting and the need to act quickly.

Table (4.22): Practice of health care providers about newborn screening

Variables	No	Percentage
Current health education (n=107)		
Lecture	69	64.4
Written material	36	33.6
Media	2	2
Providers of health education (n=97)		
Staff nurse	88	91
Physician	8	8
Lab technician	0	0
Pharmacy	1	1
Included the information about newborn screening tests in discussion with mother (n=91)		
Yes	68	75
No	23	25
Time of health education about screening (n=91)		
During antenatal care	46	51
Before sample collection	37	41
After sample collection	4	4
After results	4	4
Used education material (n=88)		
Yes	39	44
No	49	56
Types of education material (n=39)		
Brochure	29	74
Booklets	5	13
Posters	5	13
Consent informed should be mandatory (n=94)		
Yes	66	68
No	28	29
Permission before take the specimen (n=93)		
Yes	36	38
No	57	62

4.7.1 Information giving to parents about newborn screening test by health care providers:

The researcher examined the most important information about the PKU and CH, which must be known by parents. High percentage of health providers believed that parents must know all information. So information must be submitted to parents during counseling before sample drawing; where 76.3% of health providers informed information for parents about the necessity of this type of test performance, while 84.4% informed about importance of C.H 61% gave information about importance of PKU and 90% gave information about process of conveying the results (table 4.23).

The results reveal the weakness of submitted information to parents during educational program, while 61% only inform parents about PKU test, which has the worst consequences to carrier infant if it not detected early. The researcher thinks that these all information about screening test must be given to parents, so any percentage lowest than 100% reveals the weakness of counseling program.

Table (4.23): Information given to parents by health care providers (n =97)

Item	**Yes**		**No**	
	No	%	No	%
Type of test performance	74	76.3	23	23.7
Importance of congenital hypothyroidism	79	81.4	18	18.6
Importance of PKU	59	61	38	39
Process of conveying the results	88	90	9	10

4.7.2 Screening results:

The following up for screening test and knowing the results of test if it is positive or negative it is important to start the proper intervention and reduce any complications may occur due to result delay. As shown in table (4.24) there are only 10.3% of parents who are asked about results of their child-screening test. The percentage of health providers who meet positive result during their working career was 53 %. Parents were informed about test results mainly by staff nurse where 75% of positive result mainly by stuff nurse but approximately 25% informed by other health care provider as lab technicians, physicians and administrative.

The health care providers believe that the physician is responsible for following up the positive cases, about 68% of health care providers who think that the physician is responsible follow up the positive result. While 16.5% of health providers believe that, the parents themselves are responsible to follow the result of their child. Moreover, 15.5% return this responsibility to nurse. Regarding files related to registration of the positive results there are 42% only of facilities has a registration files. The results return to confirm the weakness of PKU and CH program, which is, represents her in weakness of follow up step. The weakness of educational program causes weakness of parents care about test results. Despite of the long period of the program, there are no clear policy to know who is responsible for following up the positive cases and who is responsible to inform parents. The lack of registration system causes weakness in following up the system and its improvement and this is due to absence of full information.

Table (4.24): Health care provider's knowledge about previous results

Variables	No	Percentage
Did any parents ever ask for the results? (n=95)		
Yes	10	10.5
No	85	89.5
Have you ever inform with the positive results?(n=95)		
Yes	52	54.7
No	35	36.8
I did not remember	8	8.5
Who inform the parents? (n=91)		
Staff nurse	73	80.2
Lab technician	2	2.1
Physician	12	13.3
Administrative	4	4.4
In positive case who responsible person to follow up (n=87)		
Physician	66	76
Parents	6	7
Nurse	15	17
Is there an index for the positive cases in health center?(n=107)		
Yes	45	42
No	62	58

4.8 Process management

4.8.1 Waiting time:

The average waiting time was 64.35 minutes (S.D=34), the findings show that clients who stayed 31 to 60 minutes were 55%, about 17.8% of parents stayed 61 to 90 minutes while 12.3% of them stayed 30 minutes (table 4.25). Waiting time is a good indicate for quality of submitted services. Long waiting time for parents is a common problem in health care centers, which causes patient dissatisfaction. System reform is necessary to shorten the waiting time of test performance, especially the test is making after few days from delivery when mother still sick and terrible and long time is consider tribal and risky. From a study finding researcher suggests further quality projects in different health care setting to assess the problem of long waiting time and to reform the process test performance. In general, adopting and scheduling an appointment system as implemented in UNRWA could help to organize the process test and to decrease the waiting time in governmental centers.

Table (4.25): Parents waiting time and services

Categories	UNRWA		Government	
	No	%	No	%
0-30 min	21	10.9	28	13.5
31- 60	75	38.9	145	70
61-90	43	22.3	28	13.5
91-120	39	20.2	6	2.9
>121	15	7.8	0	0
Chi	P < 0.001			

By comparison, the long of waiting time, the result express the average waiting time in UNRWA was 78 minutes, which is higher than the governmental (51 minutes). The researcher suggests long Waiting time in UNRWA is reflect to high number of newborn who receive of vaccine services in UNRWA are more than governmental primary health centers. Beside them, there are lower health provider's numbers in UNRWA clinics than governmental clinics this thing may lead to longer waiting time.

4.8.2 Newborn screening program current performance:

Process of the newborn screening program was assessed by asking the health care providers about the current system. They were asked if they inform the parents with screening results or not according the system, how to be ensure that, and if the screening test performed or not and if the result delayed, what they doing, if the results is documented and registered in child file or not, and if there is a timetable to follow up the results.

Table (4.26) clarifies that according to the system regulations 56% of health care providers informed the parents about screening results, if the result is positive, while 44% of them inform the parents in all cases and one third of the health care providers (31%) answered that they inform the mother about results in all cases while 57.7% of health care providers inform the parents in positive cases only and 11.5 % of health care providers inform parents by any results. When the health care providers are asked what they are going to do if the result delayed, 55% answered that they contact the lab, 16%of them contact the director of child health center, 13% answered they inform their manger and 16% nothing is done. Moreover, as shown in table (4.26) the majority of health care providers that represented 62% who documented the result, in child file and 38% of them did not document. The result, during their career 84.5% of health care providers was informed about the positive results while 15.5% did not inform. Only 10.5% of the study population answered there is a timetable to inform the results while 89.5% answered no. When health providers asked about how they make sure if the test is performed or not, 44% of them was talked about the presence ways to know the test process, while 55% didn't know how to follow up the test process.

When health care providers were asked about the presence of schedule time to receive the results and inform mothers; 10.5% of them answered the presence of this table by majority of them (89.5%) answered there is no such tables. Through reviewing of the child files by researcher, there are items talking about PKU and CH but unfortunately, these are incompliance to fill the results. Researcher believes that taking care of this result is very necessary and informing mother during their vaccination visit is very important for the program effectiveness.

Table (4.26): Items describing process of the PKU and congenital hypothyroidism program and its implementation

Inform about the positive results (n=95)		
Yes	82	84.5
No	13	15.5
Is there a time table to inform the result (n=95)		
Yes	10	10.5
No	85	89.5
Inform the mother about results (n=107)		
Yes in all cases	34	31
Yes in positive cases only	62	57.7
No, never	11	11.3
Insure that the screening test performed (n=89)		
Yes	39	44
No	50	56
If delay the result how explain (n=69)		
Contact the lab	38	55
Contact the director of child health	11	16
Inform the direct manger	9	13
No	11	16
Documentation the results in child file (n=91)		
Yes	57	62
No	34	38

4.8.3 Health care provider's satisfaction about current newborn screening:

Table (4. 27) illustrated the satisfaction about current newborn screening program among health care providers. More proportion of health care providers (43.3%) were satisfied about newborn screening program while (18.6%) of them unsatisfied and (37.1%) of health care providers were incomplete satisfied. And when they are asked if any necessity of introducing new tests in newborn screening program, about (27.8%) of health care providers answered yes, such as like genetic disease, galactosemia, thalasemia, hepatitis and glucose -6- phosphates Dehydrogenase (G.6.P.D) while (26.8%) of health providers show no need and (45%) of them did not know.

Table (4.27): health care provider's satisfaction about newborn screening

Variables	No	Percentage
Are you satisfied about the newborn screening (n=96)		
Yes	42	43.3
No	18	18.6
Some how	36	37.1
Necessity of introducing new tests in newborn screening program (n=90)		
Yes	27	27.8
No	26	26.8
I don’t know	37	45

When the health care providers were asked about ways for improvement of the newborn screening program, they mentioned that documentation is essential with presence of scheduled table to send the results to people on time is a crucial factor, neonatal screening service must involve the close cooperation of families with health professionals, and administrative staff. Health providers suggest that, the presence of computer net is important to connect all facilities, facilitate the communication process, and elevate the delayed time of information mutual process.

The missing of screen test for rare condition will lead to serious consequences which push to have clear quality assurance measures to ensure that the service is running in the most effective, efficient, equitable and humanitarian way possible.

Chapter (5)

Conclusions and Recommendation

Chapter Five

Conclusion and Recommendations

5.1 Conclusion

The goal of newborn screening for metabolic and inherited disorders is to identify newborn at risk metabolic, endocrine and other disorder that would otherwise be undetected until damage has occurred, and for which intervention and / or treatment can improve the outcome for the newborn. The evaluation of Phenylketonuria and Congenital Hypothyroidism newborn screening program in Gaza governorates will survive for keeping the success in improvement of health services supports controlling and preventing deterioration the health services. This study intended to find out if the program of newborn screening in Gaza governorate is achieving its preset goal of contributing to the decrease of mental retardation.

The study design was cross sectional, using evaluation of the program in the different component; parents, Guthnie screening cards, and health care providers. In order to ensure that sample was geographically representative, proportional stratified sample was used to select parents and a simple random sample technique was used to select cards while the study involved all health care providers who provided vaccination services and newborn screening test without sampling. The response rate was 95% among parents while it was 90% among providers. Face to face, interview was conducted with parents; self-administered questioners were handed to the health care providers while a checklist evaluated the specimen cards.

The findings of this study showed that the majority of cards were from UNRWA 66% while governmental were 34%. Weather the card was complete or incomplete for filling the card with all the required information, 34.7% of the cards shown to be complete while

65.3% of the cards shown to be incomplete. Among the cards that had complete data filling, 81% were from UNRWA, while 19 % were governmental cards. The study illustrated the relationship between the data components of the cards and the primary health care providers. Variations were discussed in details among the different variables and the data deficits in the cards.

Governmental performance in completing infant name of the specimen (96%) was greater than UNRWA performance (88.9%). In completing the date of specimen, collection was higher in UNRWA (45.7%) than governmental 29.7%. Drawing the four spots of blood correctly were 94% in governmental health centers, it was 71.3% in UNRWA. The difference between two groups of PHC centers demonstrated that a statistically significant. UNRWA performance in suitability of the specimen for the test was higher than governmental, in UNRWA it was 87.4% while this percentage was 59.4% in governmental health centers. Regarding the availability of material and equipment for PKU and CH test 30% of the health care providers claimed that the material and equipment were always available.

On evaluating the parents knowledge about newborn screening, the findings from this study have demonstrated that parents who heard about newborn screening were 17% while most of parents 83% did not hear about it. Most of parents preferred to get medical information from the physician (94%) followed by staff nurse. Parents who wanted to get the information about newborn screening test in early pregnancy were 87 % while 10 % wanted to know about it before delivery. Moreover, parents who knew what are going to be done for their child before drawing the specimen was 24%. The majority of parents did not receive any information about PKU and CH.

Regarding the health care providers knowledge, the study revealed that about 92% of health providers were familiar with PKU test but less than half of them, 46.4% knew about congenial hypothyroidism test. The study reflected that there is lack of health educational programs in developing health care provider's knowledge, as well as lack of educational facilities.

Referring to the parent's practice, the study shown that 36% of infants were delayed for vaccination (more than 7 days according to WHO standards). Among delayed infants, 59% were delayed up to eight days and 41% were delayed for more than 8days. Regarding the reasons for delay, the study found out that 48% were given late appointment by health care providers and 30% lack of knowledge about the importance of vaccination in the first week of child's life. The average waiting time was 64.3 min for receiving the service. Most of parents were not informed about the previous results of screening while they preferred to know the results regardless results were normal or abnormal. However, the current situation parents were informed if the cases were positive only. Mainly the parents were looking to know more information about the disease in 90.5% of the subjects and impact of the disease on their children were 98.5% while 81 % of them wanted to know when they know will receive the test result.

On evaluating the health care providers education practice the study showed that about 38% of HCP give the health education before specimen drawing while 47% of them give the health education during antenatal care and 88% of HCP used educational material. In the study, 91 % of HCP stated that staff nurses give information while 8 % only stated that physicians are giving information. It seems that the number of physicians is too much lower than staff nurses. The physician role should be strengthened in away that decrease the gab between nurses and physicians.

There is a big difference between the answers of health care providers and parents answers regarding the information given to mothers, health care providers said that they provided mothers with all information needed while mothers answered they did not receive enough information. The study showed that 10.3% of parents only asked about results of their child-screening test. The health care providers who believed that the physicians are responsible about following up positive cases were 68% while 16.5% of health providers believed that the parents themselves are responsible for following up their child and 15.5% of them return this responsibility to the nurse. Regarding files related to registration of positive cases, 42% only of health care providers has known a registration files in their facilities.

The study showed that 56% of health care providers informed the parents about screening results if the result is positive only, while 44 % of them inform the parents in all cases. Of the health care providers, 84.5% was ever informed about the positive results during their career. Regarding to service satisfaction, among health care providers 43.3 % were satisfied of newborn screening program while 37.1% of health care providers was incomplete satisfied and 18.6 % of them unsatisfied. Mean while 99.5 % of the parents were satisfied of the vaccination services, 97 % were satisfied of accuracy of physical examination. On the other hand, only 58.8 % of parents were satisfied of the health education practices.

The neonatal screening service is a complex process requiring the close cooperation of a wide range of people, including midwives, nurses, child health computing staff, central laboratory staff, general physicians, pediatricians, and parents. They must all work together to provide an efficient, effective, and equitable service while trying to minimize the anxiety and discomfort caused to families and babies by the process.

5.2 Recommendations

Efforts to be done according to the following recommendations could have a positive impact to improve child lives either in health and social aspects and their families awareness and there by the whole community.

5.2.1 Recommendation for Health policy makers:

- Health policy makers ought to be entitled to include the newborn screening in the agenda of health education plan for the health settings and motivating and increasing parent's awareness and attitude that may help early diagnosis and avoid mental retardation.
- More efforts need be made to ensure availability of health education materials for newborn screening tests such as brochures, posters and mass media to disseminate information for each Palestinian family.
- Policy makers could be enhancement the effectiveness the newborn screening program by committed to availability and sustainability of required materials and equipment for the tests.
- Establishment of protocols and guidelines for the newborn screening is a necessity that include:
  - Proper newborn age for sample collection
  - Appropriate method for sample collection and data filling
  - Time scale for results feedback and family notification
  - Responsibilities for following up of results.
- Increased coordination and uniformity among clinic newborn screening systems and other child health programs will greatly benefit families, health care

professionals, and public health agencies. Development of internet work system will facilitate such coordination and communication.

- Encouraging and enhancing specific training for health care providers in newborn screening process and impact of the disease and prevention of related complications of brain damage and mental retardation.
- Strengthening the top management role in supervision and motivation of the staff to ensure the earliest diagnosis possible and the proper management and follow up for the cases.
- Improvement of waiting time at the services delivery level for the newborn screening as to be more procedures that are comfortable for both mothers and newborns. More organized appointment system and adherence to such appointment would facilitate smooth flow of work and better communication.
- Emphases should be development towards improving documentation protocols including follow up and monitoring.

5.2.2 Recommendations for further studies:

- Specific studies need to be done to actually test the validity of the PKU and CH screening tests.

- Prospective studies to identify the different impact on the diseased newborns (PKU and congenital hypothyroidism) and the out come of different managements and follow-up.
- Studies for other congenital disorders and identification of familial risk factors among Palestinian population.

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Annexes

Annex no. (1): Map of Palestine

Source: MOH, 2000

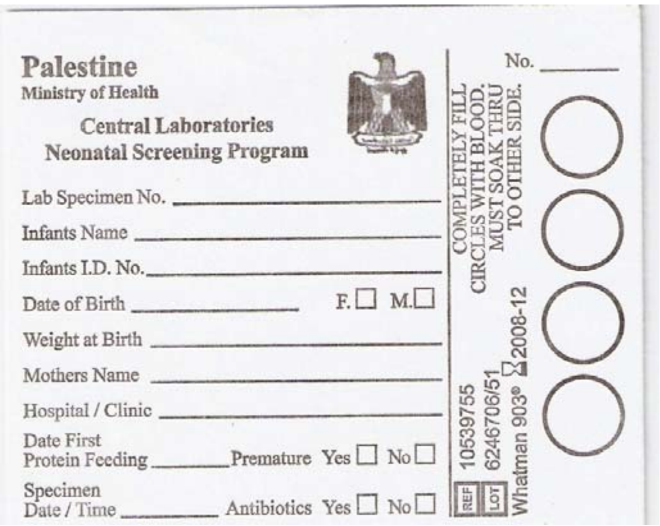
Annex no. (2): Map of Gaza Strip:

Source: www. Islamonline.net

Annex no. (3): Vaccination schedule in Palestine from Jan.1995

Vaccines	Age
B.C.G , HB1	1 day
HB2 , I.P.V1	1 month
D.P.T.1 , T.O.P.V1 , I.P.V2	2 months
D.P.T.2 , T.O.P.V2	4 months
HB3 , D.P.T.3 , T.O.P.V3	6 months
Measles	9 months
D.P.T.4 , T.O.P.V4	12 months
MMR	15 months
DT , O.P.V	6 years
Rubella , for female students only	12 years
Dt	15 years

Annex no. (4): Cards Newborn Screening test



Palestine
Ministry of Health

Central Laboratories
Neonatal Screening Program

Lab Specimen No. ____________

Infants Name ____________

Infants I.D. No. ____________

Date of Birth ____________ F. ☐ M. ☐

Weight at Birth ____________

Mothers Name ____________

Hospital / Clinic ____________

Date First Protein Feeding ________ Premature Yes ☐ No ☐

Specimen Date / Time ________ Antibiotics Yes ☐ No ☐

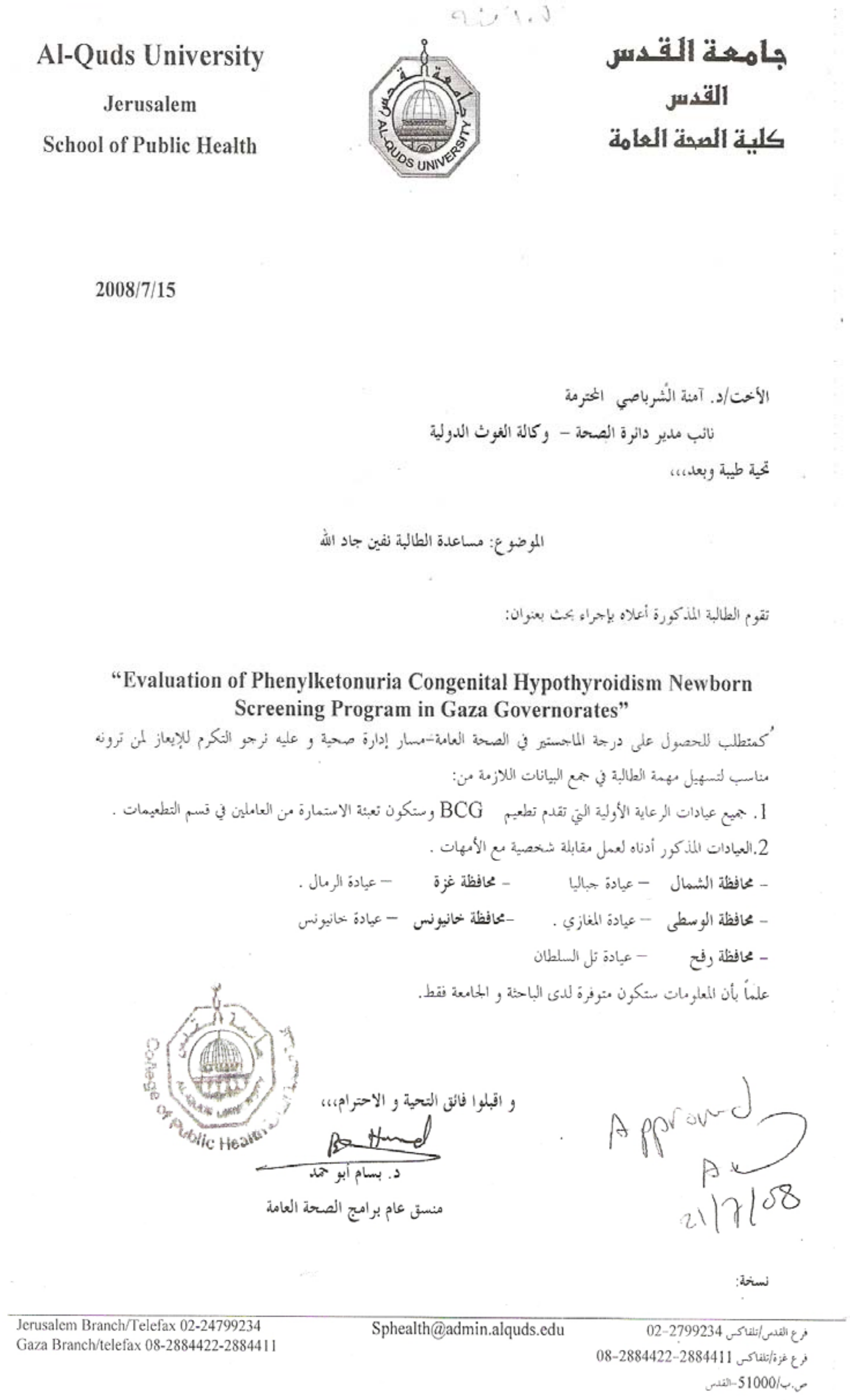
No. ________

COMPLETELY FILL
CIRCLES WITH BLOOD.
MUST SOAK THRU
TO OTHER SIDE.

○ ○ ○ ○

REF 10539755
LOT 6246706/51
Whatman 903® 2008-12

Annex no. (5): Ethical Approval: UNRWA



Al-Quds University
Jerusalem
School of Public Health

جامعة القدس
القدس
كلية الصحة العامة

2008/7/15

الأخت/د. آمنة الشُرباصي المحترمة
نائب مدير دائرة الصحة – وكالة الغوث الدولية
تحية طيبة وبعد،،،

الموضوع: مساعدة الطالبة نفين جاد الله

تقوم الطالبة المذكورة أعلاه بإجراء بحث بعنوان:

"Evaluation of Phenylketonuria Congenital Hypothyroidism Newborn Screening Program in Gaza Governorates"

كمتطلب للحصول على درجة الماجستير في الصحة العامة-مسار إدارة صحية و عليه نرجو التكرم للإيعاز لمن ترونه مناسب لتسهيل مهمة الطالبة في جمع البيانات اللازمة من:

1. جميع عيادات الرعاية الأولية التي تقدم تطعيم BCG وستكون تعبئة الاستمارة من العاملين في قسم التطعيمات .
2. العيادات المذكور أدناه لعمل مقابلة شخصية مع الأمهات .

- **محافظة الشمال** – عيادة جباليا – **محافظة غزة** – عيادة الرمال .
- **محافظة الوسطى** – عيادة المغازي . –**محافظة خانيونس** – عيادة خانيونس
- **محافظة رفح** – عيادة تل السلطان

علماً بأن المعلومات ستكون متوفرة لدى الباحثة و الجامعة فقط.

و اقبلوا فائق التحية و الاحترام،،،

د. بسام أبو حمد
منسق عام برامج الصحة العامة

Approved
A
21/7/08

نسخة:

Jerusalem Branch/Telefax 02-24799234
Gaza Branch/telefax 08-2884422-2884411
Sphealth@admin.alquds.edu
فرع القدس/تلفاكس 02-2799234
فرع غزة/تلفاكس 08-2884422-2884411
ص.ب/51000-القدس

Annex no. (6): Ethical Approval: MOH

Al-Quds University
Jerusalem
School of Public Health

جامعة القدس
القدس
كلية الصحة العامة

30/6/2008

الأخوة / مديرا لتوزيع
الأخوة / المرضية
لا مانع من مساعدة
الأخت / نفين
ولكم جزيل الشكر

الأخ/د. فؤاد العيسوي المحترم
مدير عام الرعاية الأولية – وزارة الصحة
تحية طيبة وبعد،،،

الموضوع: مساعدة الطالبة نفين جاد الله

تقوم الطالبة المذكورة أعلاه بإجراء بحث بعنوان:

"Evaluation of Phenylketonuria and Congenital Hypothyroidism Newborn Screening Program in Gaza Governorates"

كمتطلب للحصول على درجة الماجستير في الصحة العامة-مسار إدارة صحية و عليه نرجو التكرم للإيعاز لمن ترونه مناسب لتسهيل مهمة الطالبة في جمع البيانات اللازمة من مراكز الرعاية الأولية التابعة لدائرتكم.
علماً بأن المعلومات ستكون متوفرة لدى الباحثة و الجامعة فقط.

و اقبلوا فائق التحية و الاحترام،،،

د. بسام أبو حمد
منسق عام برامج الصحة العامة

لا مانع من مساعدة

نسخة:
– الملف

Jerusalem Branch/Telefax 02-24799234
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فرع غزة/تلفاكس 08-2884422-2884411
ص.ب/51000-القدس

Annex no. (7): Ethical Approval: MOH

Palestinian National Authority
Ministry of Health
Helsinki Committee

السلطة الوطنية الفلسطينية
وزارة الصحة
لجنة هلسنكي

Date: 15/8/2008

Name: Neveen Gadalla

I would like to inform you that the committee has discussed your application about:

التاريخ:١٥/٨/٢٠٠٨

الاسم: نفين جاد الله

نفيدكم علماً بأن اللجنة قد ناقشت مقترح دراستكم حول:-

Evaluation of Phenylketonuria and Congenital Hypothyroidism Newborn Screening Program in Gaza Governorates.

In its meeting on August 2008
and decided the Following:-
To approve the above mention research study.

و ذلك في جلستها المنعقدة لشهر أغسطس ٢٠٠٨

و قد قررت ما يلي:-

الموافقة على البحث المذكور عاليه.

Signature
توقيع

Member عضو	Member عضو	Chairperson

Conditions:-

- Valid for 2 years from the date of approval to start.
- It is necessary to notify the committee in any change in the admitted study protocol.
- The committee appreciate receiving one copy of your final research when it is completed.

Gaza Etwam – Telefax 972-7-2878166

Annex no. (8): Consent form: parents

بسم الله الرحمن الرحيم

عزيزتي المشاركة:

أنا الطالبة ***نفين طلال جادالله*** أدرس بكلية الصحة العامة – جامعة القدس أبو ديس، أقوم بإعداد بحث بعنوان " **تقييم برنامج المسح الروتيني حول كسل الغدة الدرقية الخلقي والفنيل كيتونيوريا عند حديثي الولادة بمحافظات فلسطين الجنوبية** " باعتباره متطلب للتخرج والحصول على درجة الماجستير وتم اختيارك بناءاً لمطابقتك شروط اختيار العينة.

تهدف هذه الدراسة إلى تقييم برنامج المسح الروتيني حول كسل الغدة الدرقية الخلقي والفنيل كيتونيوريا عند حديثي الولادة بمحافظات الجنوبية والذي يؤدي إلي تأخر شديد في انجاز هذه الفحوصات في الأشهر الأولي من عمر الطفل مما يترتب عليه ظهور علامات التخلف العقلي الممكن تجنبه بالفحص المبكر.

ونشكر لك مشاركتك في هذه الدراسة بالإجابة على بعض الأسئلة خلال المقابلة، مع العلم أن المقابلة لن تستغرق أكثر من 10 دقيقة تقريبا.

مشاركتكم تطوعية يمكنكم رفض الإجابة على أي سؤال وأرغب أن أؤكد لكم أن المعلومات التي تذكروها ستكون مصدر ثقة وسرية وستستخدم فقط لغرض البحث العلمي وبدون ذكر الأسماء ولذا أرجو أن تكون الإجابات دقيقة.

- قبل البدء في المقابلة هل تودين الاستفسار حول أي شيء عن الدراسة؟
- هل من الممكن أن نبدأ المقابلة الآن؟ 1. نعم 2. لا

وشكراً لكم على حسن تعاونكم

للاستفسار الرجاء الاتصال علي الرقم 2833450

الباحثة: نفين جادا لله

Annex no. (9): Consent form: Health care providers

بسم الله الرحمن الرحيم

عزيزي المشارك:

أنا الطالبة ***نفين طلال جادالله*** أدرس بكلية الصحة العامة – جامعة القدس أبو ديس، أقوم بإعداد بحث بعنوان " **تقييم برنامج المسح الروتيني حول كسل الغدة الدرقية الخلقي والفنيل كيتونيوريا عند حديثي الولادة بمحافظات فلسطين الجنوبية** " باعتباره متطلب للتخرج والحصول على درجة الماجستير وتم اختيارك بناءً لمطابقتك شروط اختيار العينة.

تهدف هذه الدراسة إلى تقييم برنامج المسح الروتيني حول كسل الغدة الدرقية الخلقي والفنيل كيتونيوريا عند حديثي الولادة بمحافظات فلسطين الجنوبية والذي يؤدي إلي تأخر شديد في انجاز هذه الفحوصات في الأشهر الأولي من عمر الطفل مما يترتب عليه ظهور علامات التخاف العقلي الممكن تجنبه بالفحص المبكر.

ونشكر لك مشاركتك في هذه الدراسة بالإجابة على بعض الأسئلة، مع العلم أنها لن تستغرق أكثر من 15 دقيقة تقريبا.

مشاركتكم تطوعية يمكنكم رفض الإجابة على أي سؤال وأرغب أن أؤكد لكم أن المعلومات التي تذكروها ستكون مصدر ثقة وسرية وستستخدم فقط لغرض البحث العلمي وبدون ذكر الأسماء ولذا أرجو أن تكون الإجابات دقيقة.

وشكراً لكم على حسن تعاونكم

للاستفسار الرجاء الاتصال علي الرقم 2833450

الباحثة: نفين جادا لله

Annex no.(10): Assessment structure checklist of evaluation newborn screening program

Assessment checklist of blood collection card. **Serial no _______**

No	Item	Complete	Incomplete
1.	Is the infant name complete?		
2.	Is infant sex clear?		
3.	Is infant I.D.No. clear.		
4.	Is the mother name full?		
5.	Is the date of Birth complete?		
6.	Is the PHC address clear?		
7.	Is the Date of specimen collection written on the card?		
8.	Is the collector sample written?		
9.	Are there four blood spots complete ?		
10	Is the sample suitable for tests?		

Annex no.(11): Data collection Instrument parents (Arabic).

1	اسم الطفل ثلاثي :.............................	2	رقم الطفل في المركز الصحي : ____________
3	الجنس : 1 –ذكر 2 – أنثي	4	العنوان: _________________
5	تاريخ ميلاد طفلك : _ _ _ / _ _ _ / 2008	6	المحافظة: ا . شمال غزة ب . غزة ج .المنطقة الوسطي د. خان يونس ه . رفح
7	مركزا لرعاية الأولية: ا.الوكالة ب. الحكومة	8	عدد الأفراد الذين يعيشون في المنزل: __________
9	مستوي تعليم الأم بالسنوات:1 . أمية 2 .عدد السنوات ____	10	مهنة الأم:_______
11	مستوي تعليم الأب بالسنوات : 1 . أمي 2. عدد السنوات ________	12	مهنة الأب: ___________
13	دخل الاسرة الشهري (جميع مصادر الدخل) : _______.	14	عدد الأطفال الذين أنجبتيهم : _______
15	هل يتم تسمية المولود قبل التوجه للمركز الصحي لأخذ التطعيم الأول؟ ا . نعم ب . لا	16	ما هو ترتيب مولودك في الأسرة؟ _________
17	التأخر عن موعد التطعيم (أكثر من أسبوع من تاريخ الميلاد): أ .نعم ب . لا	18	. إذا كان الجواب بنعم، كم مدة التأخير: _____ أيام
19	ما هو السبب؟ حدد (يمكن اختيار أكثر من إجابة). أ . حسب الموعد المحدد من المركز الصحي. ب . عدم المعرفة بضرورة الالتزام بموعد التطعيم. ج . دخول الطفل إلي المستشفي في نفس الفترة. د . نقص وزن المولود عند الولادة. ه . قيصرية.	20	هل سمعت عن برنامج المسح الروتيني لأطفال حديثي الولادة؟ ا . نعم ب . لا
21	من هو مصدر المعلومات الطبية المتعلقة بهذا الموضوع بالنسبة لك (اختيار أكثر من واحدة). ا. التمريض ب. الطبيب ج. وسائل الإعلام د. جيران وأصدقاء ه. أقرباء و.أخري حدد______	22	متى تفضلين الحصول علي المعلومات عن برنامج الفحص الروتيني للمواليد حديثي الولادة؟ ا.في بداية الحمل ب. قبل الولادة ج. بعد الولادة
23	ممن تفضلين الحصول علي المعلومات؟ ا. التمريض ب. الطبيب ج. وسائل الإعلام د. جيران وأصدقاء ه. أقرباء و.أخري حدد_____	24	هل تم لك الشرح قبل أخذ عينة الدم من كعب طفلك ؟ ا . نعم ب . لا
25	هل تم مسح كعب طفلك بمادة مطهرة قبل أخذ العينة؟ أ.نعم ب. لا ج. لا أعلم	26	وقت المكوث في العيادة لتلقي هذه الخدمة(التطعيم والمسح الروتيني) __________

<table dir="rtl">
<tr><td>27</td><td>هل تلقيت معلومات عن فحص PKU قبل عمله بعد الولادة ؟ ا . نعم ب . لا</td><td>28</td><td>إذا كان الجواب نعم:ما هي مصدر للمعلومات:
ا. التمريض ب. الطبيب ج. وسائل الإعلام
د. جيران وأصدقاء ه. أخري،حدد ______</td></tr>
<tr><td>29</td><td>. هل يوجد في الاسرة احد مصاب ب PKU :
ا . نعم ب . لا</td><td>30</td><td>هل تلقيت معلومات عن مرض كسل الغدة الدرقية الخلقي ؟
ا . نعم ب . لا</td></tr>
<tr><td>31</td><td>هل تلقيت معلومات عن كسل الغدة الدرقية الخلقي أثناء الحمل؟
1 . نعم 2 . لا</td><td>32</td><td>. إذا كان الجواب نعم : من أعطاك المعلومات؟
ا.التمريض ب. الطبيب ج. وسائل الإعلام د. جيران وأصدقاء
ه. أخري،حدد ______</td></tr>
<tr><td>33</td><td>هل يوجد في الاسرة احد مصاب بمرض كسل الغدة الدرقة الخلقي:
ا . نعم ب . لا</td><td>34</td><td>هل أنت راضية عن الخدمات الصحية المقدمة لرعاية الطفل؟
<table dir="rtl">
<tr><th>الرقم</th><th>الموضوع</th><th>نعم</th><th>لا</th></tr>
<tr><td>1</td><td>خدمات التطعيم</td><td></td><td></td></tr>
<tr><td>2</td><td>دقة الفحص الطبي للمولود</td><td></td><td></td></tr>
<tr><td>3</td><td>التثقف الصحي</td><td></td><td></td></tr>
<tr><td>4</td><td>المتابعة للحالات المرضية</td><td></td><td></td></tr>
</table></td></tr>
<tr><td colspan="4">خاص بالأمهات التي أنجبن أكثر من طفل .</td></tr>
<tr><td>35</td><td>هل تم إبلاغك بنتائج فحوصات المسح الروتيني لأطفالك السابقين ؟
ا .نعم ب . لا ج. لا أعلم</td><td>36</td><td>إذا كان نعم كم عمر الطفل وقت التبليغ: _____</td></tr>
<tr><td>37</td><td>هل تفضلين إعلامك بالنتائج؟
ا . نعم إذا كانت النتيجة غير طبيعية.
ب . نعم اذا كانت النتيجة طبيعية.
ج . نعم في كل الأحوال.
د . لاتهمني.</td><td>38</td><td>هل لديك أطفال قاموا بإعادة اختبار لهم؟
ا .نعم ب . لا ج. لا أعلم</td></tr>
<tr><td>39</td><td>1اذا كانت الإجابة بنعم
1. هل تم أخذ العينة بالمركز الصحي
2. هل تم أخذ العينة في البيت
3. هل تم أخذ العينة في المختبر</td><td>40</td><td>هل استفسرت عن سبب الإعادة؟
1. نعم 2. لا</td></tr>
<tr><td>41</td><td>هل تلقيت معلومات عن فحص PKU أثناء الحمل؟
ا .نعم ب . لا</td><td>42</td><td>بعد تعبئة هذا الاستبيان ما هي أهم الأشياء التي تعتقدين أن الأباء يجب أن يعرفوها عن برنامج المسح الشامل للأطفال حديثي الولادة؟ (ممكن أكثر من خيار).
ا . الغرض من الاختبار ب . معلومات عن هذا المرض
ج . تأثير المرض علي الطفل. د .المدة الزمنية اللازمة لإعطاء النتائج
ه. نوع الاستشارة المقدمة للحالات الموجبة</td></tr>
</table>

Annex no. (12): Data collection instrument health care providers (Arabic)

<table>
<tr><td>1</td><td>العيادة : ....</td><td>2</td><td>مركزا لرعاية الأولية: ا.الوكالة ب. الحكومة</td></tr>
<tr><td>3</td><td>المحافظة: ا . شمال غزة ب . غزة ج .المنطقة الوسطي د. خان يونس
ه . رفح</td><td>4</td><td>الجنس : 1 –ذكر 2 – أنثي</td></tr>
<tr><td>5</td><td>المسمي الوظيفي:____________________</td><td>6</td><td>العمر بالسنوات: ___________</td></tr>
<tr><td>7</td><td>التخصص: أ.Staff nurse ب.Practical Nurse
ج.Midwife د.lab technician
ه.Physician
و.Others, specify ____________</td><td>8</td><td>لمؤهل العلمي: أ.دبلوم ب. بكالوريوس
ج. دبلوم عالي د. ماجستير ه. دكتوراه</td></tr>
<tr><td>9</td><td>عدد سنوات الخبرة منذ التخرج:________</td><td>10</td><td>عدد سنوات الخبرة في مجال المسح لحديثي الولادة:_______</td></tr>
<tr><td>11</td><td>هل تلقيت /ي دورة تدريبية في برنامج المسح لحديثي الولادة؟
ا .نعم ب.لا
إذا كان الجواب بنعم حدد/ي<table><tr><td>تاريخ الدورة التدريبية</td><td>عدد ساعات الدورة التدريبية</td><td>منظم الدورة</td></tr><tr><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td></tr></table></td><td>12</td><td>ما هي الفحوصات المخبرية الروتينية التي تجري لحديثي الولادة في مركزكم الصحي؟
-1
-2</td></tr>
<tr><td colspan="4">أ. التعليم المستمر</td></tr>
<tr><td>13</td><td colspan="3">هل تقوم بمتابعة التطور العلمي الحديث ؟
ا . نعم ب. لا</td></tr>
<tr><td>14</td><td>إذا كانت الإجابة نعم من خلال- حدد/ي؟
ا . البروتوكولات.
ب . بحث ذاتي في المصادر الطبية والشبكة العنكبوتية.
ج. توزيع النشرات والدوريات من قبل وزارة الصحة.
د. الماجستير والدكتوراه، برامج التعليم المستمر.</td><td>15</td><td>هل لديكم جهاز الكمبيوتر في العمل؟
ا. نعم ب. لا</td></tr>
<tr><td>16</td><td colspan="3">إذا كان الجواب نعم هل خدمة الانترنت متوفرة بانتظام:
ا. نعم ب. لا</td></tr>
<tr><td colspan="4">ب. الممارسة الحالية</td></tr>
</table>

<table>
<tr><td>17</td><td>ما هو برنامج التثقيف الصحي الحالي الذي يعطي للأمهات؟
ا . محاضرات.
ب . مادة مكتوبة.
ج . وسائل بصرية سمعية.</td><td>18</td><td>من الذي يقدم التثقيف الصحي للأمهات في المركز الصحي ؟
ا. التمريض ب. الطبيب ج. فني المختبر د. الصيدلي</td></tr>
<tr><td>19</td><td>هل التثقيف الصحي يشمل تقديم معلومات عن المسح الروتيني لحديثي الولادة أثناء المشورة مع الأمهات؟
ا. نعم ب . لا</td><td>20</td><td>متى يعطي التثقيف الصحي؟
ا. خلال الرعاية قبل الولادة.
ب . قبل جمع العينات.
ج . بعد جمع العينات.
د . بعد إعطاء النتائج. .</td></tr>
<tr><td>21</td><td>فيما يخص النقاط التالية هل يتم إعطاء معلومات للأهل عن التالي أم لا
<table>
<tr><td></td><td></td><td>نعم</td><td>لا</td></tr>
<tr><td>1.</td><td>أليه الفحص</td><td></td><td></td></tr>
<tr><td>2.</td><td>أهميه عمل فحص كسل الغدة الدرقية الخلقي</td><td></td><td></td></tr>
<tr><td>3.</td><td>أهمية عمل فحص لفنيل كيتونيوريا</td><td></td><td></td></tr>
<tr><td>4.</td><td>طبيعة النتيجة</td><td></td><td></td></tr>
<tr><td>5.</td><td>كيفية الحصول علي النتيجة</td><td></td><td></td></tr>
</table></td><td>22</td><td>هل تستخدم أي مواد تعليمية؟
ا. نعم ب . لا</td></tr>
<tr><td>23</td><td>إذا كان الجواب نعم حدد/ي ؟
ا. الكتيبات ب .مطوية ج. ملصقات د. وسائل الأعلام</td><td>24</td><td>. هل تعتقد/ي أن الموافقة علي اخذ العينة إلزامي؟
ا. نعم ب . لا</td></tr>
<tr><td>25</td><td>هل تأخذ/ي موافقة قبل اخذ العينة من الطفل ؟
ا. نعم ب . لا</td><td>26</td><td>حسب اعتقادكم/ملاحظاتكم هل لدي السيدات معرفة عن اختبارات المسح الروتيني لحديثي الولادة ؟
ا. نعم ب . لا ج. الى حدا ما</td></tr>
<tr><td>27</td><td>هل تستخدم وسائل مساعدة للتذكير بالنقاط المطلوبة لعملية التثقيف الصحي للأمهات؟
ا. نعم ب . لا ج. الى حدا ما</td><td>28</td><td>إذا كانت الإجابة بنعم فما هي الوسائل؟
أ. اللوحة القلابه ب. الملصقات
ج. كتيبات د. صور
ه. قائمة المهام و. أخري______</td></tr>
<tr><td>29</td><td>حسب نظام مركزكم هل يتم إعلام الأم بنتيجة المسح؟
ا. نعم ب . لا</td><td>30</td><td>هل تقومون بإبلاغ الأم نتيجة المسح ؟
ا. نعم دائما ب. نعم أحيانا ج. نادرا د. لا مطلقا</td></tr>
<tr><td>31</td><td>إذا كانت الإجابة نعم في أي زيارة يتم إبلاغ الأم نتيجة المسح :________</td><td>32</td><td>هل يوجد نظام للتحقق من إجراء الفحص ؟
ا. نعم ب . لا</td></tr>
<tr><td>33</td><td>إذا كانت الإجابة بنعم حدد/ي
ا. من خلال قائمه ب. برتوكول
ج. ملفات د. اتصال بالمدير المباشر</td><td>34</td><td>إذا تأخرت نتيجة الفحص كيف يتم الاستفسار؟
ا. إبلاغ الرئيس المباشر.
ب. الاتصال بمدير صحة الطفل.
ج. الاتصال بالمختبر.</td></tr>
</table>

35	هل يتم توثيق نتيجة الفحص وتاريخها في ملف الطفل؟ أ. نعم ب . لا	36	هل يتم إبلاغكم بالنتيجة الايجابية فقط ؟ أ. نعم ب . لا
37	هل هناك جدول زمني لإبلاغكم النتيجة؟ أ. نعم ب . لا	38	إذا كانت الإجابة بنعم أذكره: ______
39	هل استفسر أحد الوالدين عن النتيجة؟ أ. نعم ب . لا	40	هل سبق أن أعلمت بنتائج ايجابية للمواليد؟ أ. نعم ب . لا
41	من يبلغ الوالدين؟ أ. التمريض ب. فني المختبر ج. الطبيب د. الإداري	42	في حالة وجود الحالات الايجابية من المسئول عن متابعتها؟ 1. الطبيب 2. الوالدين 3.المختبر 4.التمريض
43	هل يوجد أرشيف للحالات الايجابية في المركز الصحي؟ أ. نعم ب . لا	44	هل أنت راضي/ة عن برنامج المسح الروتيني لحديثي الولادة الحالي؟ أ. نعم ب . لا ج. إلي حد ما
45	1إذا كانت الإجابة بلا ما هي اقتراحاتك لتحسين البرنامج؟ (لكل من الأمور التالية) أ. نتيجة الفحص المخبري. ______ ب. الاتصال مع الجهات الأخرى. ______ ج. جمع وارسال العينات. ______ د. دورات تثقيفية للوالدين. - ه. دورات لمقدمي الخدمة. ______	46	هل تري ضرورة لإدخال فحوصات جديدة في برنامج المسح الشامل للمواليد حديثي الولادة ؟ أ. نعم ب . لا ج. لا أعلم 47-1 إذا كانت الإجابة بنعم حدد
	دون أي ملاحظات أخري:		

هذا الجزء للعاملين بالمختبر فقط.

1. ما هي الإجراءات المتخذة عند وجود خلل في تدوين البيانات علي البطاقة المولود؟

الرقم	الأجراء	نعم	لا
1.	يتم إبلاغ الرئيس المباشر.		
-2	يتم إبلاغ المركز الصحي الذي جمعت منه العينة.		
-3	يتم إبلاغ مدير صحة الطفل الرعاية الأولية .		
-4	يتم عمل الفحص بالرغم من عدم اكتمال البيانات.		

2.ما هو وقت وصول بطاقة الطفل إلي المختبر عادةً من تاريخ جمع العينة؟

1. أقل من أسبوع 2. أسبوع 3. أسبوعان 4. ثلاث أسابيع 5- أربع أسابيع 6- أكثر

3. ما هي درجه الحرارة المناسبة لحفظ العينات ؟

1. الغرفة 2.الثلاجة 3. الفريزر

4.ما هو الوقت المناسب حسب رأيك لعمل الفحص من تاريخ جمع العينة؟

1.أسبوع 2.أسبوعان 3. أكثر حدد_____________

5. هل الأجهزة المستخدمة لعمل الفحص مناسبة مع حجم العينات؟

أ . نعم ب. لا ج. لا أعلم

6. هل مواد الفحص متوفرة باستمرار؟ أ . نعم ب. لا ج. لا أعلم د. أحيانا

6-1 إذا كانت الإجابة بلا حدد: الأسباب و الفترة الزمنية التي ينقطع فيها المواد:

1- نقص مواد فحص PKU فقط. أ- شهر ب- شهران ج- أكثر من شهرين.

2- نقص مواد فحص N.TSH فقط. أ- شهر ب- شهران ج- أكثر من شهرين.

3- نقص الاثنين معاً . أ- شهر ب- شهران ج- أكثر من شهرين.

7. ما الإجراء العلمي المتبع لتأكيد نتيجة الفحص الايجابي؟

1. إعادة جمع العينة. 2. إصدار النتيجة. 3. إعادة الفحص مرة أخرى

8. هل تواجه مشاكل عند انجاز الفحص؟ أ . نعم ب. لا

8-1 إذا كانت الإجابة بنعم حدد/ي:

1. ناتجة عن الأجهزة 2. مواد الفحص. 3. العينة نفسها 4. نقص عدد الفنيين المؤهلين

9. كيف يتم التبليغ عن النتيجة الايجابية؟

1. الاتصال هاتفيا بأهل المريض. 2. الاتصال هاتفيا بوحدة صحة الطفل. 3. الاتصال هاتفيا بمركز الرعاية التابعة له.

4-الاتصال بالبريد العادي.

10. معدل عمر الأطفال عند التبليغ عن النتائج الايجابية ؟...........

Annex no.(13): Data collection Instrument (1) for health care provider (English)

Serial No.: ---------		**Date :------------**
1. Clinic **2. Primary health care:**	☐UNRWA	☐Government
3.Governorate	☐North Gaza ☐ M. zone ☐Rafah	☐Gaza City ☐ Khan younis
4.Sex	☐ Male	☐Female
5. Job title :	**……………**	
6.Age by years	**……………**	
7. Specification	☐ Staff nurse ☐Midwife ☐Physician	☐Practical Nurse ☐lab technician ☐Other, specify …….
8.Qualification	☐Diploma ☐Licensed, Practical Nurse. ☐PhD	☐ B.S.c ☐Master degree
9. Years of experience since graduation ……………		
10.Number of years experience in the newborn screening program: ………..		
11. Did you receive any training courses in newborn screening program? ☐ Yes ☐ NO		
11-1 If yes, when? __		
12. What are newborn screening tests in primary health center? **1. ______________ 2.______________**		
13. How many employees in your department are participating in newborn screening program? ______________		

.

A- Continuing Education

14. Are you up date with the latest scientific development?

1. Yes 2. No

14-1If yes, specify:

1. Guideline protocol
2. Distribution of leaflets and curriculums by MOH
3. Personal search in medical resources and internet
4. Post graduate continued education programs

15. Do you under medication?

1. Yes 2. No

16. Do you have access to computer in work?

1. Yes 2. No

16-1. If yes, is the internet service a variable?

1. Yes 2. No

B- Current practice

17. What type of health education is currently given to parents?

1. Lecture 2. Written

3. Media

18. Who provides health education to mothers in the clinic?

1. Staff nurse 2. Physician 3. Lab technician

4. Pharmacy

19. Do you include information about new screening tests in discussions with mother?

1. Yes 2.No 3. Sometimes

20. When give health education about new screening tests?

1. During antenatal care 2. Before sample collection 3. After sample collection

4. After results

21. For this point do you give information to parents for the following or not?

No		Yes	No
1	Type of test performance		
2	Importance of Congenital Hypothyroidism		
3	Importance of PKU		
4	Nature of result		
5	Process of conveying the results		

22. Do you use any educational material?
1. Yes 2. No

23-1. If the answer is yes, specify?
1. Brochure 2. Booklets 3. Posters 4. Media

24. Do you think informed consent should be mandatory?
1. Yes 2. No

25. Do you permit before take the specimen?
1. Yes 2. No

26. Do you have mothers who are knowledgeable about newborn screening test?
1. Yes 2. No 3. Some how

27. Do you use prompts to remind you to inform parents of health education?

1. Yes 2. No 3. Some how

27-1 If the answer yes, what type?

1. Flip chart 2. Posters 3.Brochures 4.Picture

C-Process of program

28. According to the system of your center, do you inform the mother with the screening results?

1.Yes 2. No 3. I don't know

29. Do you inform the mother about the newborn screening results?

1.Yes, if there is abnormality 2.Yes, in all cases 3. No

30. If the answer is yes, in which visit has the mother informed about result.
…………..

31. Do you make insure that the screening test performed?

1. Yes 2. No

31-1 If the answer is yes, specify

1.From checklist 2.Guideline 3.Files 4.Inform the direct manger

32. If, there is a delay in the results of the test you make sure of that through

1.Contact the lab 2.Contact the director of child health 3.Inform the direct manger

33. Are results and dates documented in the child file?

1. Yes 2. No

34. Are you inform about the positive results only?

1. Yes 2. No

34-1 Is there a timetable to inform you with the result?

1. Yes 2. No

34-2 Is the answer is yes, mention it …

35. Did any of the parents ever ask for the results?

1. Yes 2. No

36. Have you been ever inform with the positive results for neonates?

1. Yes 2. No 3.Sometimes

37. Who informs the parents?

1. Staff nurse 2. lab technician 3. Physician 4. Administrative

38. In case of positive cases who is the responsible person to follow up?

1. Physician 2. Parents 3. lab technician 4.Nurse

39. Is there an index for the positive cases in the health centre?

1. Yes 2. No 3. Don't know

40. Are you satisfied about the newborn screening current program?

1. Yes 2. No

40.1 If the answer is no, what are your suggestions to improve the program (identify by one sentence)

1. The result of lab
2. Contact the other sides
3. Collecting and transporting samples
4. Health edification for parents
5. Courses for health service providers

41. Do you think of any necessity of introducing new tests in newborn screening program?

1. Yes 2. No 3. Don't know

41.1 If the answer is yes, specify them:

This part is only for the employees who work in the center lab.

42. What are the procedures if you find on error in writing the data on the card specimen?

No	Item	Yes	No
1	The direct manger will be informed.		
2	The health center, which the specimen is collected, will be informed		
3	Child health care manger will be informed.		
4	The test will be completed in spite of not completing the data.		

43. What is the expected period for the arrival of the specimen to the lab since collection date?

a- Less than one week b- Two weeks c- Three weeks d- Four weeks e- More than

44. What is the temperature suitable to keep specimen?

a- Room temperature

b- Fridge

c- Freezer

45. What is the suitable age of the neonate to collect the blood sample?

a. 3-5 days after delivery

b. After one week

c. After two weeks

d. After a month

46. Are the equipments of measurement suitable for the way of the used test?

a. Yes b. No c. Don't know

47. Are the test material always available?

a. Yes b. No c. Don't know d. Sometimes

47-1. If the answer is no, specify the reasons the duration of that the material which are not available?

a. Shortage of PKU only a. 1 month b. 2 month C. more than 3 month

b. Shortage of N.TSH only a.1month b. 2month C. more than 3 month

c. Shortage of two together a. 1month b. 2month C. more than 3 month

48. What are the used procedures when a positive case appears?

a. Repeated the test before the result is issued

b. Asking for anew specimen from PHC

c.Issuing the result as it is.

49.Are there any problem when performing the test?

a. Yes b. No

50.1if the answer yes, specifies:

1. Equipments 2. Material used 3. Specimen 4.Shortage in lab technician

51- How the positive result is informed?

a. Telephone the patient

b. Telephone the child health unit

c. Telephone the health care canter

d. Contact through mail

10.Old of child when inform the positive results …………

Annex no.(14): Data collection Instrument parents (English)

Serial Number**:** ________

1. Name of Child: _________________

2. ID No.: _____________________

3. Sex: a. Male b. Female

4. Address**:** __________________________

5. Date of birth**:** _ _ _ / _ _ _ / 2008

6. Governorate: a. North Gaza b. Gaza. City c. M. zone
d. Khan Younis e. Rafah

7. Primary Health Care Center: a. UN b. Government

8. Total number in household**:** ________

9. Mother education level (in years):
a. Illiterate b. No. of years________

10. Mother occupation: ___________

11. Father education level (in year):
a. Illiterate b. No. of years________

13. Father occupation: __________

14. Family income: _________

15. Number of children: ____

16. Newborn sequence in the family: ________

17. Vaccine defaulter: a.Yes b. No

18. If yes, Period of defaulter (more than one weak): ____ Days

19. What is the reason?

a.Late appointment

b.Lack of knowledge

C.Hospital admission of newborn

d. Newborn is low birth weight (LBW).

e. CS (Caesarian section)

20. Have you heard about newborn screening program?

a.Yes b. No

21. Who provide this information about newborn screening program?

a.Staff nurse b. Midwife c.Nurse d. Doctor e.Neighboures and friends f.Media

22. When do you prefer to have the information about newborn screening program?

a. At the beginning of pregnancy.

b. Before delivery.

c. After delivery.

23. From who receive the information?

a.Staff Nurse b. Midwife c.Nurse d. Doctor e.Neighboures and friends f.Media

24. If any one explains for you before tack the specimen form your child.

a.Yes b.No

25. Have you received information about PKU examination before the test?

a. Yes b. No

26. Do you receive information about PKU during pregnancy?

a. Yes b. No

27-1. if the answer is yes: what is the source of information?

a.Staff Nurse b. Midwife c.Nurse d. Doctor e.Neighboures and friends f.Media

28. Family history of PKU disease:

a. Yes b. No

29. Have you received information about congenital hypothyroidism?

a.Yes b. No

30. Do you receive information about congenital hypothyroidism during pregnancy?

a.Yes b. No

31. If the answer is yes, who provides the information?

a.Staff Nurse b. Midwife c.Nurse d. Doctor e. Neighboures and friends f.Media

32. Do you have a family history of CH disease?

a. Yes b.No

33. Are you satisfied with the provided health services?

No.	Items	Yes	No
1.	Vaccine services		
2.	Accuracy of Physical examination of child		
3.	Health education		
4.	Follow up for positive cases		

For women with previous children

34. Have you ever been informed about the results of the test of your previous children?

a. Yes b. No c. I don’t Know 4.Sometimes

35. Do you prefer being informed about the results?

a. Yes, if there is abnormality.

B.Yes, if there is normality.

C.Yes, in all cases

d.It doesn’t mater

36. Was any of your babies retested?

a- Yes   b- No   c- I don’t Know

37-1.If the answer is yes.

a. Do you draw in the health center?

b. Do you draw blood at home?

c. Do you draw blood at the lab?

38. Do you inquire about the cause of re-testing?

a- Yes   b- No

39. After filling this questionnaire, what do you think are the most important things that parents need to know about newborn screening program?(It could be more than one).

a. Purpose of the test

b. Information on the disease

c. Impact of the tested disease on child

d. Time duration for results

e. Mode of counseling for positive cases

Annex (15): list of Arbitrations:

No	Name	Place of work
1	Dr. Bassam Abu Hamad	School of Public Health-Gaza Al-Quds University
2	Dr. Fouad Alaisawi	MOH
3	Dr. Dina Abu Sha'aban	MOH
4	Dr. Mahmoud Serdah	Alazher University - Gaza
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7	Dr. .Mahmoud Edda'ma	MOH-Director of planning and policy making
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9	Dr. Majdi Ashour	UNRWA
10	Ms. Ahlam Shakora	UNRWA
11	Dr. Yosif Awadallah	MOH
12	Dr. Basim Ayesh	MOH
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