

Cost-Benefit Analysis of the Neonatal Screening Program Implementation for Congenital Hypothyroidism in I. R. Iran

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Congenital Hypothyroidism (CH) is one of the most preventable causes of mental retardation and can be detected through neonatal screening; it is estimated 1200 CH patients are born in Iran, annually. The aim of this investigation was to provide a report on the outcome and estimate the cost-benefit ratio of the screening program implementation for CH in Iran based on the pilot study.

Materials and Methods: The cost of the screening program for CH for each newborn was based on data gathered from the pilot study of three provinces and the amount then multiplied by the number of births per year. The care cost of mentally retarded individuals is calculated based on the Welfare budget of caring for these people. **Results:** Total cost of implementation of the neonatal screening program for CH during the first year is 16, 256, 400, 000 Rials (\$ 2, 000, 000). The ratio of the cost of care for the children to the cost of implementation of the screening program is about 1 to 16 and the ratio of the benefit (cost saving) to the implementation cost is 1 to 15.

Conclusion: The neonatal screening program for CH has a very high potential for implementation in the country. As a result, the implementation of the CH screening program as the first screen-

ing of newborns provides a basis for better understanding and timely detection of CH and other metabolic diseases in Iran.

Key Words: Cost-benefit analysis, Congenital hypothyroidism, Implementation, Newborn screening program.

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Introduction

Neonatal screening provides an opportunity for early detection and timely cure of newborns suffering from various genetic, glandular, vascular, hematological, and lung diseases. Congenital hypothyroidism (CH) is one of the most preventable causes of mental retardation that can be detected through neonatal screening. Screening for CH is regularly performed in most developed countries and in some of the third world countries as well.^{1,5,8,17-19} Its etiology has not yet been clarified. Early diagnosis of CH is difficult during neonatal period due to lack of signs or symptoms in this period and routine screening is the only means of detection. Late diagnosis of CH results in reduction of intellectual quotient (IQ) at different levels in patients suffering from the condition.^{3,5,7,9,12}

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Congenital hypothyroidism is a relatively common congenital disorder occurring in about 1 of 3000 to 1 of 4000 live births. Previous studies have reported a high incidence of CH in Iran.^{11, 13, 16} It is estimated to be 1 of 1000 live births. The high incidence of this disease and its irreversible consequences, if it goes undetected, persuaded the ministry of health and medical education of Islamic republic of Iran to plan a systematic neonatal screening program in the country; the program was designed to make use of the existing health infrastructure in the country. As with any other program, positive cost-benefit ratio is an important factor in the acceptance and implementation of a health care program.^{2,6} The cost-benefit ratio of screening for CH is reported to range between 1:3.4 and 1:13.8.^{10,14,15}

The aim of this investigation was to provide a report on the outcome and estimate the cost-benefit ratio of the screening program implementation for CH in Iran based on the pilot study.

Materials and Methods

Following designing of the screening program, it was examined as a pilot study in the three provinces of Isfahan, Boushehr and Fars. Heel blood samples were taken between 3 to 5 days of life on a 903 S&S filter paper; they were dried and immediately transferred to the screening laboratory of the province by an express mail service. TSH was tested using the ELISA method and was employed as the screening test.

TSH values ≥ 10 mU/L were categorized as positive screening test results and recalled for confirmation. Neonates with positive screening test were taken to the laboratory designated in their city, and blood samples were taken for testing serum T_4 , TSH, and T_3 R uptake levels. Levothyroxine replacement in neonates with positive result (if $T_4 < 6.5$ $\mu\text{g/dL}$ and TSH > 10 mU/L) was initiated.

The cost of the screening program for CH for each newborn was based on data gathered from the pilot study of three provinces it was then multiplied by the number of births per

year. The care cost of mentally retarded individuals is calculated based on the Welfare budget for caring of these people. Cost/benefit ratio was calculated by using the above data.

Results

15598 newborns were screened in three provinces in the first three months with a 90% program coverage. The recall rate for further testing was 0.3 percent of the screened population.

Based upon the incidence of CH is 1 to 1000 live births in Iran; 1200 CH patients are born and identified yearly. The average cost of the 24 hour care for a mentally retarded individuals was 1,500,000 Rials (about \$200) per month for the year 2005. The care for mentally disabled children starts at the 6th year of life which is when they begin elementary school education. The minimum duration of care for these children is 14 years (until the age to 20 years) although in many cases this care continues for longer periods.

The implementation cost of the program in the country and all activities leading to identification of patients during the first year was computed and is summarized in Table 1.

Total cost of implementation of the neonatal screening program for identification of newborns suffering from CH during the first year was 16,256,400,000 Rials (\$ 2,000,000).

Calculation of care costs for 1200 mentally retarded individuals would be as follows:

Care Costs = Number of mentally retarded individuals in one year \times cost of care per month $\times 12$ months \times number of years of care $= 200 \times 1,500,000 \times 12 \times 14 = 302,400,000,000$ Rials (\$32,240,000)

On the other hand, cost savings due to early diagnosis and proper metabolic control of patients during the first year of implementation would be as follows:

Cost savings = Care costs of mentally retarded individuals minus the total implementation cost during the first year

i.e $302,400,000,000 - 16,256,400,000$
 $= 286,143,600,000$ Rials (\$30,240,000)

Table 1. Summary of the cost computations for the implementation of the neonatal screening program

| Activity | Provider | Frequency | Cost in Rials |
|--|---|-----------------------------|---|
| Meetings discussions | National Scientific Committee | 4 times per year | $1,500,000 \times 4 = 6,000,000$ |
| | Provincial Scientific Committee | twice per year for 30 state | $30 \times 2 \times 1,000,000 = 60,000,000$ |
| | District Executive Committee | twice per year, 360 cities | $360 \times 2 \times 200,000 = 144,000,000$ |
| Preparing/providing educational material | Center for Diseases Control For: Rural health worker, GPs, laboratory experts, and public | Once a year | 600,000,000 |
| Blood Sampling & TSH testing | Blood sample center, The screening Lab. | 1,200,000 | $1,200,000 \times 9,000 = 10,800,000,000$ |
| Express postal services | Post office | 1,200,000 | $1,200,000 \times 3400 = 4,080,000,000$ |
| Visits of neonates with positive screening test | Physician | 3600 | $3600 \times 24000 \times 1 = 86,400,000$ |
| Regular visit of patients & Lab. tests | Physician & selected Lab. | During the first year | 480,000,000 |
| Total cost of implementation during the first year | | | 16,256,400,000 |

Conclusion

Thyroid hormones play an important role in initial development and functioning of the brain; some of the development processes of the brain continue after birth and in general during the first three years.³ The thyroid hormones are vital for the development of a normal IQ. Late diagnosis of CH results in reduction of IQ in children affected by CH it,³ making the child mentally retarded and dependent on special care for the rest his/her life.

In this study, the indirect and unquantifiable costs for the family such as mental and social problems caused by having a debilitated child in the family and direct healthcare cost due to high risk of suffering from other congenital diseases including lack of hearing and heart disease, have not been considered. Only considering the direct cost of care, the cost savings due to implementation of the neonatal screening program in the first year

has been estimated at 286,143,600,000 Rials (\$30,240,000). The ratio of the cost of care for the children to the cost of implementation of the screening program is about 1 to 16 and the ratio of the benefit (cost saving) to the implementation cost is 1 to 15, which is higher than the ratio reported in other studies.^{10,14,15}

The humane aspect of the program is clear and does not need to be mentioned. Timely diagnosis and early and proper metabolic control of the neonates with CH identified through the screening program would eventually lead to more healthy, normal and useful members of society. Furthermore, the screening program for CH is designed to be a appropriate base for screening of newborns for other congenital diseases (such as: PKU, G6PD, Galactosemia, etc).

Screening other metabolic diseases does not alter the current process of sampling and transfer of the specimens to the screening laboratory. Facilitating provision of the re-

lated test kit and performing other screening tests, would identify more metabolic diseases on the same Guthrie card.

Considering the results of the pilot program in the three provinces, the 90% coverage within the first 2-3 months, and the outstanding cost to benefit ratio of 1 to 15, the neonatal screening program for CH has a very good potential for implementation in the country. Significant developments in the medical sciences provide many beneficial enterprises to identification of etiology, natural

history, and also preventive strategies for numerous diseases, facilitating prevention of their subsequent complications. Such preventive programs have high priority in health strategies for the country.

As a result, the implementation of CH screening program as the first screening of newborns provides a basis for better understanding and timely detection of CH and other metabolic diseases in Iran.

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