

Structure, Process, and Outcome Evaluation of Hospitals about Neonatal Screening Program in Karbala in 2022

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Abstract

Background: The newborn screening program has been evaluated in several parts of the world, with varying outcomes (1). In terms of incidence, severity, age of onset, and diagnostic and therapeutic techniques, they vary greatly. The program screens a group of conditions that causes major metabolic abnormalities in newborns, resulting in irreversible damage and illness. There is a treatment for some of them that, if given soon after birth, can prevent such damage. Many countries have suggested, developed, and implemented population-based newborn screening for these illnesses, although at differing rates and using various criteria(2). **Materials and Methods:** This evaluation study was conducted between the first of September 2021 and the end of June 2022. This research was carried out in the Holy Karbala Governorate, to assess a pilot program implemented by the Governorate Directorate of Health in Karbala Children's Teaching Hospital and Al-Hindiya General Hospital. A checklist has been used to evaluate hospitals after reviewing the "National Guideline of Newborn Screening for Care Providers in Primary Health Care Centers in Iraq". The list was built and developed by the researchers. **Results:** It was documented that the program worked in only one hospital, where the trained medical staff. However, there was untrained health staff available, in addition to the lack of the program's needs for laboratory testing follow-up, food, and milk needed for the program patients. **Conclusion:** Although, this program could contribute to "reducing the rate of under-five mortality by two-thirds", the necessary tools to meet these objectives were not found in the hospitals.

Keywords: neonatal screening, congenital metabolic disorders, rare diseases, coverage rate.

INTRODUCTION

Screening is a basic classification method. In medicine, it works like a filter, separating people who are possible to be diseased from others who are not. A screening test is at no time completely accurate; it just shows whether or not someone is at risk (or risk-free) from the disease of focus (World Health Organization, 2020).

Newborn screening programs examine infants for disorders that are not often obvious at birth. Such issues can be inherited, infectious, or due to the effect of a mother's medical condition. If these conditions are not recognized and treated quickly after birth, they might cause mental damage, significant sickness, or even death. Every year, about 4 million babies in the United States are examined, and thousands of infants are spared from damage and death (Kelly et al., 2016).

According to information from worldwide newborn screening programs, one out of every 320 infants screened had one of 29 actual core illnesses; almost 10% of them have hereditary metabolic problems that can be intellectually debilitating or deadly if untreated during the infant period or early infancy. Routine screening provides the opportunity to intervene in this pre-symptomatic period and minimize morbidity or fatality (Sahai and Erbe, 2022). The purpose of this screening program is to identify persons in a good health population who are at increased risk of health conditions developing or disease with the purpose of early treatment or intervention may be offered. Therefore, some people who were screened may improve health (Raffle and Gray, 2019).

A large number of metabolic illnesses are covered by newborn screening in Canada, however less than in the United States. Some Central and South American countries, especially Costa Rica and Uruguay, have high-quality, well-established newborn screening programs that use tandem mass spectrometry to screen all babies for a variety of metabolic disorders. However, in addition to phenylketonuria, most South American screening programs include just a few other diseases, and only a few use mass spectrometry for newborn screening. (3).

Some countries in the Middle East, such as Qatar and Saudi Arabia, have programs that screen all newborns for a wide range of metabolic disorders. Others, such as the UAE and Kuwait, have only two disorders on their newborn screening list, while a third group has no screening program at all (4). Saudi Arabia has sponsored newborn screening programs for 16 major biochemical and endocrine genetic disorders since 2005(5).

The program in Iraq screens for three diseases: phenylketonuria, galactosemia, and congenital hypothyroidism.

A lack of the enzyme phenylalanine hydroxylase causes phenylketonuria, which leads to a rise in phenylalanine in the blood and phenylalanine metabolites in the urine. Patients who are not treated with phenylketonuria suffer from mental impairments and other neurological disorders. This disease affects around one out of 10,000 live newborn infants (6).

A deficiency of thyroid hormone at birth is referred to as congenital hypothyroidism. Thyroid hormone deficiency is most usually caused by a defect in thyroid gland development (dysgenesis) or a congenital defect in thyroid hormone production (dyshormonogenesis)(Rastogi and LaFranchi, 2010). Because thyroid hormone is necessary for optimal development of the brain, children with congenital hypothyroidism who do not get thyroid hormone at a critical period of development threat brain damage and mental impairment. Since the introduction of newborn screening programs in the 1980s, the majority of countries have provided diagnosis and treatment for this disease during the first 2-3 weeks of life (Rovet and Daneman, 2003)cited in (9).

Classic galactosemia is an uncommon inborn carbohydrate metabolism error marked by a severe deficiency of the enzyme galactose-1-phosphate uridylyltransferase. (10)(11). It is a potentially fatal autosomal recessive inborn metabolic defect that affects between 1/30,000 and 1/60,000 live births worldwide. (12).

Materials and Methods

An evaluative study was conducted between the first of September 2021 and the end of June 2022. This research was carried out in the Holy Karbala Governorate, which is around 105 kilometers southwest of Baghdad, Iraq's capital, and has an area of approximately 52,856 km² and a population of 1,350,577 people in 2022 (central statistical organization Iraq).

The present research has assessed a pilot program implemented by the Governorate Directorate of Health in Karbala Children's Teaching Hospital and Al-Hindiya General Hospital.

A checklist has been used to evaluate the hospitals' performance, after reviewing the “National Guideline of Newborn Screening for Care Providers in Primary Health Care Centers in Iraq”. It was built and developed by researchers, and it was upgraded by experts.

Contents of the hospital evaluation checklist

It consisted of three parts:

1. Structure approach: This section of the checklist evaluated the program's needed input for follow-up, treatment, and prevention of complications for diagnosed patients. Input included human resources: pediatrics specialist, dietitian, and trained nurses; and material resources: patient file, suitable room, antibiotics, plasma, thyroxin, vitamins, galactose free milk, phenylketonuria milk, galactosemia test, phenylketonuria test, and congenital hypothyroidism test.
2. Process evaluation: The number of relevant clinic opening days was included in this part of the checklist, in addition to the details of patient follow-up.
3. Outcome evaluation: This section of the checklist evaluated the number of patients who have been followed up in the hospital.

Statistical data analysis

Analysis of data was carried out via the available statistical package of SPSS-24 (Statistical Packages for Social Sciences-version 24). Data were shown in simple measures of frequency and percentage and compared with standards.

Results

Outcome approach

The outcome approach will be presented in the beginning to determine the overall performance level. Figure (1) shows the numbers of followed-up patients in the last three years.

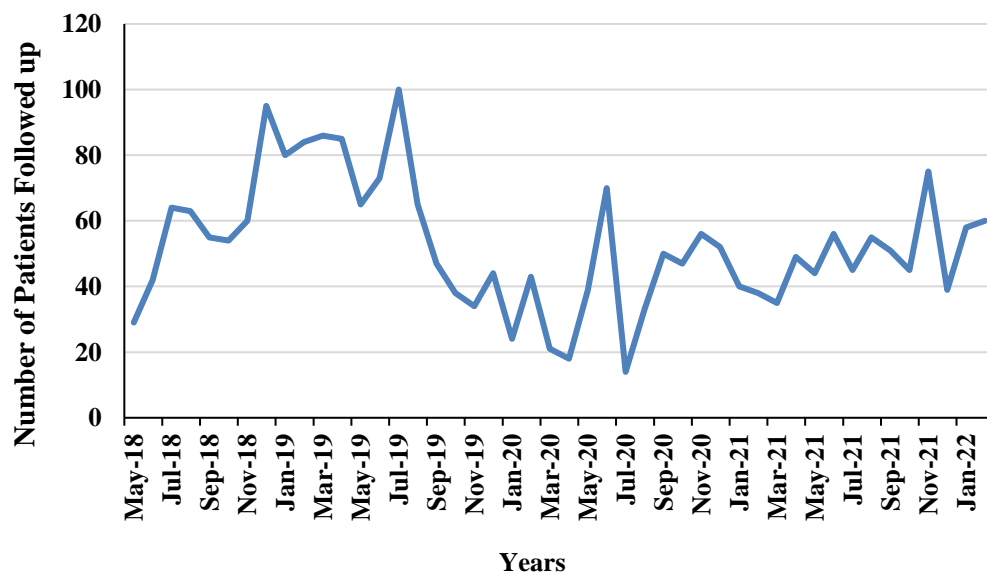


Figure (1): The number of patients followed up in Karbala Children's Teaching Hospital

There was no information available on the number of deaths and the cause(s) of death in the hospitals.

Structure approach: Table (1) shows the presence of a pediatrician but the lack of a dietician, disease-specific milk, and laboratory testing.

Table (1): Structure evaluation of the hospitals

S.	Item	Standard*	Availability No. (%)	Sustainability No. (%)
1	Pediatric specialist doctor	2 (100)	2 (100)
2	Dietitian	0 (0)	0 (0)
3	Trained nurse	1 (50)	1 (50)
4	Patient file	1 (50)	1 (50)
5	Suitable room	1 (50)	1 (50)
6	Antibiotics	2 (100)	2 (100)
7	Plasma	2 (100)	2(100)
8	Thyroxine	0 (0)	0 (0)
9	Vitamins	2 (100)	2(100)
10	Galactose free milk	0 (0)	0 (0)
11	Phenylketonuria milk	1 (50)	0 (0)
12	Galactosemia test	0 (0)	0 (0)
13	Phenylketonuria test	0 (0)	0(0)
14	Congenital hypothyroidism test	0 (0)	0 (0)

* The program hospital structure standard which is found in the “National Guideline of Newborn Screening for Care Providers in primary health care centers in Iraq” considers availability only without any quantities.

Process approach:

Table (2); showed the overall variation in the number of days the clinic was open between Karbala Children's Teaching Hospital and Al-Hindiya Hospital.

Table (2): Process approach of the hospitals

S.	Item	Standard*	Availability No. ** (%)	Sustainability No. (%)
1	Karbala Children's Teaching Hospital clinic opening day	Not mention	1 (....)	1 (....)
2	Al Hindiya Hospital	Not mention	5 (....)	5 (....)

* The clinic at Karbala Children's Teaching Hospital is only open one day a week, but it is open six days a week at Al-Hindiya Hospital.

** The numbers in the availability field indicate the number of days the clinic has been open.

Patient Management

After the disease was confirmed in newborns through the program of newborn screening, then treatment had to be started and preventive measures had to be determined. For each disease in the program, regular, scheduled follow-ups had been required to monitor for treatment effectiveness, disease prognosis, and adverse effects. The decision-making for all of these processes had been determined by the doctor and according to the disease diagnosis and its development. There was a recording of the date of the visits and the results of the laboratory analyses, if obtainable.

Discussion

Outcome

Following confirmation of the laboratory findings, the diagnosed children and their health status are followed up in the hospital. The frequency of follow-up of patients is determined by the specialist. Due to a shortage of laboratory analysis in the hospital, many children's families turn to monitor their children's health in private clinics. The data show variability in the number of followed-up patients during the past years. According to what the health workers informed the researchers during their interviews, this was most likely due to the tidal pattern availability of milk for phenylketonuric children that determined the rate of patients visiting the hospital. This was the case although following up on the health status of children in the hospital is vital to get necessary knowledge about the progression of their condition.

According to the "National Guideline of Newborn Screening for Care Providers in primary health care centers in Iraq", number and causes of death information are not requested to be documented by the hospital, despite the importance of monitoring the number of sick children who die within the program, understanding the reasons for death is an important component of determining the program's efficiency.

Structure

Although the instructions of the Ministry of Health stated that the screening program includes 2 hospitals, Karbala Children's Teaching Hospital and Al-Hindiya General Hospital, in this study, the program inputs were found only available in Karbala Children's Teaching Hospital, but not in Al-Hindiya General Hospital.

According to the observations of Al-Hindiya General Hospital staff members during the evaluation process, the reason for the absence of patient follow-up in the hospital was the parents' lack of awareness of the presence of the program in the hospital, which caused the milk marked for sick children to expire, resulting in non-allocation of milk and complete dependence on Karbala Teaching Hospital for Children. Although the clinic for the program is open five days a week, as opposed to the Children's Hospital, where the clinic is only open one day a week.

In the "National Guideline of Newborn Screening for Care Providers in Primary Health Care Centers in Iraq", the patient would be referred to a regional center where a pediatric specialist and a dietitian with a biochemist would provide support. Because there is no such center within the Karbala Directorate of Health institutions, the hospitals had to compensate for it.

It was found that the laboratory analyses were not available in the hospitals. Accordingly, when the patients were referred to the hospital laboratory, they were obliged to attend another facility, which was the Department of Public Health Central Laboratory, where analyses had been conducted for follow-up purposes.

The researchers recognized in the interviews that the number of patients who have been brought to the hospital for follow-up varies according to the availability of milk designated for certain diseases in irregularly intermittent periods, and the number of follow-ups had been increasing when milk had been available.

According to the parents' statements, it was noticed that there was no support for any form of nutrition for patient children, which had caused a significant financial burden on the patients' families, as well as difficulties in purchasing the treatment foods from the local markets.

Process

Although most program requirements have not been met at Al-Hindiya General Hospital, the clinic used to be open 5 days a week, under the supervision of a professional specialized doctor without attendants.

Sick children, on the other hand, had been brought to Karbala Children's Teaching Hospital, which had met the program's counseling requirements but had not been offering analyses or food. The counseling clinic used to be open for only one day. While in developing countries, government public health clinics have given patients the ability of patient make contact that has been especially useful in both settings, rural and urban. In the urban site, the government is very essential. The NBS follow-up system includes clinics and government hospitals, which are normally accessible to the majority of the population(13).

Conclusion

According to the “National Guideline of Newborn Screening for Care Providers in primary health care centers in Iraq”, this program could contribute to reducing of under-five mortality rate by two-thirds of the annual rate, but the necessary tools to meet this objective were not completely available in the hospitals. Although the program has been piloted in Iraq, it is critical to monitor its progress and meet all of its requirements to properly evaluate its effectiveness.

Declarations

Author contributions

The authors drafted and approved the manuscript.

Conflicts of interest

The authors declare that they have no conflicts of interest.

Ethical approval

The authors requested permission to conduct the research from both the Ministry of Health and the Public Health Department.

Consent to participate

Before conducting the data, the Ethics Committee of the Karbala Directorate of Health was consulted, as well as the verbal consent of each patient's parent(s)

Consent to publication

The manuscript did not contain any personal data.

Availability of data and materials

Not applicable

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