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UK National Screening Committee

Is there evidence to alter the current UKNSC recommendation to offer a national screening programme for congenital hypothyroidism in newborn babies? A pilot of the triage approach.

Topic: Newborn screening for congenital hypothyroidism (CHT)

Delivery date: February 2015

Contents

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1. Background to the triage reports

This report is a rapid (triage) assessment of evidence relating to whether the existing national screening programme (NSP) for congenital hypothyroidism (CHT) in newborns should be continued.

For conditions for which population screening programmes are recommended by the National Screening Committee (NSC) the triage process focuses on whether there is new evidence suggesting that the NSP should be stopped.

It consists of an externally produced report on a literature search undertaken to identify whether any papers have been published:

- addressing screening programme cessation
- reporting harms from screening
- reporting balance of harms and benefits from screening

The aim of these reports is to identify any "red flags" that suggest that an NSP needs to be reviewed in greater detail. They do not aim to identify all new literature relating to screening for the condition; instead they focus specifically on evidence relating to the three areas specified above.

If no papers are identified on the above topics, a recommendation to continue the programme is made. If papers on programme cessation or harms from screening are identified, the UK NSC will consider whether further work is necessary before making a recommendation on the topic.

Stakeholders will be contacted for comments on the recommendation and a three month consultation will be hosted on the UK NSC website.

Based on the triage report and stakeholder comments the Committee decides whether to recommend that the issue is considered in more depth. Where further evaluation is considered appropriate, the options may include an evidence summary, primary research, systematic review, cost effectiveness assessment, modelling.

2. Executive summary

This triage assessment identified one study with potential relevance to the three questions above, and that related to the possible harms of CHT screening.

This study reviewed published literature on the harms of six newborn screening programmes in the US, one of which was for CHT (Brosco et al. 2006). This was the only directly relevant study identified. The report concluded that their comprehensive search did not find a widespread problem of harm to children with false positive results receiving medical treatment across the six programmes. There were no specific details of the CHT newborn screening programme in the study abstract.

Recommendation: The single relevant study identified suggested that the CHT screening programme in the US has not led to widespread harm. It does not provide sufficient evidence to suggest that the evidence supporting the national CHT screening programme needs to be reviewed in more depth or that the programme should be stopped.

3. Introduction to the condition

The current NSP being assessed is newborn bloodspot screening for congenital hypothyroidism (CHT).

Underactivity of the thyroid gland (hypothyroidism) can arise for a number of reasons. Hypothyroidism can occur in newborn infants (congenital hypothyroidism, CHT) as well as later on in childhood (acquired hypothyroidism, AHT). Affected newborns look, and usually act, normal for the first few days and the national screening programme for CHT, by blood spot collection, ensures that affected infants are identified and treated as early as possible.

The most common cause of CHT is a poorly developed or absent thyroid gland; the underlying basis of this abnormality is only clear in a small proportion of cases. CHT can also occur if there is a defect in thyroxine production within the gland. These defects may be permanent or transient. It is recommended that every child with CHT should be started on thyroxine promptly. However they should be evaluated at some time later to exclude a transient problem. Children with CHT do very well as adults in the long-term, as long as they receive adequate thyroxine replacement.

CHT is one of the conditions currently screened for as part of the NHS newborn bloodspot (NBS) screening programme. This is offered for all newborn babies, with the blood sample usually taken 5 days after birth (in exceptional cases it can be taken between Day 5 and Day 8). The screening test examines levels of thyroid stimulating hormone (TSH) in the blood.

This external review has searched the literature published between 2006 up to February 2016, and reviewed the results at title and abstract level to establish whether there is evidence:

- indicating that other countries have terminated CHT screening
- reporting harms from CHT screening
- reporting balance of harms and benefits from CHT screening

4. Description of the evidence

Forty-three publications were selected at the first pass sift as being potentially relevant to these three questions based on title and abstract. These were reviewed more closely at abstract level at a second pass appraisal.

No studies were identified which reported cessation of newborn CHT screening programmes, or explicitly weighed up the balance of harms and benefits from CHT screening. One of these 43 publications met inclusion criteria as having relevance to potential harms of screening. Details of this study are extracted in Table 1.

This study was a historical overview which reviewed the published literature on the issue of possible harm from false positive screening results and subsequent inappropriate medical treatment across six US newborn screening programmes including one for CHT. There were no details of the individual screening programmes or specific adverse outcomes in the abstract.

The excluded studies predominantly included surveys of screening and management practice (including in the UK and other countries), alternative methods of detection and treatment of CHT. There were a number of studies that looked at the impact of utilising different thresholds of thyroid-stimulating hormone (TSH) to screen for the condition (i.e. modifications to the screening programme), and the proportions of permanent and transient hypothyroidism found and missed by the test. These studies were not included as the issues discussed may be more closely related to modification of the existing programme rather than harms suggesting that the programme should be stopped. These studies also did not explicitly report harms related to these differences.

Table 1: Details of relevant studies identified

Publication details	Study details	Population	Intervention/ test and comparator	Main findings	Comments
Screening programme cessation					
No studies identified					
Harms from screening					
Brosco et al. 2006	Historical overview of universal newborn screening programmes in the US. Including a review of published literature on whether universal screening has led to substantial morbidity and mortality from misguided medical treatment of false positives. A "comprehensive search" was reported to be carried out, but other methods not reported)	Newborns screened for CHT or 5 other conditions	Universal newborn screening for CHT (which was contrasted with 'screening' in at risk populations). Details of the screening and diagnostic tests, or treatments used were not provided in the abstract.	The search "did not reveal a widespread problem of harm ensuing from medical treatment of children with false positive screening test results" No further details were provided.	It was unclear from the abstract whether the study would qualify as a systematic review. No details of the literature identified, or e.g. proportion of false positives or harms resulting from their treatment were described in the abstract
Balance of harms and benefits from screening					
No studies identified					

5. Methodology

It is intended that the triage process for each NSP will be performed every three years. This review is the first triage review for CHT and includes literature published in the last 10 years.
Sifting was carried out in two stages. The first pass sift was conducted by an information specialist at title and abstract level, to remove clearly non-relevant material e.g. animal studies, or studies of different screening programmes. The second pass sift was performed by a health research analyst and this sift examined the results more closely at title and abstract level to remove those studies clearly not relevant, and select those meeting inclusion criteria for summary.

The reports focus on high quality studies, i.e. systematic reviews, randomised controlled trials, non-randomised controlled trials, cohort studies or screening programme evaluations that appear at abstract level to have covered potential harms of the NSP, the balance of harms and benefits, or screening programme cessation. Lower level evidence such as case series and case reports, non-systematic reviews, editorials or opinion pieces are not included unless they clearly highlight potential harms of the NSP indicating the need for further evaluation.

Studies on any issues other than the three questions of interest are not included. For example, studies examining cost effectiveness (unless relevant to the UK and highlighting the balance of benefits and harms), or studies assessing modifications to an existing screening programme (e.g. changing age at screening, screening test used, screening interval etc.) would be excluded. Studies evaluating management of the condition are also excluded unless they indicate that the existing treatment is ineffective or harmful, which may suggest that harms of screening may outweigh any benefits.

These triage reports are rapid assessments to identify any “red flags” which indicate the need for further assessment of the NSP. They are complemented by consultation with stakeholders to identify any additional issues which may not be represented in the literature identified.

6. Search strategy

We searched the following bibliographic databases:

- Medline (via Embase.com)
- Embase
- The Cochrane Library: including the Cochrane Database of Systematic reviews; Cochrane Central Register of Controlled Trials (CENTRAL); Database of Abstracts of Reviews of Effects (DARE); Health Technology Assessment Database (HTA); NHS Economic Evaluation Database (EED)

The searches were limited by date to include studies published since 2006. No language limits were used. Methodological filters were not used as they would not have been appropriate given the focus of the research questions.

The search strategy was developed through testing to identify the best balance between sensitivity and specificity that was fit for purpose. The search strategy used both indexing terms and text words as relevant records could have been indexed in different ways (or not indexed at all). The Embase search strategy was translated for the other databases and adapted to take into account the databases size, coverage and available indexing terms.

The search strategy was based on the PICO framework and combined three major concepts: the population (condition), neonatal screening, and harms from screening or screening programme cessation.

Embase.com search strategy

#1	'newborn screening'/de	13,746
#2	((neonat* OR newborn*) NEAR/2 screen*):ab,ti	12,206
#3	'mass screening'/de	49,630
#4	'newborn'/de	498,406
#5	#3 AND #4	2,463
#6	#1 OR #2 OR #5	19,026
#7	ceas*:ab,ti OR cessation:ab,ti OR stop:ab,ti OR stopped:ab,ti OR continu*:ab,ti OR discontinu*:ab,ti	1,265,546
#8	appropriate*:ab,ti OR inappropriate*:ab,ti OR unnecessary:ab,ti OR question*:ab,ti	1,495,204
#9	harmful:ab,ti OR harm*:ab,ti OR adverse:ab,ti	609,591
#10	benefit*:ab,ti AND (risk*:ab,ti OR harm*:ab,ti)	166,742
#11	'side effect'/exp	398,996
#12	(side NEAR/1 effect*):ab,ti	268,067
#13	overdiagnosis:ab,ti OR 'over diagnosis':ab,ti	3,449
#14	'patient safety'/exp	68,643
#15	'risk assessment'/de	369,811
#16	'risk benefit analysis'/exp	43,498
#17	#7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16	3,954,884
#18	'congenital hypothyroidism'/de	5,559
#19	hypothyroid*:ab,ti	38,590
#20	thyroid*:ab,ti	194,474
#21	cht:ab,ti OR cretin*:ab,ti OR thyroxine:ab,ti OR tsh:ab,ti OR t4:ab,ti	89,562
#22	#18 OR #19 OR #20 OR #22	258,971
#23	#6 AND #22	2,427
#24	#17 AND #23	469
#25	#17 AND #23 AND [2006-2016]/py	285

Cochrane Library search strategy

#1	MeSH descriptor: [Congenital Hypothyroidism] this term only	43
#2	hypothyroid*:ti,ab	731
#3	thyroid*:ti,ab	3745
#4	(cht or cretin* or thyroxine or tsh or t4):ti,ab	3632
#5	#1 or #2 or #3 or #4	6287
#6	MeSH descriptor: [Neonatal Screening] this term only	287
#7	((neonat* or newborn*) near/5 screen*):ti,ab	446
#8	MeSH descriptor: [Mass Screening] this term only	4625
#9	MeSH descriptor: [Infant, Newborn] explode all trees	14298
#10	#8 and #9	123
#11	#6 or #7 or #10	628
#12	#5 and #11 Publication Year from 2006 to 2016	16

Search results

Databases searched	Dates searched	Number of hits
Medline and Embase (Embase.com)	2006-10/02/2016	285
Cochrane Database Syst Rev (Cochrane Library)	2006-11/02/2016	2
CENTRAL (Cochrane Library)	2006-11/02/2016	12
NHS EED (Cochrane Library)	2006-11/02/2016	2
HTA (Cochrane Library)	2006-11/02/2016	0
Total number of hits		**301**
Total number after de-duplication		**296**
Total number after first appraisal		**43**

7. References

Included after second pass sift (n=1)

1. Brosco, J. P., M. I. Seider and A. C. Dunn (2006). "Universal newborn screening and adverse medical outcomes: A historical note." Mental Retardation and Developmental Disabilities Research Reviews 12(4): 262-269.

Included after first pass sift (n=43)

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Full search results (n=296)

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