European Journal of Biology and Medical Science Research

Vol.3, No.6, pp.29-47, December 2015

Published by European Centre for Research Training and Development UK (www.eajournals.org)

EVALUATION OF NEONATAL SCREENING PROGRAM APPLIED AT PRIMARY HEALTH CARE CENTERS IN BAGHDAD /IRAQ

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ABSTRACTS: *Background: The neonatal screening program in Iraq is considered as a systematic public health program to screen infants in the first 3 to 5 days after delivery up to 2 month of age,for congenital hypothyroidism ,phenylketonuria and classical galactosemia. Objectives: To evaluate the program applied at Baghdad /Al-Karkh Health Directorate. Design: A cross- sectional study of one year duration of 10 districts which belongs to Baghdad /Al-Karkh Health Directorate using the special statistical form of the program. Results: The coverage rate was 66% of the number should be screened, the number of positively screened case was 59, the number of positively diagnosed case was 24 while the detection ability of the program was (0.028%). Conclusion: there was a low coverage rate in Baghdad /Al-Karkh Health Directorate compared to the international standard. The overall results of diagnosed cases was low but it comprise more than one third of positively screened cases.*

KEYWORDS: (PKU) Phenylketonuria, (GALT) Galactosemia, (CH) Congenital hypothyroidism, Screening Test, Detection Ability, Coverage Rate

INTRODUCTION

Neonatal screening is a systematic public health program for screening infants in the first few days after birth. Genetic and metabolic disorders are among the major causes of mortality before birth and during infancy. More than half of the congenital abnormalities usually remain undetected and are only incidentally diagnosed later in life. In general, congenital disorders during the first month of life are the most important cause of infant mortality, as the infant gets older, the chance of detecting the congenital abnormalities increases[(1)].

Each year >98% of approximately 4 million newborns in the United States are screened. Through early identification, newborn screening provides an opportunity for treatment and significant reductions in morbidity and mortality [(2,3)].Today, almost 7.6 million infants with genetic or congenital abnormalities are annually born around the world and 90% of such births occur in mid- and low-income countries[(4)].

The Middle East and North Africa (MENA) is home to over 300 million people spanning 17 countries and 4000 miles, with over 7 million annual births and some of the highest rates of consanguinity in the world. Several studies suggest that the incidence of inherited metabolic and endocrine disorders in MENA are higher than in Western countries. Early detection and treatment of these conditions can reduce morbidity and mortality, but newborn screening (NBS) can be sparsely performed in parts of these regions [(5)].

Published data on MENA NBS programs are insufficient, only a small number of MENA countries accounting for 12.2% of regional births, have widespread neonatal screening for

ISSN 2053-406X(Print) ISSN 2053-4078(Online)

multiple disorders. In most of the region, screening is limited to a few conditions in select portions of the population. As a consequence of insufficient access, the incidence of heritable diseases are likely underestimated in the MENA region[5].

More than four decades ago many countries started up neonatal screening programs to identify newborns with conditions for which early treatment would prevent serious irreparable health damage. Phenylketonuria (PKU) was in many countries the first disorder for which newborn screening (NBS) programs were started[6]. Rapidly, screening for hypothyroidism, and galactosemia gained wide acceptance for inclusion in newborn screening programs[7] .

In the decades thereafter the programs expanded gradually. Disorders included are individually rare conditions, that have a high impact for individuals affected. Since the turn of the century, high-throughput screening techniques such as Tandem mass spectrometry as well as the increase of possibilities for treatment led to expansions of the screening programs in many countries[6].

Many newborn screening programs have expanded their capabilities to also include hearing screens for congenital deafness in the newborn[8] . And early screening for DDH by clinical examination, ultrasound examination (universal or targeted to high risk groups) or a combination of both [9].

Thus, thousands of children with genetic and metabolic diseases have had an opportunity for a healthy life with early diagnosis and treatment. Unfortunately, in many countries, the screening programs have been unable to expand further, and thus have been limited to a few diseases. The need for an established organization for screening and costs are some reasons for the limited number of screened disorders in these countries[10] . The benefit of screening programs is the improved health status in patients diagnosed early and treated optimally. Harms of screening programs include false positives (causing additional costs, parental stress and anxiety) and false negatives (potentially causing a delay in diagnosis in missed cases)[11] .

In Iraq, the Ministry of Health(MOH) paid particular attention to the newborns as they are the basis for a society free of disease and their members are in good health, thus it establish programs needed to achieve this goal [12]. The health promotion units and media begun awareness campaigns for this program through seminars and meetings for parents and urged them to cooperate for the success of the program [13].

Aim of the study

1) To evaluate the neonatal screening program results in Baghdad /Al-karkh Health Directorate during 2014.

2) To estimate screening efficiency based on: the number needed to screen to diagnose one case in the whole program and for congenital hypothyroidism ,phenylketonuria and galactosemia respectively.

ISSN 2053-406X(Print) ISSN 2053-4078(Online)

REVIEW OF LITERATURE

Newborn Screening

The term 'newborn screening' is used to describe various types of tests that are done during the first few days of a newborn's life. Screening separates those who might have the disorder from those who probably do not have the disorder. In contrast, diagnostic testing is performed to establish the presence of a condition[14].

The conditions under which screening is conducted vary. They are usually influenced by factors such as prevalence (population characteristics), testing and treatment availability, outcome, geography, economics (including cost and cost effectiveness), transfer of science and technology, and politics. In general, the barriers to newborn screening are the same whether the program is in a developing nation or a more developed one[15], and they include:

(1) Education(awareness and understanding of health practitioners, politicians and the public);

(2) Finances (funding for education, testing, diagnosis and treatment);

(3) Logistics (delivery of testing, follow-up and treatment services);

(4) Politics (decisions concerning degree of government involvement including program purpose, system organization, financing and personal privacy);

(5) Culture (sensitivity to ethno-cultural issues concerning both medical care and parenting) [15].

Advanced newborn screening programs now include screening for up to 40 health disorders using high-throughput technology such as tandem mass spectrometry (MS/ MS) and second tier testing with DNA. In some cases, the term 'newborn screening' may also refer to a more comprehensive testing for newborns which includes testing for congenital hearing loss in addition to biochemical testing[15].

Neonatal Screening Program in Iraq

The Newborn Screening program has been started on April, 2013 as a pilot project taking two provinces: Baghdad and Karbala as starting provinces. The preparatory phase for more than one year has focused on capacity building bringing the most updated technology for early identification of two assigned inborn error of metabolism which are, phenylketonuria (PKU) ,Galactosemia(GAL) ,also congenital hypothyroidism(CHT) by Dissociation Enhancement lanthanid fluoroimmun assay (DELFIA technique) testing blood from a baby's heel prick [16].

Screening is the first step in a two-step process. The first screening test indicates a problem may be present (primitive) , and then a second diagnostic test (confirmative) confirms whether or not the problem or disease is present. To test for these diseases, Sample of blood is collected at appropriate age (72 hours-5days) after delivery and also those who had not screened up to 2 month of age in primary health care centers (PHC) and hospitals that have neonate care units (NICU). The blood is dried onto a newborn screening filter paper (F.P.) aims to detect a certain rare, but serious genetic, congenital and/or metabolic conditions that may be life threatening.

ISSN 2053-406X(Print) ISSN 2053-4078(Online)

Newborn screening program is available and free to all infants in Iraq and is done shortly after birth, while most infants look perfectly healthy. All babies are offered screening for CH, PKU and GALT [16].

Disorders Screened

Congenital Hypothyroidism

CH is defined as thyroid hormone deficiency present at birth[17]. Thyroid hormones play a crucial role in early neurodevelopment so that untreated severe CH results in neurological and psychiatric deficits, including intellectual disability, spasticity, and disturbances of gait and co-ordination. CH is one of the most common preventable causes of mental retardation. Screening programs, have led to the successful early detection and treatment of infants with CH and have eliminated the severe neurodevelopmental deficits resulting from late diagnosis. Estimates of the prevalence of CH vary about 1 in 2000 to 3000 live births in countries with neonatal screening vs. about 1 in 6700 live births before the screening era[18]. Recent reports have indicated that the incidence of primary CH may be increasing in some countries, particularly for cases with a normally located (eutopic) thyroid gland and milder dysfunction. This increase has been attributed to the widespread shift from primary T4 to primary TSH screening strategies and to the diagnosis of milder cases of CH[19]. Another factor in the increasing incidence of CH is changing demography, as initially suggested by data from the United States [20].

Phenylketonuria(PKU)

PKU is a metabolic disorder in which an inability to properly metabolize the amino acid phenylalanine (Phe) leads to a buildup of Phe in the blood, causing neurotoxicity and resulting in intellectual disability, delayed speech, seizures, and behavior abnormalities. Individuals with PKU are also susceptible to other adverse outcomes, including impaired executive function, reduced processing speed, attention problems, impaired fine motor skills, and mental health concerns (such as anxiety and depression symptoms)[21,22].The incidence of PKU varies based on ethnicity, with a higher prevalence among Native American and Caucasian individuals[23,24].

Universal newborn screening for PKU is typically described as one of the most successful public health programs in the history of modern medicine. Since their introduction in the early 1960s, state programs to identify and treat infants with PKU have prevented intellectual disability (formerly “mental retardation”) in thousands of children[25]. PKU is typically diagnosed soon after birth using biochemical tests that are performed after an abnormal newborn screening result. The most severe form of PKU, classic PKU, is typically characterized by blood Phe levels exceeding 1200 μmol/L while on a normal diet. With adherence to a Phe-restricted diet, poor outcomes can be mitigated. Nonetheless, management of PKU can be difficult and onerous for the patient and the family, leading to interest in identifying new ways of managing this lifelong condition [26].

Galactosemia

Classical galactosaemia is a genetically determined deficiency of the enzyme galactose- 1-phosphate uridyl transferase (GALT) activity. This deficiency causes accumulation of galactose, galactose-1- phosphate and galactitol in tissues of affected individuals. The primary source of galactose is lactose, found in mammalian milk. Newborn infants are immediately exposed to lactose in human milk and most infant formulas. The clinical signs of this defect

ISSN 2053-406X(Print) ISSN 2053-4078(Online)

(feeding problems, hepatomegaly, jaundice, failure to thrive, cataracts, hypoglycaemia, gram negative sepsis and acute liver failure) become evident during the neonatal period[27,28]. Affected infants are also at increased risk of delayed development, speech difficulties, and intellectual disability. Females with classic galactosemia may experience reproductive problems caused by ovarian failure [29]

Patients and methods

Design: Cross- sectional study.

Duration: From January 1st 2014 – December 31st 2014.

Setting: Baghdad /Al-karkh Health Directorate which includes ten districts, these are:

1. Al-Karkh district.
2. Al-Doura district.
3. AboGareb district.
4. Al-Mahmoodia district.
5. Al-Kadhemiya district.
6. Al-Adil district.
7. Al-Ilam district.
8. Al-A'amil district.
9. Al-Tajee district.
10. Al-Tarmia district.

All of these districts involved in the study, In addition to Al- Yarmook Teaching Hospital and Central Teaching Hospital of Pediatric (we add the screened number of infants in these two hospital to Al-Karkh statistics because they have no specified number should be screened monthly).

Data source: The information about the newborns that are tested in the PHCC are sent to the district in a special statistical form , then these information will be collected, analyzed, and interpreted at the district into another statistical form , that are forwarded to the directorate from each district. And ultimately at the directorate all the statistics in appendices 2 from all districts will be collected, analyzed and kept in a final statistical form .

Sample size: The number should be screened in Baghdad/ Al-Karkh from 1st of January – 31st of December 2014 was 122009, 80409 of them screened and 41600 was missed. These numbers are obtained from the statistical form (appendix-3-) of Baghdad /Al-Karkh Health Directorate.

Screening method

- Every infants aged 3-5 days up to 2 month are involved in the screening program. Actually Most of the infants that involved in the screening program were brought to the PHCCs for receiving BCG vaccine and not for performing dried bloodspot card test. The healthcare providers will explain the screening test and its importance to the families of babies and encourage them to participate in the program.
- In the PHCC : Recording of the required information about the identity of the infant , the insurance of the accuracy of the demographic data on the filter paper cards (appendix-4-) and the collection of blood specimens take place .

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- In the Central Public Health Laboratory : if Positive screening tests results detected then the test is repeated in the same filter paper, if it is still positive then confirmatory tests Should be performed to confirm CH by tacking blood serum sample while in case of PKU and GALT a new filter paper is used for confirmation.
- The confirmatory tests for PKU and GALT are performed outside Iraq by tandem mass spectrometry.
- If the diagnosis is confirmed then the infant is referred to one of these four specific hospitals (Central Teaching Hospital of Pediatric, Al- Kadhimiya Teaching Hospital of Pediatric, Abin Al-Baladi Hospital and Al-Elwiya Teaching Hospital of Pediatric) to be followed up and managed by the pediatricians.
- Occasionally, the infant is referred to the hospital after a Positive screening test detection.

Screening method for Congenital Hypothyroidism

- For screening test: n TSH filter paper is measured.
- For confirmatory test: serum n TSH and free T4 are measured.
- The result interpreted according to the following reference value :

	Test	Reference value*		
		Age	Male	Female
1	n TSH	1-30 day	0.5-16µunit/ml	0.7-13µunit/ml
		1mo- 5yr.	0.52-7.1µunit/ml	0.48-8.1µunit/ml
2	Free T4	1-3 day	10-35pmol/L	10-35pmol/L
		4-30 day	6-29pmol/L	8-24pmol/L
		1-11month	9.7-25pmol/L	11.3-23pmol/L

Screening method for Phenylketonuria:

- For screening test: n phenylalanine filter paper is measured.
- For confirmatory test: n phenylalanine, Tyrosine and Phenylalanine/ Tyrosine ratio filter paper are measured.
- The result interpreted according to the following reference value :

	Test	Reference value*
1	n phenylalanine	10-150 µM/L
2	Tyrosine	10-200 µM/L
3	Phenylalanine/ Tyrosine ratio	0.28-3.0

Screening method for Galactosemia

- For screening test: n total galactose filter paper is measured.

ISSN 2053-406X(Print) ISSN 2053-4078(Online)

- For confirmatory test: n total galactose, (GALT) G 1-p uridyl transferase filter paper are measured.
- The result interpreted according to the following reference value:

	Test	Reference value*
1	n total galactose	< 9.9mg/dl
2	(GALT) G 1-p uridyl transferase	> 3.0 U/g Hb

(*Adopted by Central Public Health Labrotary in Baghdad)

Statistical Analysis

We used the following equation:

1. Coverage rate = $\frac{\text{Number screened(NS.)}}{\text{Number should be screened (NSS.)}}$ x 100

2. Number needed to screen to= diagnose one case (NNS.) $\frac{\text{Number screened(NS.)}}{\text{Number of positive diagnostic tests.}}$

3. Percent of clients with positive = screening test $\frac{\text{Number of positive screening test (+ve ST.)}}{\text{Number screened(NS.)}}$ x 100

4.Percent of true positive= screening test $\frac{\text{Number of positive diagnostic test(+ve DT.)}}{\text{Number of positive screening test (+ve ST.)}}$ x 100

5. Detection ability (DA.)= $\frac{\text{Number of positive diagnostic tests.(+ve DT.)}}{\text{Number screened(NS.)}}$ x 100

Ethical approval: Ethical approval was obtained from:

1- Arabic Council of Medical Specialization/ ministry of health /Iraq

2- Scientific committee of Alkindy college of medicine / university of Baghdad

RESULTS

The number should be screened in Baghdad/ Al-Karkh from 1st of January – 31st of December 2014 was 122009, 66% of them screened for CH, PKU and GALT, 34% was missed (as shown in figure -1-), 0.073% of those screened showed positive screening test for either CH, PKU or GALT.

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The total number of screening tests performed in the program during the whole period of the study was 80409, 0.047% of the total number of screening test was positive for CH, 42.10% of those positively screened was diagnosed as CH. 0.014% of the total number of screening test was positive for PKU, 50% of them was diagnosed as PKU and 0.011% of the total number of screening test was positive for GALT and 22.22% of them was diagnosed as GALT, as shown in (figure -2-).

From the total number of clients should be screened for the three diseases in Al-Karkh districts during 2014 , 66% of them are actually involved in the program (as shown in table -1-). Three of ten districts had coverage rate above 70% (Al-Adil, Al-Doura and Al-Tajee), five districts had coverage rate between 60% and70% (Al-Karkh, Al-Ilam, AboGareb,

Al-A'amil and Al-Kadhemiya) and tow districts had coverage rate below 60% (Al-Mahmoodia and Al-Tarmia).The percentage of the clients with positive screening test was 0.072%(0.047%for CH, 0.014% for PKU and 0.011% for GALT), while the percentage of the clients with true positive screening test 40.6% (42.1% for CH, 50% for PKU and 22,2% for GALT), the detection ability of the program was 0.028%.

It's clear from(table-3-) that the number needed to screen to diagnose one case in the whole program was 3350, while the number needed to screen to diagnose one case of CH. Was 5025, and those needed to screen to diagnose one cases of P.K.U. and GALT were (13401 and 40204) respectively

DISCUSSION

Screening Coverage Rate

Screening coverage rate is one of the vital indicators used to evaluate newborn screening programs, and it is important for the prediction of future public health decisions on such programs. This is especially the case in developing countries with large populations, undeveloped economies and unequal regional development[15].

The number of infant should be screened during periods of study was 122009, only 80409 (66%) of infants had been screened, and 41600 (34%) was missed. One of the causes of missed cases is the delay in receiving BCG vaccine after 2 month of age, another cause is refusal of parents as they considered the test painful and unnecessary and may results in secondary complications in case of unhealthy ill infants.

However , the coverage rate was 66% at Baghdad Al-Karkh. This rate is lower than the international standard of (99%)[30] In a study done in the United Arab Emirates (UAE) the coverage rate of neonatal screening in the UAE increased from 50% in 1998 to reach 95% in 2010[31]. in Alexandria program the rate of coverage was 49.4% in 2001 and increase to 82.7% in 2005[32]. In Saudi Arabia (Al-Madina Al-Munawara region)[33], the screening program coverage was nearly 97% of the total infants born in Madina region over 10 years. In developed countries the calculated program coverage already exceeds the 99.5%[34,35].

Reasons for this low rate may be deficiency of resources and lack of awareness of families about the importance of newborn screening. Another explanation to this low rate is that evaluation was done early in the implementation of the program and this program is the first

ISSN 2053-406X(Print) ISSN 2053-4078(Online)

newborn screening program applied in Iraq suggesting that continuous increase in coverage will remain a priority for the program for several years.

The total no. of screening test of whole program:

The total no. of screening test performed was 80409, (0.073%) of those screened showed positive screening test for either CH, PKU or GALT. and (40.67%) of these positive results diagnosed with CH, PKU or GALT. which is much higher than those obtained by study in Germany[36] [In a single observational study 0.034% of cases present with confirmed diagnosis of a metabolic disorder from a total of 1,084,195 neonates screened in one newborn screening laboratory between January 1, 1999, and June 30, 2009] this may be due to short period of our study and fewer disorders involved. In addition, the program was applied on rare diseases so the total number of the diagnosed cases is low but it is considered worthy with minimum burden and better outcome for patients, fewer deaths and fewer clinically significant disabilities achieved from early diagnosis and treatment of inherited metabolic diseases which in turn will come back with benefit to the society. Economic cost of early detection of such disabilities should also be taken into account, as each Euro spent on the screening program saved more than 25 Euros in health and social costs[15].

The total no of screening test of CH

The total no of screening test of CH Performed was 80409, (0.047%) of those screened showed positive screening test for CH, which is much lower than those obtained by study done in Iran, Fars Province[37][in this study 0.20% of 63031 had a positive screening test] and also lower than those obtained in Macedonia[38] [from 9757 newborns have been screened 0.18% of neonates was recalled], This difference in the number of recalled test may be due to different sampling methods, different methods of performing the laboratory tests, different TSH cutoff values, and may also reflect the levels of iodine deficiency in different regions. From the total positive screening result, only 42.10% of them were diagnosed with CH ,which is lower than those obtained in Alexandria[32] [In the year 2003 the total positively screened cases were 14 and only 64.3% of them were diagnosed with CH] and near those obtained in Macedonia[39][out of 18 recalled neonates, 44.4% of them were diagnosed as CH cases] Iodine deficiency and/or dyshormonogenesis might be contributing factors. And 57.89% From the total positive screening tests results had negative diagnostic tests, this may be due to transient abnormalities of thyroid function in the newborn period such as iodine deficiency, iodine excess, drugs and maternal TSH receptor blocking antibodies which are the most common abnormalities.

The total no of screening test of PKU

The total no of screening test of PKU Performed was 80409, 0.014% of those screened showed positive screening test for PKU, which is higher than those obtained in Fars Province, South Iran[0.011% out of 76966 newborns screened had a positive screening test] and 50% of these positive results diagnosed with PKU, which is lower than those obtained in Fars Province, South Iran[40] [88.8% of cases were confirmed from 9 positively screened cases]. And 50% of these positive screening results not diagnosed with PKU. *Once the diagnosis of hyperphenylalaninemia is established, additional studies for biopterin metabolism should be performed to rule out biopterin deficiency as the cause of hyperphenylalaninemia. One of the tests used is BH4 loading test which is not available in our screening program.*

ISSN 2053-406X(Print) ISSN 2053-4078(Online)

The total no of screening test of GALT

The total no of screening test of GALT Performed was 80409, 0.011% of those screened showed positive screening test for GALT, which is lower than these obtained in India[41] [in this study total of 10300 newborn were tested and 0.388% of thobbbse screened show positive screening test for GALT]. 22.22% of these positive results diagnosed with GALT, which is higher than these obtained in India[41] [2.5% confirmed with galactosemia from 40 cases that screened positive] and 77.77% of these positive screening results not diagnosed with GALT. High level of n total galactose in the screening tests may be caused by deficiency of any one of the other two enzymes causing galactosemia (GALK and GALE) that are not included in our screening program, so referal to pediatric metabolic specialist must be done in these cases to measure the level of the other two enzyme (Galactosemia variants).

The total percent of clients with positive screening and Detection ability

Of the whole program was 0.072%,0.028% respectively which was higher than for each disease alone , **(**the percent of clients with positive screening for CH was0.047%,for PKU was 0.014% and for GALT was 0.011%) while (the detection ability was 0.019% for CH, 0.007% for PKU and 0.002% for GALT). The percent of true positive screening test for the whole program was 40.6% which is lower than those for CH and PKU 42.10%, 50% respectively but higher than those for GALT 22.22% , there is no published study to compare this results but it is clear that using the program for the three diseases gives better results than using it for each disease alone which may be important if cost effective analysis is to be applied.

Number needed to screen to diagnose one case

Number needed to screen to diagnose one case through the whole program was 3350 which is lower than these obtained in India[41][NNS=3600], while number needed to screen to diagnose one case of congenital hypothyroidism CH was 5052, which disagree with that obtained in Fars Province, Iran[24], Turkey [42] and Macedonia [38] [NNS=1465, NNS= 469, NNS= 1220 respectively] This wide variability with the same methodology in mentioned studies may reflect the degree of iodine deficiency in different region, and number needed to screen to diagnose one case of PKU was 13401 which is higher than those obtained in Michigan[43] and Fars Province, South Iran[40] [NNS= 7.686, NNS=10000 respectively] but lower than these obtained in India [41] [NNS=18300],and number needed to screen to diagnose one case GALT was 40204 which is markedly higher than those obtained in India[41][NNS=10300] It could be due to high consanguineous marriages but more studies are required to know how much consanguineous marriages are affected.

The results of the program during the periods of the study should be a source for program modification as its impact will be definitively great in term of benefit to the society. Screening for inherited metabolic disease is indeed needed in country like Iraq as it will benefit from early diagnosis, which is the hallmark of a successful NBS program, help to establish the prevalence of these disorder and in planning therapeutic interventions for the betterment of society. the overall success of NBS should be assessed by the program's ability to provide ongoing long-term disease management services for affected children and their families in a culturally appropriate manner. Newborn screening should be established as a preventive public health program on priority basis on par with immunization program.

ISSN 2053-406X(Print) ISSN 2053-4078(Online)

The Central Public Health Laboratory in Baghdad adopt the notion to expand the program through the following target: 1)The intention to cover all Iraqi governorates 2) Include more diseases (treatable, preventable) and 3) To supply tandem mass spectrometry TM/TM. The Central Public Health Laboratory contacted the Ministry of Health about their requirements and several discussions made to achieve these targets.

Disclosure of interest

The neonatal screening program was newly applied in Iraq , evaluation of such program will through a light on the total number of the diagnosed cases thereby shows if it is worthy to apply such screening program with minimum burden and better outcome for patients, fewer deaths and fewer clinically significant disabilities achieved from early diagnosis and treatment of inherited metabolic diseases which in turn will come back with benefit to the society. Economic cost of early detection of such disabilities should also be taken into account, as each Euro spent on the screening program saved more than 25 Euros in health and social costs[(15)].

CONCLUSIONS

- The national neonatal screening program in Iraq currently includes screening for 3 disorders: congenital hypothyroidism, phenylketonuria and galactosemia. In this study there was a low coverage rate in Baghdad /Al-Karkh Health Directorate compared to the international standard.

- The overall results of diagnosed cases was low but it comprise more than one third of positively screened cases. The detection ability of the whole program was higher than the detection ability for each disease alone. The number needed to screen to diagnose on case through the whole program was lower than the number needed to screen to diagnose on case of each disease separately.

RECOMMENDATIONS

In light of the present findings, the following are recommended:

1- More effort should be made to improve the program through building up enhanced direct communication systems, linking curative newborn screening programs to community-based primary health care centers.

3- Referral to pediatric metabolic specialist if galactose is still elevated with normal G 1-p uridyl transferase (GALT) activity.

4- Expansion of the program through involvement of more disorders, more governorates.

5- Improvement of the monitoring and supervision system of the program through calculation of the coverage rate at each health zone.

ISSN 2053-406X(Print) ISSN 2053-4078(Online)

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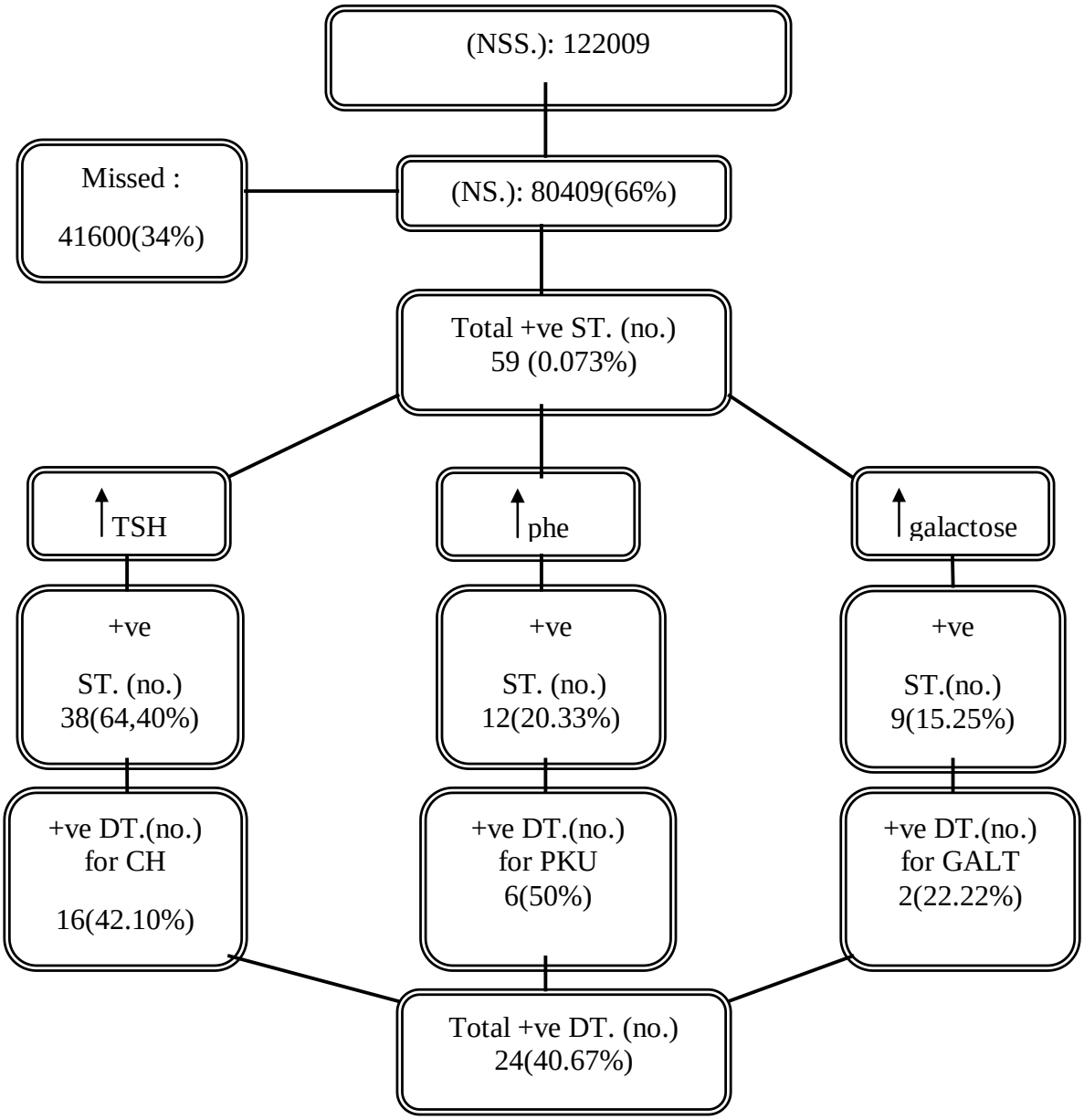

Figure -1- flow chart to show data sets available for the program evaluation .

NS: number screened, NSS: Number should be screened, +ve: positive, ST: screening test, DT: diagnostic test, no: number, CH: congenital hypothyroidism, PKU: phenylketonuria, GALT: galactosemia, DT: diagnostic test.

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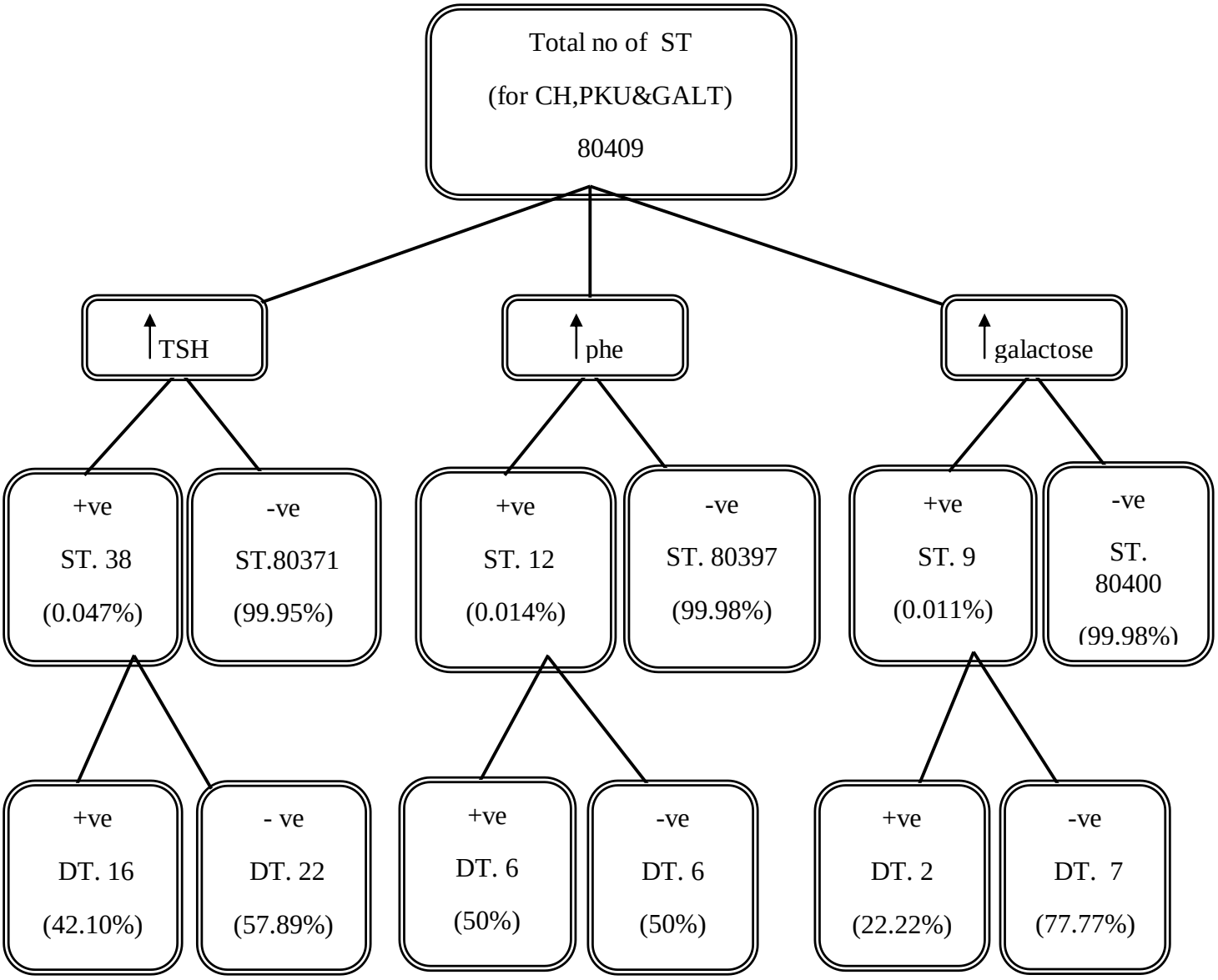

Figure-2- flow chart show distribution of the tests performed during the program.

no: number, ST: screening test, CH: congenital hypothyroidism, PKU: phenylketonuria, GALT: galactosemia, +ve: positive, -ve: negative, DT: diagnostic test.

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District	*NSS. no.*	*NS. no.*	*Coverage rate(%)*
Al-Karkh	14427	8817	61%
Al -Adil	7506	5665	75%
Al-Doura	12673	9742	77%
Al-Ilam	11235	7800	69%
AboGareb	12295	8569	69%
Al-A'amil	12757	8632	67%
Al-Mahmoodia	13111	7812	59.5%
Al-Tajee	5276	4113	78%
Al-Kadhemiya	26161	15862	60%
Al-Tarmia	6568	3397	52%
Total	122009	80409	66%

Table -1-Coverage rate of the program

NSS: number should be screened, NS: number screened, n.: number, %: percent

Table-2- Show positive and true positive screening tests and detection ability of the program.

District	*DS.*	*+ve ST.(no.)*	*+ve DT.(no.)*	*(%)C. +ve ST.*	*(%) T. +ve ST.*	*DA. (%)*
Al-Karkh*	CH	4	1	0.045	25	0.011
	PKU	0	0	0	0	0
	GALT	3	0	0.034	0	0
	total	7	1	0.079	14.2	0.011
***NS.(no.) = 8817 is the number of al-karkh district total screening test and it is the same for each of the 3 disease separately.**						
AL- Adil*	CH	5	3	0.088	60	0.052
	PKU	2	0	0.035	0	0
	GALT	0	0	0	0	0
	total	7	3	0.123	42.8	0.025
***NS. (no.) = 5665 is the number of Al-Adil district total screening test and it is the same for each of the three disease separately.**						
Al-Doura*	CH	4	2	0.041	50	0.020
	PKU	3	1	0.030	33.3	0.010
	GALT	0	0	0	0	0
	total	7	3	0.071	42.8	0.030

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***NS. (no.) = 9742 is the number of Al-Doura district total screening test and it is the same for each of the three disease separately.**

District	*DS.*	*+ve ST.(no.)*	*+ve DT.(no.)*	*(%)C. +ve ST.*	*(%) T. +ve ST.*	*DA. (%)*
Al-Ilam	CH	2	1	0.025	50	0.012
	PKU	0	0	0	0	0
	GALT	2	1	0.025	50	0.012
	total	4	2	0.050	50	0.024
***NS. (no.) = 7800 is the number of Al-Ilam district total screening test and it is the same for each of the three disease separately.**						
AboGareb	CH	2	0	0.023	0	0
	PKU	1	1	0.011	100	0.011
	GALT	1	0	0.011	0	0
	total	4	1	0.045	25	0.011
***NS. (no.) =8569 is the number of AboGareb district total screening test and it is the same for each of the three disease separately.**						
Al-A'amil	CH	3	2	0.034	66.6	0.023
	PKU	0	0	0	0	0
	GALT	2	1	0.023	50	0.011
	total	5	3	0.057	60	0.034
***NS. (no.) =8632 is the number of Al-A'amil district total screening test and it is the same for each of the three disease separately.**						
Al-Mahmoodia	CH	1	0	0.012	0	0
	PKU	1	1	0.012	100	0.012
	GALT	0	0	0	0	0
	total	2	1	0.024	50	0.012
***NS. (no.) =7812 is the number of Al-Mahmoodia district total screening test and it is the same for each of the three disease separately.**						

District	*DS.*	*+ve ST.(no.)*	*+ve DT.(no.)*	*(%)C. +ve ST.*	*(%) T. +ve ST.*	*DA. (%)*
Al-Tajee	CH	5	1	0.121	20	0.024
	PKU	1	0	0.024	0	0
	GALT	0	0	0	0	0
	total	6	1	0.145	16.6	0.024
***NS. (no.) =4113 is the number of Al-tajee district total screening test and it is the same for each of the three disease separately**.						
Al-kadhemiya	CH	9	5	0.056	55.5	0.031
	PKU	2	1	0.012	50	0.006
	GALT	1	0	0.006	0	0

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District	*CH*			*PKU*			*GALT*			*Prog.*		
	NS.	+ve DT.	NNS.	NS.	+ve DT.	NNS.	NS.	+ve DT.	NNS.	NS.	+ve DT.	NNS.
Al-Karkh	8817	1	8817	8817	0	0	8817	0	0	8817	1	8817
Al-Adil	5665	3	1888	5665	0	0	5665	0	0	5665	3	5665
Al-Doura	9742	2	4871	9742	1	9742	9742	0	0	9742	3	3247
Al-ILAM	7800	1	7800	7800	0	0	7800	1	7800	7800	2	3900
Abo-gareb	8569	0	0	8569	1	8569	8569	0	0	8569	1	8569
Al-A'amil	8632	2	4316	8632	0	0	8632	1	8632	8632	3	2877
Al-Mah Modia	7812	0	0	7812	1	7812	7812	0	0	7812	1	7812
Al-Tajee	4113	1	4113	4113	0	0	4113	0	0	4113	1	4113
Al-Kadh emiya	15862	5	3172	15862	1	15862	15862	0	0	15862	6	2643
Al-Tarmia	3397	1	3397	3397	2	1698	3397	0	0	3397	3	1132
Total	80409	16	5025	80409	6	13401	80409	2	40204	80409	24	3350
	total	12		6		0.074	50		0.037			
***NS. (no.) =15862 is the number of Al-kadhemiya district total screening test and it is the same for each of the three disease separately.**												
Al-Tarmia	CH	3		1		0.088	33.3		0.029			
	PKU	2		2		0.058	100		0.058			
	GALT	0		0		0	0		0			
	Total	5		3		0.146	60		0.087			
***NS. (no.) =3397 is the number of Al- Tarmia district total screening test and it is the same for each of the three disease separately.**												
Total	CH	38		16		0.047	42.10		0.019			
	PKU	12		6		0.014	50		0.007			
	GALT	9		2		0.011	22.22		0.002			
	total	59		24		0.072	40.6		0.028			
***NS. (no.) =80409 is the sum of the screening tests from all districts and it is the same number for each disease screened from all the districts.**												

DS: disease, NS: number screened, +ve: positive, ST: screening test, DT: diagnostic test, C: clients, t: true, DA: detection ability, no: number, %: percent

Table-3- Number needed to screen to diagnose one case.

CH: congenital hypothyroidism, PKU: phenylketonuria, GALT: galactosemia, prog: program, NS: number screened, +ve: positive, DT: diagnostic test, NNS: number need to screen to diagnose one case

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