United Arab Emirates National Newborn Screening Programme: an evaluation 1998–2000

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البرنامج الوطني لتحرّي الولدان في الإمارات العربية المتحدة. تقييم للفترة 1998 – 2000

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الخلاصة: لتقييم البرنامج الوطني لتحرّي الولدان في الإمارات العربية المتحدة قمنا بمقارنة مؤشرات التغطية وملاءمة التوقيت الملائم (العمر وقت أخذ العينات، بدء المعالجة، توقيت أخذ العينة إلى المختبرات والحصول على النتائج) إلى جانب جودة العينات مقيسة بالمعايير الدولية. ثم حسبت معدلات التذكر والقيم التنبؤية الإيجابية، والنوعية والمَناسب النسبية لبيلة الفنيل كيتون والخاصة بقصور الدرقية الخلقي وقد اشتملت دراسات وظائف الدرقية (T_3، T_4، T_4 الحر، الهرمون المنبِّه للدرقية) والتفرُّس باستخدام التكنسيوم 99 للدرق عند توافره ومعايرة أضداد الدرق والغلوبولين الدرقي إذا كان هناك دواعٍ لإجراء ذلك. أما الاستقصاءات الخاصة ببيلة الفينول كيتون فتشتمل على الحموض الأمينية في المصل وقياس نقص البيوبتيرين. وخلال الفترة التي غطت ست سنوات قبل حلول شهر كانون الأول/ديسمبر 2000 تم تحرّي 138 718 من المواليد، وكانت معدلات الحدوث النسبية لقصور الدرقية الخلقي: 1 إلى 1570 ولبيلة الفينول كيتون الكلاسيكية: 1 إلى 20050.

ABSTRACT To evaluate the United Arab Emirate National Newborn Screening Programme we compared coverage, timeliness of programme indicators (age at sampling, recall and treatment initiation, timing of specimen delivery and laboratory results) and specimen quality with international standards. Recall rate, sensitivity, specificity, positive predictive values and relative incidence rates for phenylketonuria (PKU) and congenital hypothyroidism (CH) were calculated. Investigations for hypothyroidism included thyroid function studies (T_3, T_4, fT_4 and TSH), technetium-99m thyroid scan when possible and thyroglobulin and thyroid antibodies when indicated. PKU investigations included plasma amino acids and measurement of biopterin defects. In the 6 years before December 2000, 138 718 neonates were screened. Relative incidences for CH and for classic PKU were 1:1570 and 1:20 050 respectively.

Programme de dépistage national chez les nouveau-nés aux Emirats arabes unis : évaluation sur la période 1998-2000

RESUME Afin d'évaluer le programme de dépistage national chez les nouveau-nés aux Emirats arabes unis, nous avons comparé la couverture, l'actualité des indicateurs du programme (âge du nouveau-né au moment du prélèvement, rappel et mise en route du traitement, temps d'acheminement des échantillons au laboratoire et de retour des résultats) et la qualité des échantillons prélevés par rapport aux normes internationales. Le taux de rappel, la sensibilité, la spécificité, les valeurs prédictives positives et les taux d'incidence relative ont été calculés pour la phénylcétonurie et l'hyperthyroïdie congénitale. Les examens effectués pour l'hyperthyroïdie comprenaient l'étude de la fonction thyroïdienne (T_3, T_4, fT_4 et TSH), la scintigraphie de la thyroïde au technetium 99m lorsque possible et la recherche des anticorps de la thyroïde et de la thyroglobuline lorsque indiqué. Les investigations de la phénylcétonurie comprenaient le dosage des acides aminés plasmatiques et la mesure des déficits en bioptérine. Au cours des six années précédant décembre 2000, 138 718 nouveau-nés ont fait l'objet d'un dépistage. Les incidences relatives de l'hyperthyroïdie congénitale et de la phénylcétonurie étaient de 1:1570 et 1:20 050 respectivement.

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Introduction

Newborn screening is a preventive health service that should be available to all neonates. Newborn screening no longer refers only to the screening tests themselves, but encompasses all of the elements essential for every neonate to have access to a screening system that has optimal quality and performance [*1*].

Phenylketonuria (PKU) is an inborn error of phenylalanine metabolism and has a global incidence of 1:12 000 to 1:15 000 live births. In the absence of treatment during infancy, nearly all children with this disorder develop severe, irreversible mental retardation and a variety of neurobehavioural symptoms. The clinical manifestations of PKU have rarely developed in children born after the mid-1960s when routine screening for and early treatment of PKU was established [*2*].

Congenital hypothyroidism (CH) is one of the most common treatable causes of mental retardation and has a worldwide incidence of 1:2500 to 1:5500 live births. Unfortunately a clinical diagnosis is made for less than 5% of neonates with hypothyroidism because symptoms and signs are often minimal. Without prompt treatment, most affected children gradually develop growth failure and irreversible mental retardation. These complications have become rare since the introduction in the 1970s of routine neonate screening and early treatment of CH [*3*].

In the rapidly advancing health care system of the United Arab Emirates (UAE), neonate screening for metabolic disorders has become a necessity. In 1994, the Ministry of Health established an advisory committee for newborn screening that supervises the programme. The programme commenced screening for PKU in January 1995 and for CH in January 1998.

The aim of our study was to evaluate the progress of the programme and to determine the incidence of PKU and CH in the UAE.

Methods

The National Newborn Screening Programme procedures are as follows: The parents of every baby born in a hospital setting in the UAE (99% of mothers deliver in hospital settings in the UAE) are given a form for newborn screening. The baby attends a designated maternal and child health centre on the fifth day of life where blood is collected by heel prick onto Schleicher and Schuell 903 filter paper. For babies remaining in hospital for 5 days or more, blood is collected before departure. Premature and sick term babies have a repeat screen at day 14. For transfused babies, sample collection is delayed until 72 hours post transfusion.

All filter papers are tested for phenylalanine and thyroid stimulating hormone (TSH) either in the Abu Dhabi Laboratory for the Abu Dhabi emirate or the Sharjah Laboratory for the northern emirates. TSH and phenylalanine are assayed by DELFIA fluorometric kits (Wallac Oy, Turku, Finland). For CH, infants are recalled if TSH is abnormal (> 20 mU/L) or persistently borderline (10–20 mU/L). For PKU, infants are recalled if phenylalanine is abnormal (> 3 mg/dL) or persistently borderline (2–3 mg/dL).

To evaluate the programme, we compared the percentage of neonates screened, the timeliness of specific programme indicators and specimen quality, e.g. adequacy of specimen volume and presence of repeated spotting or contamination, to internationally accepted standards [*4–6*]. Specific programme indicators included

age at sampling, time taken to deliver the specimen to the laboratory, time taken by the laboratory to produce the result, age at recall (neonate age when parents were requested to present the infant for confirmation follow-up after the availability of the first specimen results) and neonate age when treatment was initiated.

Also calculated were the recall rate (percentage of neonates with a positive screening result for which diagnosis had not yet been confirmed divided by the total number of screened babies, regardless of age at recall), test sensitivity, specificity and positive predictive value (PPV), or the probability of disease in a subject who has screened positive for the disease, and the incidence of confirmed cases for PKU and CH [*7*].

Investigations for confirmation and cause of CH include thyroid function studies of triiodothyronine (T_3), thyroxine (T_4), free thyroxine (fT_4) and TSH, technetium-99m thyroid scan where possible and thyroglobulin and thyroid antibodies when indicated. Investigations for confirmation and cause of PKU included plasma amino acids and measurement of biopterin metabolism defects [*8*].

Results

From the implementation of the programme in January 1995 through to December 2000, 138 718 newborn infants were screened with an incidence of 1:20 050 for classic PKU and 1:1570 for CH.

Table 1 shows the increase in coverage by district during the evaluation from 1998 to 2000. The highest coverage rates were in Abu Dhabi, the Western Region, Ras Al-Khaimah and Umm Al-Qaiwain. The greatest relative increase in coverage (> 100%) was in Dubai, although absolute coverage by 2000 remained very low at 10.7%. Total coverage for all regions increased from 50.3% in 1998 to 65.0% in 2000, which was still well below the international standard of 99%.

Table 1 **United Arab Emirates National Newborn Screening Programme coverage (percentage uptake) by district, 1998–2000**

District	1998			1999			2000		
	Live births	No. tested	% uptake	Live births	No. tested	% uptake	Live births	No. tested	% uptake
Abu Dhabi	11 281	8 265	73.3	11 914	10 354	88.9	12 968	12 273	94.6
Al-Ain	7 500	4 320	57.6	7 800	5 888	75.5	8 132	6 241	76.8
Western Region	1 028	736	71.6	1 053	952	90.4	1 127	1 040	92.3
Dubai	13 962	740	5.3	12 530	1 341	10.7	15 355	1 648	10.7
Sharjah	5 172	3 932	76.0	5 998	5 179	86.4	6 674	5 869	87.9
Ajman	1 688	1 593	94.4	1 897	1 673	88.2	1 964	1 789	91.1
Fujairah	1 210	797	65.9	2 373	1 653	69.7	2 176	1 764	81.1
Ras Al-Khaimah	2 559	1 759	68.7	2 788	2 269	81.4	2 948	2 534	86.0
Umm Al-Qaiwain	644	378	58.7	721	593	82.3	716	669	93.4
Total	45 044	22 646	50.3	49 075	29 886	60.9	52 070	33 853	65.0

Table 2 Timeliness indicators of the United Arab Emirates National Newborn Screening Programme compared with international standards

Indicator	Timeliness measure	National Programme: percentage achieved			International standard
		1998	1999	2000	
Age at sampling	% sampling at age < 10 days	89.5	96.0	98	100
Timing of specimen delivery	% specimens received at laboratory on or before 5 working days after sample taken	69.0	79.0	86	95
Timing of results	% results available on or before 2 working days after receipt at laboratory	77.8	83.1	89	90
Age of newborn at time of recall	% results of first specimens available on or before 20 days postpartum	84.5	89.5	93	95
Age at initiation of treatment	% positive cases started on treatment on or before 21 days postpartum	72.0	86.0	91	95

Table 2 shows the timeliness of screening programme indicators compared with international standards. The mean age at sampling was 5.3 days (range: 3–17 days) with 89.5% (1998), 96% (1999), and 98% (2000) of subjects aged less than 10 days. The percentage of specimens received at the laboratory by the fifth working day after samples were taken increased from 69% in 1998 to 79% in 1999 and 86% in 2000. The percentages of results available within 2 working days of receipt at the laboratory were 77.8% (1998), 83.1% (1999) and 89% (2000). The mean age of infants at recall were 15.4 days (range: 6–23 days) with 84.5% (1998), 89.5% (1999) and 93% (2000) of results of first specimens available at or less than 20 days after birth. The mean age of treatment initiation was 16.8 days (range: 6–28 days) with 72% (1998), 86% (1999) and 91% (2000) of positive cases starting treatment ≤ 21 days. Unsatisfactory specimen quality in the UAE was reduced from > 3% during 1995, 1996 and 1997 to 1.3% (1998), 0.7% (1999) and 0.2% (2000). The international standard for unsatisfactory specimen quality is < 3% of specimens.

Table 3 shows the recall rate, sensitivity, specificity and PPV for PKU and CH. The recall rates were 0.09% for CH and 0.04% for PKU. Unfortunately, confirmation was not possible for 4 infants either because of neonatal death (2 cases) or travel outside the country (2 cases). An apparent sensitivity of 100% and specificity more than 99% were reported for both CH and PKU. The PPV for CH was 79.6% and for PKU, 13.7%.

A total of 80 positively screened CH cases (25 infants with borderline and 55 with abnormal results) were further investigated and followed up (Table 4). Of the 25 borderline cases, 10 (40%) were confirmed CH (of whom 3 defaulted), 4 were transient (16%) and 11 were false positives

Table 3 **Indicators for screening efficacy for phenylketonuria and congenital hypothyroidism**

Indicator	Congenital hypothyroidism (%)	Phenylketonuria (%)
Recall rate	0.09	0.04
Sensitivity	100.00	100.00
Specificity	> 99.00	> 99.00
Positive predictive value	79.60	13.70

(44%). Of the infants with abnormal test results, 45 (81.8%) were confirmed and 6 (10.9%) were diagnosed as transient. There were 4 (7.3%) instances of failure to recall among infants in the abnormal screen category.

Tc99m thyroid scan was performed on 36 confirmed cases. The gland was ectopic in 16 cases (44.4%), eutopic with increased uptake in 15 (41.7%) and athyrotic in 5 cases (13.8%). Among the transient cases, there was maternal history of autoimmune thyroid disease in 4 cases (40%), 2 premature cases (20%) and 4 cases (40%) with unidentified causes.

Table 5 shows 54 positive screen cases for PKU (47 borderline and 7 abnormal). All 7 cases of abnormal PKU were reported as classic PKU (phenylalanine > 20mg/dL, normal tyrosine and normal biopterin) compared with none from the borderline category. Of the borderline cases, 44 (93.7%) were false positives.

Discussion

In the past 4 decades, many countries and regions have developed newborn screening programmes. An effective neonatal screening programme requires careful planning and includes education, administration, laboratory analysis, follow-up, management, evaluation and, most importantly, the commitment of all involved. Quality evaluation must not only be applied to the laboratory analysis phase, but also to the pre-analysis phase (i.e. coverage and age at sampling) and to the post-analysis phase (i.e. follow-up, treatment and long-term outcome) [*9*].

Our data indicate that coverage was acceptable in all districts except Dubai. There was a satisfactory increase in the coverage from 1998 to 2000 in all districts particularly in Abu Dhabi, the Western Region, Ras Al-Khaimah and Umm Al-Qaiwain (Table 1). This improvement could be due to increased community awareness, a better recall system for defaulters, perinatal health education combined with a breastfeeding programme and the recording of the screening status of the baby on the child welfare record along with vaccination information. However, the coverage for the whole of the UAE was still low (65%) by the end of the evaluation period (2000). To reach the target coverage (the international standard of 99%), further effort is required, especially efforts to increase community awareness. A strategy has been adopted so that the Dubai newborn screen programme will be fully integrated with other Dubai health programmes by January 2003.

A comparison of the timeliness of screening programme indicators shows that the UAE indicators improved between 1998 and 2000 and now approximate international standards. However, the mean time of delivery of specimens to the laboratory remains above the international standard. The central Maternal and Child Health Department has taken important steps to achieve its goal of early identification and

Table 4 **Follow-up of cases screened positive for congenital hypothyroidism**

Categories	Borderline (TSH 10–20 mU/L)		Abnormal (TSH > 20 mU/L)		Total
	No.	%	No.	%	
Confirmed	10[a]	40.0	45	81.8	55
Transient	4	16.0	6	10.9	10
False positive	11	44.0	0	0.0	11
Failure to recall	0	0.0	4	7.3	4
Total positive screens	25	100.0	55	100.0	80

[a] *In 3 default cases the infants were aged > 1 month when screened.*
TSH = thyroid stimulating hormone.

Table 5 **Follow-up of positive screened phenylketonuria (PKU) cases, United Arab Emirates National Newborn Screening Programme, 1998–2000**

Categories	Borderline (Ph 2–3 mg/dL)		Abnormal (Ph > 3 mg/dL)		Total
	No.	%	No.	%	
Transient	4	16.0	6	10.9	10
Classic PKU	0	0.0	7	100.0	7
Benign hyperphenylalaninaemia	1	2.1	0	0.0	1
Transient	2	4.2	0	0.0	2
False positive	44	93.7	0	0.0	44
Total positive screens	47	100.0	7	100.0	54

Ph = phenylalanine.

treatment of affected babies. These include vehicle delivery of specimens to the laboratory 2–3 times per week, the addition of new laboratory staff, the registration of the laboratory in two external quality assurance schemes, that is, the United Kingdom National External Quality Assessment Service (NEQAS) and the United States of America Centers for Disease Control and Prevention, and initiation of treatment by a designated consultant at the earliest opportunity prior to confirmation of results when appropriate.

The quality of laboratory specimens received for testing during 1998–2000 was similar to the international standard (unsatisfactory specimen quality < 3%). This was probably due to the training provided to laboratory technicians and nurses.

The programme protocol had a high recall rate (0.09%) for CH and an acceptable recall rate (0.04%) for PKU. Apparent sensitivity (100%) and specificity (> 99%) for both CH and PKU (Table 3) were acceptable. To decrease the recall rate for CH, the TSH cut-off point for diagnosis of the disease should be reduced from 20 mU/mL to 25 mU/mL as per the NEQAS recommended level.

The PPV of 79.6% for congenital hypothyroidism indicated an acceptable number of false-positives. However, the PPV of 13.7% for phenylketonuria was unacceptably high. To improve the PPV for PKU, the phenylalanine cut-off point for diagnosis should be increased from 3 mg/dL to 4 mg/dL as per NEQAS recommendations [*10*].

The incidence of CH among the screened neonates was 1:1570. Of 55 confirmed cases, 45 had abnormal screenings (TSH > 20 mU/L) and 10 had borderline TSH (10–20 mU/L) (Table 4). Although high by international standards [*11*], the incidence of CH in the UAE was similar to that of other countries in the region such as Oman (1:2200) and Saudi Arabia (1:2666) [*12*].

Our research, which used TSH as an indicator in the evaluation of iodine defi-

ciency, indicated that the relatively high incidence of CH was unlikely to be explained through iodine deficiency mechanisms. Furthermore, if newborns with positive screen results where confirmation was not possible (4 cases of failure to recall) were factored in as true positives, the incidence of CH would be higher still.

Thyroid scintigraphy is recommended after a positive screening result, if feasible, because it provides important information regarding:

- The etiology of CH in the UAE, i.e. ectopic thyroid, athyrosis or dyshormonogenesis;
- The likelihood of hypothyroidism being permanent and the risk to any future newborns in that family (especially important when counselling families);
- Whether or not to treat in cases where the free T_4 is normal and TSH is high [*13*].

Thyroid ectopy was most common (44.4%). Furthermore, the high percentage of patients having normally located glands and high uptake (41.7%) suggested dyshormonogenesis. This may have a genetic basis influenced by consanguinity and may be the cause of the relatively high incidence of CH in the UAE [*14*]. The iodine situation should be investigated and perchlorate discharge tested for babies with suspected dyshormonogenesis [*15*].

Of the 80 cases that screened positive, 10 transient cases were normal on follow-up (Table 4). This was easily explained by maternal history and investigations of autoimmune thyroid diseases in 4 cases and the presence of prematurity in 2 cases. However, in 4 cases no specific cause was found. This deserves further investigation, e.g. obtaining an accurate clinical history of perinatal exposure to iodine, maternal antithyroid medication intake during pregnancy, TSH receptor antibodies and thyroid peroxidase antibodies. These measures should help to decrease the recall rate when screening for CH and thus eliminate unnecessary stress to families while contributing to a decline in the relatively high incidence of CH in the UAE [*16*]. The relatively high incidence of CH in the UAE could also be reduced by trials of treatment for dyshormonogenesis cases to exclude transient cases after 3 years.

There were 7 confirmed PKU cases (Table 5) with a relative incidence of 1:20 050 for classic PKU. The incidence of PKU in the UAE was similar to that of other Gulf countries [*17*] and was low compared to other countries [*18*].

Follow-up of 47 positive screened cases with phenylalanine values in the range 2–3 mg/dL (i.e. borderline cases) produced only 1 case diagnosed with benign hyperphenylalaninaemia and 2 cases with transient hyperphenylalaninaemia; 44 cases were false positives (Table 5). The high incidence of false positives might be due to genetic heterogeneity of hyperphenylalaninaemia and might indicate a need to adjust the cut-off point for the screening test [*19*].

Conclusions

Based on the statistical data of the incidence of PKU and CH in the UAE and the success achieved in early detection, treatment and follow-up, we stress the importance of programme continuity and the necessity of strengthening programme capacity. Indicators of programme quality currently approximate international standards although the coverage ratio is still relatively low with some regional variation. We are, however, progressively approaching coverage targets despite a number of obstacles.

To increase the coverage ratio, we recommend that increased population awareness of the importance of the screening programme be promoted through different media and that a coordinator be established in each medical district to facilitate screening programme protocols.

To increase the positive predictive value of the screening test, we recommend that the cut-off point for diagnosis of PKU be increased from 3 mg/dL to 4 mg/dL. For the diagnosis of CH, the TSH cut-off point should be increased from 20 mU/mL to 25 mU/mL to decrease the recall rate for the disease.

Further studies are recommended for more accurate classification of confirmed permanent and transient cases of CH and to identify the effect of epidemiological factors on the profile of CH in the UAE.

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Needs of the newborn

Improving newborn survival will dramatically reduce infant mortality worldwide. Of the 7.1 million infants who die each year, approximately two-thirds die in the first 28 days after birth, the neonatal period. Of these deaths, two-thirds take place in the first week after birth. Ninety-eight percent of all neonatal deaths occur in developing countries.

There are basic needs of a newborn that can help ensure a healthy start in life. Interventions to prevent neonatal death and disability, many of them simple and low cost, can be integrated into existing maternal and infant health programmes. The USAID/WHO document *Newborn health and survival: a call to action* outlines these needs and can be accessed free on line at: http://www.who.int/child-adolescent-health/New_Publications/ADH/A_Call_to_Action.pdf