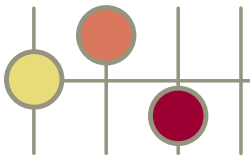

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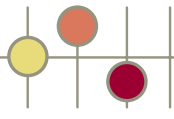
Systematic Review of the Clinical and Cost Effectiveness of Ultrasound in Screening for Developmental Dysplasia of the Hip in Newborns



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REPORT 28

SYSTEMATIC REVIEW OF THE CLINICAL AND COST EFFECTIVENESS OF ULTRASOUND IN SCREENING FOR DEVELOPMENTAL DYSPLASIA OF THE HIP IN NEWBORNS

Dr Nerys Woolacott*
Dr Milo A Puhan**
Ms Kate Misso*
Prof Johann Steurer**
Prof Jos Kleijnen*

***Centre for Reviews and Dissemination**
University of York
York
YO10 5DD

****Horten-Zentrum Fur praxisorientierte Forschung und Wissenstransfer**
Universitaetsspital
Zurich, Switzerland

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LIST OF ABBREVIATIONS

BSV	Bundesamt fur Sozialversicherung
CI	Confidence intervals
CRD	Centre for Reviews and Dissemination, University of York, York, UK
DDH	Developmental dysplasia of the hip
DOR	Diagnostic odds ratio
MHz	Megahertz
NHS EED	National Health Service, Economic Evaluations Database, Centre for Reviews and Dissemination, University of York, York, UK
NOK	Norwegian Krona
NPV	Negative predictive value
PPV	Positive predictive value
RCT	Randomised controlled trial
ROC	Receiver operating characteristics
sROC	Summary of receiver operating characteristics

SUMMARY

Objective

The objective of this research was to evaluate the effectiveness, clinical impact and cost-effectiveness of ultrasound in screening of newborns for developmental dysplasia of the hip (DDH).

Methods

This systematic review of the evidence on the effectiveness and cost-effectiveness of ultrasound screening of newborns for detecting DDH addressed the following questions:

1. What is the diagnostic accuracy of ultrasound in screening of newborns for DDH?
2. What is the impact of ultrasound in screening of newborns for DDH on the therapeutic decisions and on patient outcomes?
3. What is the cost-effectiveness of ultrasound in screening of newborns for DDH?
4. What is the evidence relating to questions 1,2 and 3 for ultrasound screening of newborns with the method of Graf?

The review was based on the best available clinical and economic studies.

The literature search involved a wide range of medical, economic and grey literature databases. The searches to retrieve literature published from 1975 to March 2004, were not limited by study design, or language. Further studies were identified by examining the reference lists of all included articles. In addition some literature was provided by BSV and by individuals.

Using the inclusion and exclusion criteria two reviewers independently assessed the titles and abstracts for relevance and recorded their decision to order or reject. They then appraised each full manuscript received and made a decision whether to include or exclude each study.

For the evaluation of the diagnostic accuracy of ultrasound in screening for DDH in newborns, all studies that had compared ultrasound, using any method, versus any reference standard (gold standard), and that allowed the generation of 2 x 2 tables, were eligible for inclusion in the review. A reference standard had to be a measure of true disease, i.e. clinically relevant DDH. In addition, all comparative studies of newborns that had evaluated the impact of ultrasound in screening for DDH on the therapeutic decisions and on patient outcomes were included in the review. The comparison could be either with another group using a different screening method or the same population prior to the introduction of the ultrasound screening. For the evaluation of the cost-effectiveness of ultrasound in screening of newborns for DDH, all studies that provided a synthesis of cost and effectiveness data of ultrasound screening for DDH in accordance with the criteria specified for the NHS EED database were eligible for inclusion in the review.

The main outcome measure of effectiveness for studies comparing an ultrasound technique with a reference standard technique for the diagnosis of DDH were to be rates of true disease, true non-disease, false disease and false non-disease (accuracy data).

For studies that had evaluated the impact of ultrasound screening on therapeutic decisions and/or patient outcomes, and for those that had evaluated the method of Graf in the screening of newborns, the outcomes were to include overall treatment rates, rates of operative intervention, rates of abduction splinting, rate of delayed diagnosis, time to treatment, duration of treatment, rate of treatment complications, false diagnostic labelling and any long-term functional outcomes e.g. osteoarthritis.

For economic evaluations, the outcomes reviewed were cost-effectiveness and related assessments.

Specifically the following types of studies were excluded.

- Studies in which the population was a selected one, for example, one that only included infants with clinical signs of DDH or with risk factors for DDH.

- Technical reports describing the technique of ultrasound screening, but containing no clinically relevant outcomes.

In addition, descriptions of clinical experience were excluded from the main analysis. Typically such papers would describe a large screening program with no comparator group, where all cases identified as having ultrasound DDH were treated, where no information was obtained on the natural course of the disease or the incidence of true, clinically relevant DDH.

Data from all included studies were extracted and each study was assessed for quality. The data were combined in a narrative synthesis.

The completed report was posted on the CRD website in September 2002 and comments were invited. The comments received were incorporated into the final version of the report. This did not result in any major changes.

Results

The search strategy generated 787 references. A total of 195 papers were of potential interest and of these 188 were obtained and appraised for inclusion in the review. A total of 63 references describing 62 studies were included in the review. These comprised 11 papers: one study of diagnostic accuracy, 10 studies on the impact of ultrasound in screening for newborns for DDH, four economic evaluations and 47 descriptions of clinical experience.

The one study of diagnostic accuracy was a prospective cohort study conducted in the Eastern Netherlands between 1 September 1998 and 30 November 1999. The ultrasound screening programme involved ultrasound imaging at the age of one, two and three months, with a reference test performed at eight months. Only children with sustained physical abnormality were referred for further diagnostic work-up and, where necessary, treatment. This study was flawed due to the choice of reference standard. In addition to those children who had an abnormal result at the reference test at eight months, infants were diagnosed with DDH if they were deemed to require treatment at any stage in the screening process. Thus, an unknown number of children treated during the screening program may in fact have been instances of overtreatment, and the sensitivity was likely to have been overestimated. The results from this study generated the following values: the sensitivity of ultrasound was 88.5%; the specificity was 96.7%; the positive likelihood ratio was 29.1; the negative likelihood ratio was 0.12; the positive predictive value (PPV) was 61.6%; the negative predictive value (NPV) was 99.4%; and the diagnostic odds ratio was 245.8.

The studies that evaluated the impact of ultrasound in screening newborn infants for DDH on the therapeutic decisions and on patient outcomes were of poor overall quality. Only two were randomised controlled trials (RCT) of limited quality, the others were mostly retrospective observational studies with historical controls.

The populations included in the studies came from seven countries (Austria, Jordan, Norway, Poland, the UK, the Netherlands and Croatia) all from various periods between 1980 and 2001. The findings from one RCT indicated that general ultrasound screening of newborns at birth for DDH appears to result in the overtreatment at a rate of around 16 infants per 1000 screened. This result was reflected in the findings of observational studies. General ultrasound screening of newborns at birth for DDH reduced the number of cases of DDH late detected by 1 to 2 per 1000 when this was defined as diagnosed after one month of age but not when defined as after eight months of age. Both RCTs found that general ultrasound screening was not statistically significantly better at reducing the number of cases of DDH diagnosed after one month of age than was selective ultrasound screening (in which only those infants with known risk factors for DDH are examined with ultrasound). General ultrasound screening of newborns at birth or one month resulted in 1 to 2 fewer cases per 1000 requiring treatment with open or closed reduction or other in-patient treatment. The need for an operative intervention may be recognised earlier with ultrasound, rather than clinical screening (reduced from 12 months to 7 months in one study) and ultrasound screening may be associated with a shorter treatment duration (1.74 months in one study).

Only one comparative study of Graf's methodology conducted in the context of general newborn screening for DDH was identified. The findings did not indicate any meaningful difference between the utility of the two imaging techniques studied.

The available economic evaluations are limited by the quality of the clinical data available. Overall the cost of ultrasound screening of newborns for DDH may be comparable with that of other screening programmes.

Conclusions

- Ultrasound imaging performed initially at age one month appears to be a sensitive diagnostic screening test. However, better quality diagnostic accuracy studies are required
- General screening of newborns at birth or at one month of age for DDH using ultrasound rather than clinical examination appears to increase overall treatment rates and may be associated with overtreatment.
- General ultrasound screening of newborns may reduce the severity and invasiveness of the treatments required for DDH.
- There is no evidence that ultrasound screening reduces the number of clinically relevant cases of DDH diagnosed late.
- Limited evidence indicates that general ultrasound screening of newborns offers little, if any increased benefit over selective use of ultrasound imaging.
- There are no reliable data relating to the possible adverse consequences associated with general ultrasound screening of newborns for DDH or any associated treatments. Further research is required.
- Few economic evaluation data are available and these are of limited value due to the quality of the clinical data upon which they are based. Overall the cost of ultrasound screening of newborns for DDH may be comparable to or better than that of other screening programmes
- There is a lack of evidence. Studies that address the questions relating to the true course of DDH, the effects of treatment, and the accuracy of ultrasound screening are required.

Implications for practice

The decision on whether or not to implement ultrasound in the general screening of newborns for DDH has to be based on many factors: needs, resources, costs, preferences and evidence of effectiveness and safety. This review highlights the lack of clear evidence in terms of the effectiveness, and to a lesser extent the safety of ultrasound in the general screening of newborns for DDH. However, this reflects a lack of evidence *per se* rather than any evidence that ultrasound screening is not effective or safe. Thus any decision at the present time will depend on weighting the preferences, needs, costs and lack of evidence.

Implications for research

Clearly, good quality research is required in this field. Suggestions for an 'ideal study' and for a re-evaluation of existing screening programmes are described in the review.

1. BACKGROUND

1.1 Objective

The objective of this research was to evaluate the effectiveness, clinical impact and cost-effectiveness of ultrasound in screening of newborns for developmental dysplasia of the hip (DDH).

1.2 Description of disease and current position regarding identification and treatment

Developmental dysplasia of the hip (DDH) is an all encompassing term for the entire spectrum of hip abnormalities due to an abnormal relationship between the head of the femur and the acetabulum in infants. The term includes dislocation (when the femoral head is completely outside the acetabulum but contained within the elongated joint capsule), subluxation (when the femoral head is sitting on the edge of the acetabulum and is prone to dislocation if left untreated), hip joint laxity (when there is an abnormal increase in the mobility of the hip joint as a result of a stretched capsule, muscles and /or ligaments), plus a whole array of abnormalities that express inadequate acetabular development.[1]

The natural history and long term sequelae of DDH are still a matter of some debate.[2] If established dislocation is left untreated, hip or low back pain, knee pain and deformity may develop. Without treatment, it is uncertain how many dysplastic, unstable hips will retain their dysplastic features throughout life.[3] The age of symptom onset and roentgenographic degenerative joint disease is related to the amount of subluxation and dysplasia.[3] Hip dysplasia is also considered to be a common cause of osteoarthritis and may be aetiological in a substantial proportion of total hip replacements.[4]

The benefits of screening for DDH are a topic for debate.[5] Historically DDH has been identified by clinical examination and follow-up in those with known risk factors (family history of DDH, breech birth, female gender) with diagnostic confirmation using radiography, typically at around four months of age. The introduction of screening of newborn babies by clinical examination using Ortolani and Barlow manoeuvres did not eliminate the incidence of late presenting DDH. A surveillance study conducted between April 1993 and April 1994 found that the ascertainment-adjusted incidence of a first operative procedure for DDH in the UK was 0.78 per 1000 live births (95% CI 0.72, 0.84). Interestingly, of the 318 children referred to the national orthopaedic surveillance scheme, 222 (70%) had not been detected by routine screening. Similarly, a survey in Germany of infants and young children receiving inpatient treatment for DDH found that 51.2% of them had completed a general ultrasound screening program before the age of six weeks[6] Furthermore, screening has been associated with an increase in adverse consequences associated with treatment.[5, 7-9]

Ultrasound imaging has been proposed and developed by, in particular, Graf[10] and Harcke[11] (see Appendix 8). The use of ultrasound imaging for the diagnosis of DDH, in screening for DDH, in monitoring of the development of DDH and in the monitoring of treatment of DDH have been extensively studied and reviewed (for example[1,2,4,5,8,12-28]). It has been demonstrated that ultrasound imaging may be a useful diagnostic test for DDH with sensitivities of 96% and 98% reported and specificities of 88% and 95%.[29,30] However, there is still much debate regarding the appropriateness of this technique in the general screening of all newborn infants.

Although the various studies cited by Harcke[19] demonstrate the accuracy of ultrasound imaging in detecting what has been named ‘ultrasound DDH,’ there is some debate over the relationship between this and clinically relevant DDH or ‘true disease’. Ultrasound imaging at, or shortly after, birth identifies a high number of immature and abnormal hips, most of which are ‘false positives’; if left untreated they would develop normally. For example in a series of 144 hips found to be abnormal on ultrasound imaging, but which were not treated, follow-up up at around eight months found that only six hips were definitely or mildly dysplastic.[31]

There appear to have been three approaches to improving the identification of cases of DDH. One has been to improve the sensitivity of the screening procedure in newborns by using ultrasound in general newborn screening and follow-up.[32] The second has been the use of general screening, but not until the age of four to six weeks of age.[1] The third has been the use of ultrasound as a diagnostic test (often referred to as 'selective screening') in those patients at highest risk, that is, only those with clinically identified signs of DDH or with known risk factors for DDH.[33, 34]

In the approach to screening there is a gulf between those who believe that DDH detected on ultrasound should be treated very early or should be followed-up intensively, on the assumption that untreated cases will have an adverse outcome,[35] and those who believe that the risk of overtreatment is significant.

In Switzerland, in 1996, ultrasound screening as described by Graf[10,36,37] was introduced temporarily and was covered by health insurance until 31st December 2001. This was later extended to 31st December 2002. In that time period further evaluations were to be commissioned to provide evidence on the effectiveness, efficiency and cost-effectiveness of the procedure. Ultrasound performed by methods other than the one described by Graf have not been covered under this temporary arrangement.

This systematic review addresses the question "What is the evidence for the use of ultrasound in screening the general population of newborns for DDH".

1.3 Importance of evidence for the effectiveness of a screening program

Screening is the application of a diagnostic test to asymptomatic people for the purpose of dividing them into two groups: those with a higher probability and those with a lower probability of developing a disease.[38] The consequence of screening should be to treat those who can benefit from an early intervention.[39] The ideal characteristics in terms of disease, test and intervention to be incorporated into a screening program are presented in Table 1.

Table 1 Ideal characteristics of disease, test or intervention

	Ideal characteristics of disease, test or intervention
Disease:	There is an asymptomatic phase where the disease is undiagnosed but detectable
	The natural history of the disease must be known as being associated with a significant burden for the individual patient as well as for the society.
	The prevalence of the disease is known as being high.
Test:	People tested positively develop the disease without an early intervention. That means that the positive predictive value is high.
	The screening must not miss subjects who are at risk of developing the disease.
	All subjects who are at risk of developing the disease are reached by the screening system
Intervention:	There is access to early treatment as a result of screening
	Early treatment has to be more effective than late treatment. I.e., early treatment must be associated with a reduction of the expected disability when compared to late treatment.
	Early treatment must be associated with less adverse effects than late treatment.

Early stage DDH appears to conform with some of these characteristics. There is an asymptomatic phase where DDH is undiagnosed but detectable. There is, as mentioned above, a controversy about how long this phase lasts since there are several definitions of DDH. The natural history of DDH up to absolute end points like osteoarthritis is not known;[3] thus the prevalence of clinically meaningful DDH can only be estimated.[40]

In addition a screening program is only justified if it does more good than harm to the population.[38] Therefore, benefit and harm of a screening program, including the possible harm of the test itself as well as the treatment must be assessed. The potential adverse effects for all those tested including 'false positives' and 'false negatives' must be weighed very carefully against the predicted benefits of the program. Screening itself can have a

negative effect by inducing patient or carer anxiety resulting from disease labelling and potential delay of treatment with adverse consequences in those tested negative. Treatment, initiated as a result of the screening test, can do harm in two ways: direct adverse effects and iatrogenic effects in those falsely tested positive. There must be an effective and harmless intervention so that the disadvantages resulting from disease labelling are outweighed.

To assess the effectiveness of screening, the accuracy of the screening test must be considered: if the accuracy of the screening test is not known, there is no scientific basis for a screening program.

Accuracy studies done in symptomatic patients are studies of diagnostic tests and those results cannot be used to estimate the accuracy of screening tests. Even excellent diagnostic tests have low positive predictive values when the prevalence is low. This results in many false positive results.[41] Thus it is essential that the accuracy of the screening test is assessed in the screening population.

To assess the effectiveness of screening, a randomised controlled trial (RCT) with an intention-to-treat-analysis is the only study design that can adequately evaluate the effectiveness by minimizing possible biases.[38] Controlled trials without randomisation are at risk of selection bias which can lead to an inaccurate estimation of the effectiveness. Another, methodologically even weaker, study design represents the comparison between cohorts that were assessed at different time periods. In addition to selection bias, differences between the two cohorts can arise from changing prevalences of the disease, from changing characteristics of the screened people, from changing attitudes towards health care and different uses of the screening test. If there are reliable data from randomised controlled trials about the effectiveness of a screening program, economic analyses can be built on.

To assess the overall effectiveness of ultrasound screening for the detection of hip dysplasia of the newborns in a systematic review, all studies about the accuracy of the screening test and all studies that compare screened with unscreened newborns should be included. If non-randomised trials are included, the conclusions have to be drawn cautiously because of the associated methodological flaws associated with such studies.

2. METHODS

The current project provides a systematic review of the evidence on the effectiveness and cost-effectiveness of ultrasound screening of newborns for detecting DDH. It addressed the following questions:

1. What is the diagnostic accuracy of ultrasound in screening of newborns for DDH?
2. What is the impact of ultrasound in screening of newborns for DDH on the therapeutic decisions and on patient outcomes?
3. What is the cost-effectiveness of ultrasound in screening of newborns for DDH?
4. What is the evidence relating to questions 1,2 and 3 for ultrasound screening of newborns with the method of Graf?

The review was based on the best available clinical and economic studies.

2.1 Literature searching

2.1.1 Preliminary literature search

An initial search was undertaken to estimate the potential size of the literature on this topic. The following databases were searched:

- Database of Abstracts of Reviews of Effectiveness (DARE), as part of the Cochrane Library Issue 1:2002
- Cochrane Library Issue 1:2002
- Medline (1999-2002/01)
- Embase (1999-2002/01)
- National Guidelines Clearinghouse (searched 24.4.02)
- ATTRACT (searched 24.4.02)

The preliminary Medline strategy is listed in Appendix 1.

2.1.2 Main literature search

The literature search was undertaken to locate studies of the use of ultrasound for the detection of DDH. This level of searching involved searching a range of medical, economic and grey literature databases. The searches were not limited by study design, but were limited to retrieve literature published from 1975 onwards.

The following databases were searched:

- Medline (1975-2004/03 week2) (Silverplatter)
- Embase (1980-2004/03) (Silverplatter)
- Biosis (1975-2004/03) (EDINA)
- Science Citation Index (1981-2004/03) (Web of Science)
- Latin American and Caribbean Health Sciences (LILACS) (internet)
- System for Information of Grey Literature in Europe (SIGLE) (1980-2004/03) (Silverplatter)
- Health Technology Assessment database (HTA) (1975-2004/03) (internal CRD interface)
- Database of Abstracts of Reviews of Effectiveness (DARE) (1975-2004/03) (internal CRD interface)
- NHS Economic Evaluation Database (NHS EED) (1975-2004/03) (internal CRD interface)
- Health Economic Evaluation Database (HEED) (1975-2004/03) (cd-rom)
- Cochrane Controlled Trials Register (CCTR) (1975-2004) on the Cochrane Library cd-rom Issue 1:2004.
- National Research Register (NRR) (Issue 1:2004) (cd-rom)
- Econlit (1975-2004/03) (Silverplatter)
- Cinahl (1982-2004/03) (Silverplatter)
- British Nursing Index (BNI) (1994-2004/03) (Silverplatter)
- PASCAL (1973-2004/03) (Dialog)
- Index of Conference Proceedings (1973-2004/03) (Dialog)

- National Technical Information Service (NTIS) (1990-2004/03) (www)
- MetaRegister of Controlled Trials (www)
- GrayLit (www)
- Organising Medical Networked Information (OMNI) (www)
- Google (www)
- Copernic (www)

The strategies are listed in Appendix 2. Where appropriate, website addresses for these resources are listed in Appendix 3.

Terminology
The terms for the search strategies were identified through discussion between an Information Officer and the research team, by scanning the background literature, and by browsing the Medline Thesaurus (MeSH).

German language database searching
Attempts were made by the CRD Information Officer to identify potentially useful German language databases. Staff of the Horten Zentrum assessed these resources to see if they would contribute extra papers to the search. Due to the degree of overlap with other sources, no further searches were undertaken.

Management of references
The titles and abstracts of bibliographic records were downloaded and imported into Endnote bibliographic management software. Duplicate records resulting from the various database searches were removed.

Hand searching
Further studies were identified by examining the reference lists of all included articles. In addition some literature was provided by BSV and by individuals.

2.2 Study/paper selection
Two members of the review team assessed the titles and abstracts independently. Decisions were recorded (order or reject) in the Endnote library. All papers identified by at least one of the reviewers as potentially eligible for inclusion were ordered.

Two reviewers independently appraised each full manuscript received and made a decision whether to include or exclude each study according to the inclusion and exclusion criteria specified below. Each reviewer's decisions were recorded in the Endnote Library. Any disagreements were resolved by consensus with close attention to the inclusion/exclusion criteria. Final decisions on papers were then recorded in the Endnote Library. All studies that did not fulfil all of the criteria were excluded and their bibliographic details listed, with the reason for exclusion. One group of excluded studies were subjected to some minimal data extraction. This group of studies were those that were of ultrasound screening for DDH of an unselected population of newborns, but which did not address a specific research question, being mainly a description of the author's clinical experience. Typically these studies had no comparator group and provided no information on the natural course of the disease.

2.2.1 Inclusion criteria
Interventions
Any ultrasound technique for the screening of DDH in newborns.

Participants
Unselected newborn infants from the general population.

Study design
For the evaluation of the diagnostic accuracy of ultrasound in screening for DDH in newborns, all studies that had compared ultrasound, using any method, versus any reference standard, and that allowed the generation of 2 x 2 tables, were eligible for inclusion in the review. A reference standard had to be a measure of true disease, i.e.

clinically relevant DDH, and therefore must have included some assessment of the infant at one month of age or older. Thus studies had to have reported numbers of infants with true disease and numbers without true disease according to the reference standard, plus the numbers with positive and negative ultrasound findings.

All comparative studies of newborns that had evaluated the impact of ultrasound in screening for DDH on the therapeutic decisions and on patient outcomes were included in the review. The comparison could be either with another group using a different screening method or the same population prior to the introduction of the ultrasound screening.

For the evaluation of the cost-effectiveness of ultrasound in screening of newborns for DDH, all studies that provided a synthesis of cost and effectiveness data of ultrasound screening for DDH in accordance with the criteria specified for the NHS EED database were eligible for inclusion in the review.

For the evaluation of the method of Graf in ultrasound screening for DDH, all studies of screening newborns for DDH in which Graf's protocol was compared with any other protocol (including modified Graf's) were included.

Language
Studies published in any language were considered for inclusion in the review. In practice no papers were excluded on the grounds of language.

Outcome measure
For studies comparing an ultrasound technique with a reference standard technique for the diagnosis of DDH the main outcome measure of effectiveness were to be rates of true disease, true non-disease, false disease and false non-disease (accuracy data).

For studies that had evaluated the impact of ultrasound screening on therapeutic decisions and/or patient outcomes, and for those that had evaluated the method of Graf in the screening of newborns, the outcomes were to include overall treatment rates, rates of operative intervention, rates of abduction splinting, rate of delayed diagnosis, time to treatment, duration of treatment, rate of treatment complications, false diagnostic labelling and any long-term functional outcomes e.g. osteoarthritis.

For economic evaluations, the outcomes reviewed were cost-effectiveness and related assessments.

2.2.2 Exclusion criteria
Specifically the following types of studies were excluded.

- Studies in which the population was a selected one, for example, one that only included infants with clinical signs of DDH or with risk factors for DDH.

- Technical reports describing the technique of ultrasound screening, but containing no clinically relevant outcomes.

In addition descriptions of clinical experience were excluded from the main analysis. Typically such papers would describe a large screening program with no comparator group, where all cases identified as having ultrasound DDH were treated, where no information was obtained on the natural course of the disease or the incidence of true, clinically relevant DDH.

2.3 Data extraction strategy
Data were extracted onto predesigned forms. Data from studies with multiple publications were extracted and reported as a single study. All relevant data were extracted by one reviewer and independently checked for accuracy by a second reviewer.

The following information was extracted for all studies: study details (identifier, aim, study design, duration of follow-up, location, setting), participant details (number of participants,

age, sex and inclusion criteria), and results including adverse effects. In addition data specific to the different study questions were also extracted.

For studies comparing an ultrasound technique with a reference standard for the diagnosis of DDH data were to be extracted on: test details (test evaluated, reference standard, test performance, method of ultrasound examination, person who performed the examination, interrater agreement) and results (data required to construct a 2 x 2 table).

For studies that had evaluated the impact of ultrasound screening on therapeutic decisions and/or patient outcomes data on interventions, the outcomes reported and the results were extracted.

For economic evaluation studies, the data were extracted in accordance with the set of guidelines developed for the NHS EED database. These guidelines were developed in collaboration with a group of leading health economists (see http://agatha.york.ac.uk/welcome.htm).

In addition some minimal data extraction was performed on papers that described the author's clinical experience of ultrasound screening for DDH in an unselected population of newborns. Typically these studies did not address a specific research question, had no comparator group and provided no information on the natural course of the disease. The data extracted were: author and reference, study design, reason for exclusion, population, number diagnosed at screening, number treated, number normal at final follow-up and details of adverse effects.

2.4 Quality assessment strategy

Studies of diagnostic accuracy were quality assessed using the QUADAS Checklist (see Appendix 4).

It was anticipated that studies evaluating the impact of ultrasound screening on therapeutic decisions and/or patient outcomes would vary in study design. Consequently, a new checklist, addressing very general issues of study quality was created by adapting the checklist for cohort studies given in CRD Report 4.[42] The questions included in the checklist were:

- Is there a reproducible description of the screening process?
- Were the groups comparable on all confounding factors?
- If the groups were not comparable, was adequate adjustment for the effects of the confounding factors made?
- Was follow-up long enough for the reported outcomes to occur?
- Is it reported what proportion of the unselected newborn population was screened?
- Is it reported what proportion of the screened population was followed-up?

Quality assessment was carried out by one reviewer and checked by a second. The results of the quality assessment were used for descriptive purposes to provide an evaluation of the overall quality of the included studies.

The quality of economic evaluations has been evaluated in accordance with the set of guidelines developed for the NHS EED database (http://agatha.york.ac.uk/welcome.htm).

2.5 Methods of analysis/synthesis

2.5.1 Diagnostic accuracy studies

For studies comparing an ultrasound technique with a reference standard technique for the diagnosis of DDH the sensitivity, specificity, likelihood ratios (of both positive and negative tests results), positive and negative predictive values (PPV and NPV) and diagnostic odds ratios (DOR) were calculated.

A formal plan for meta-analysis was included in the protocol but was not implemented due to a lack of suitable studies.

2.5.2 Evaluation of impact studies

Studies that evaluated the impact of ultrasound screening on therapeutic decisions and/or patient outcomes have been combined in a narrative synthesis, as have those evaluating the method of Graf. Similarly, economic evaluations have also been combined using a narrative synthesis.

Within each category of study the heterogeneity of the studies was addressed in terms of the screened population (country, year, time from birth, how complete a sample of the selected population was included in the study); the screening procedure (actual technique used, type of equipment, experience of personnel, interrater agreement); and outcomes.

3. RESULTS

The search strategy generated 787 references. A total of 195 papers were of potential interest and of these 188 were obtained and appraised for inclusion in the review. Of the unobtainable references, three were unpublished or even unfinished projects for which no information could be obtained.[43-45]

A list of excluded studies is given in Appendix 8, together with the reason for exclusions. The main reason for excluding studies was that they had not been conducted in a general population of newborn infants.

A total of 63 references describing 62 studies were included in the review. These comprised 11 papers: one study of diagnostic accuracy; 10 studies on the impact of ultrasound in screening for newborns for DDH; four economic evaluations; and 47 descriptions of clinical experience.

3.1 Evaluation of the diagnostic accuracy of ultrasound in screening of newborns for DDH

One study of diagnostic accuracy was found.[46] Details of this study are presented in Appendix 5. Briefly, this was a prospective cohort study conducted in the Netherlands. The population consisted of all children born in the catchment area of two Child Health Care (CHC) centres in Eastern Netherlands between 1 September 1998 and 30 November 1999. The ultrasound screening programme involved ultrasound imaging at the age of one, two and three months, with a reference test performed at eight months. The ultrasound examination was performed using Graf's method and hip findings were recorded according to Graf's classifications. At the one-month examination, decentred hips (type D) only were referred. At the month-two or -three examinations immature (severe type IIa or worse) and abnormal hips (type IIb or worse) were also referred. Referred children were examined under a standardised assessment protocol (identification of risk factors and repeated physical examination (abduction test and Galeazzi test). Only children with sustained physical abnormality were referred for further diagnostic work-up and, where necessary, treatment. The reference standard was defined by either the decision to treat or by an abnormal ultrasound finding at the age of eight months.

3.1.1 Quality assessment

The results of the quality assessment of the diagnostic accuracy study are given in Appendix 4. This study was flawed due to the choice of reference standard. In addition to those children who had an abnormal result at the reference test at eight months, infants were diagnosed with DDH if they were deemed to require treatment at any stage in the screening process. Although the diagnosis and hence decision to treat, was based on both ultrasound and physical examinations, the researchers failed to take into account that early DDH can resolve without treatment. Thus, an unknown number of children treated during the screening program may in fact have been instances of overtreatment.

3.1.2 Findings from the diagnostic accuracy study

The data from the diagnostic accuracy study were used to generate the following 2x2 table.

	DDH+	DDH-	Total
Screen+	239	149	388
Screen -	31	4751	4782
Total	270	4900	5170

The sensitivity of ultrasound was 88.5%; the specificity was 96.7%. The positive likelihood ratio was 29.1; the negative likelihood ratio was 0.12. The positive predictive value (PPV) was 61.6%; the negative predictive value (NPV) was 99.4%. The diagnostic odds ratio was 245.8.

These values indicate that when used in an unselected population of newborn infants, ultrasound imaging performed initially at age one month is a sensitive diagnostic test.

However, the relatively low value for PPV indicates that a significant proportion of those identified as having DDH by ultrasound imaging would in fact develop normally.

It must be remembered, however, that these results were generated using a flawed reference test that may well have accepted cases of overtreatment as 'true' cases of DDH. The higher the rate of overtreatment is, the higher the sensitivity. Unfortunately, although the authors readily acknowledge this, they have not given the number of infants treated at the different stages of the screening programme and so we are unable to estimate more accurately the number of possible overtreatment cases.

This study also compared diagnostic test accuracy between ultrasound screening and clinical screening. The control population was an historical one of 2066 consecutive infants attending CHC clinics in Eastern Netherlands. Screening for DDH comprised a standardised assessment protocol (identification of risk factors and repeated physical examination (abduction test and Galeazzi test), with a reference ultrasound examination at the age of six months. The data for the control population was used to generate the following 2x2 table.

	DDH+	DDH-	Totals
Clinically+	62	335	397
Clinically -	10	1659	1669
Totals	72	1994	2066

The sensitivity of clinical screening was 86.1%; the specificity was 83.2%. The positive likelihood ratio was 5.13; the negative likelihood ratio was 0.17. The PPV was 15.6% and the NPV was 99.4%. The diagnostic odds ratio was 30.7.

When compared with the values for the ultrasound screening, the sensitivity and PPV for clinical screening are much lower.

3.2 Evaluation of the impact of ultrasound in screening of newborns for DDH on the therapeutic decisions and on patient outcomes

A total of 10 studies that evaluated the impact of ultrasound in screening newborn infants for DDH on the therapeutic decisions and on patient outcomes were identified.[34, 46-54] Details of these studies are summarised in Appendix 5 (data extraction tables).

Of the studies eligible for inclusion in this section of the review, two were conducted in Austria,[49, 50] three in Norway,[34, 47, 53] one in Jordan,[48] one in Poland,[51] one in the UK,[52] one in the Netherlands[46] and one in Croatia.[54] Two of the studies were RCTs[34, 53] whilst the others were either retrospective or prospective non-randomised studies.

3.2.1 Quality assessment

The overall quality of the included studies was poor (Table 2). Of the ten studies included in this section only two were RCTs[34, 53] and unfortunately, these studies were of limited quality. One[34] was found to have an allocation to treatment that was not truly random and there was no concealment of allocation or blinding of outcome assessors to treatment. Thus, baseline comparability was compromised and the risk of bias and confounding was not minimised. In the other RCT[53] there was no report of blinding of assessors to screening group. Not surprisingly the RCTs[34, 53] are rated the best quality on this scale, followed by the Roovers study.[46] The Eggl,[50] Grill[49] and Krolo[54] studies scored very poorly. It should be noted that the quality of the Grill study[49] appears to be particularly limited, with few details reported and the data sets being compared apparently having been derived from separate possibly unrelated data bases, the validity of comparing which is doubtful. Furthermore, it should be noted that whilst both the Eggl study[50] and the Grill study[49] claim to be reporting the experience in the whole of Austria, they report different dates for the introduction of ultrasound screening.

Table 2 Quality of the included studies

Study	Study design	Sufficient description of groups and distribution of prognostic factors?	Is there an adequate description of the screening process?	Were the groups comparable on all confounding factors?	If the groups were not comparable was adequate adjustment for the effects of the confounding factors made?	Was follow-up long enough for the reported outcomes to occur?	Is it reported what proportion of unselected newborn population was screened?	Is it reported what proportion of the screened population was followed-up?
Clegg 1999[52]	Retrospective comparator study	No	Yes	No	No	Yes	No	No
Eggl 1993[50]	Retrospective comparator study	No	No	No	No	Yes	No	No
Grill 1997[49]	Retrospective comparator study	No	No	No	No	Yes	No	No
Holen 2002[53]	Randomised controlled trial	Yes	Yes	Yes	Not applicable	Yes	Yes (98%)	Yes (100%)
Krolo 2003 [54]	Retrospective comparator study with historical control group	No	Yes	No	No	No	No	No
Maj 1989[51]	Retrospective comparator study	No	No	No	No	Yes	??	Yes (66.2%)
Malkawi 1997[48]	Retrospective comparator study	No	Yes	No	No	Yes	Yes (100%)	No
Roovers 2004[46]	Prospective cohort study with historical control group	No	Yes	No	Yes	Yes	Yes (82.6%)	Yes (94.5%)
Rosendahl 1994[34]	Randomised controlled trial	Yes	Yes	No	No	Yes	Yes (97.5%)	Yes (100%)
Tegnander 1994[47]	Retrospective comparator study	No	Yes	No	No	No	No (implies 100%)	No

Only three of the studies[34,46,53] reported an adequate description of the study groups and the distribution of prognostic factors. Because the Roovers study[46] used an historical control group, it is difficult to know how comparable the populations in that study were. Their analysis did incorporate indirect standardisation on the number of first-born children and the number of affected relatives to adjust for imbalances between the groups in these important risk factors. It was difficult, if not impossible, to appraise the comparability of the groups in the other studies. All studies reported the institutions and the time periods where the patients were included, but the databases used in three retrospective studies were not described.[47,49,50] The proportion of female and male infants was stated in only two studies[34,48] and differences between the results of the clinical examination and between the number of breech births are reported only in the RCTs.[34,53]

Seven studies provided a reproducible description of the screening process.[34,46-48,52-54] Details of the ultrasound techniques and the equipment are given in five studies[34,46,48,52,54] and the level of experience of those performing the ultrasound imaging is described in three studies.[34, 46, 52]

The length of follow up in the included studies was reported in six studies.[34,46-48,53,54] and was considered to be long enough in four of these. However it should be noted that although not reported as such, follow-up in the two retrospective Austrian and in the Polish and UK studies did appear to be adequate.

The proportion of the unselected newborn screened was reported in four studies and ranged from 82.6% to 100%.[34,46,48,53] The proportion of the screened population followed up was reported in six studies[34,46-48,51,53] and a good level of detail was reported for the RCTs.[34,53]

3.2.2 Clinical diversity of the included studies

Details of the included studies are presented in Table 3. The populations included in the studies came from seven countries (Austria, the Netherlands, Jordan, Norway, Poland, Croatia and the UK) all from various periods between 1968 and 2001. As dictated by the inclusion criteria for this review, all study populations are unselected newborns. Since the characteristics (except for gender) of the included newborns are not described, other differences between the populations cannot be assessed. In all studies the ultrasound examinations were performed with Graf`s basic technique although in three studies a modified technique after Terjesen[55, 56] was used and in another study[52] a modified technique after Harcke[11] was used. The level of experience of the examiners cannot be compared between the studies because it is described in only two studies.[34, 52]

The outcomes reported vary across the studies. Those for which data are reported in at least one study are: late-diagnosed DDH, incidence of DDH, the rate of therapeutic interventions (although the type of intervention for which the rates were reported varied between studies), duration of treatment, sensitivity, referral rate and surgery related outcomes. None of the included studies reported rate of treatment complications or any long-term functional outcomes such as osteoarthritis.

This clinical diversity limited the extent to which these data could be pooled. Consequently, the findings of the studies are summarised in a narrative, firstly by individual study and then by outcome.

3.2.3 Findings from included studies

The findings of the included studies are summarised by study in Table 4.

Table 3 Characteristics of included studies of ultrasound screening in unselected newborns (1 of 2)

Study	Participants	Screening	Treatment	Possible biases
Holen 2002[53] Norway RCT	16629 newborns at a single centre born between 1988 and 1992	Group US (n= 7840): General clinical plus ultrasound screening (ultrasound technique after Terjesen, third day after birth) Group CS+ (n=7689): General clinical screening, with selective use of ultrasound *.	Frejka pillow if clinical instability and femoral head coverage inadequate.	RCT but unblinded with risk of assessment bias.
Rosendahl 1994[34] Norway Quasi RCT	11925 newborns at a single hospital born between 1988 and 1990.	Group US (n = 3613): General clinical plus ultrasound screening (ultrasound technique after Terjesen, within 24-48 hours of birth) Group CS+ (n = 4388): General clinical screening, with selective use of ultrasound * Group CS (n = 3924): General clinical screening only	Abduction splints used if persistently dislocatable or dislocated or Graf type IIIa or worse on US	RCT but unblinded and method used for randomization not adequate with risk of assessment and selection bias.
Clegg 1990[52] UK Historic control	Newborns (n unclear) in city of Coventry born between 1976 and 1996	Group CS (n unclear): General clinical screening (1976 to 1986) Group CS+ (n unclear): General clinical screening, with selective use of ultrasound * (1986 to 1989, ultrasound technique after Harcke, within first few days after birth) Group CS (n=14050): General clinical plus ultrasound screening (1989 to 1996)	Pavlik harness used if persistent abnormality on US (grade 3 to 5) with or without clinical instability. If inadequate resolution referred for surgery	Insufficient information about populations studied and possible confounding factors and doubts over whether all patient data included.
Eggl 1993[50] Austria Historic control	89200 newborns in Austria born between 1979 and 1989.	Group CS (n= 41500): General clinical screening (1979-1983). Group US introduction (n= 24000): Introduction of general ultrasound screening (included clinical screen) (1984-1986, ultrasound technique after Graf) Group US established (n= 23700): General ultrasound screening within the first few days of life established (1987-1989).	Pavlik harness used for dysplasia and instability. Dislocation treated by closed reduction or open surgery followed by plaster cast.	Insufficient information about populations studied and possible confounding factors and doubts over whether all patient data included.
Grill 1997[49] Austria Historic control	Newborns (n unclear) in Austria born between 1985 and-1994.	Group CS (n unclear): General clinical screening (1985 -1992). Group US (n unclear): General ultrasound screening (included clinical screen) (1992-1994, ultrasound technique after Graf, within first week after birth and at age 12 to 16 weeks).	Conservative or functional therapy used (details not given), followed by reduction if necessary.	Insufficient information about populations studied and doubts over whether all patient data included. Whether populations were comparable is doubtful.
Krolo 2003[54], Croatia Historic control	9168 newborns in Leben born between 1985 and 1994.	Group CS (n=7158): General clinical screening (1985 -1992). Group US (n=2010): General ultrasound screening (included clinical screen) (1992-1994, ultrasound technique after Graf, unclear at what age: possibly at one month).	Method of treatment not reported.	Insufficient information about populations studied and possible confounding factors and doubts over whether all patient data included.

Table 3 Characteristics of included studies of ultrasound screening in unselected newborns (2 of 2)

Study	Participants	Screening	Treatment	Possible biases
Maj 1989[51]* Poland Historic control	1422 newborns at two hospitals born between 1983 and 1987.	Group CS1 (n=352): General clinical screening (1983-1984). Group CS2 (n=355): General clinical screening (1984-1985). Group CS3 (n=333): General clinical screening (1985-1986). Group US (n=382): General ultrasound screening (unclear if included clinical screen) (1986-1987, ultrasound technique after Graf).	Broad diapering, splints or overhead extensions. Other details not reported.	Insufficient information about populations studied and possible confounding factors.
Malkawi 1997[48] Jordan Non-randomised study	1900 newborns at a single hospital born between August 1988 and February 1989. Group 1 n =1823 Group 2 n =1077	Group US (12 hours) (n=1823): General ultrasound screening within 12 hours of birth (unclear if included clinical screen). Group US (3 months) (n=1077): General ultrasound screening when infants were 3 to 4 months old (unclear if included clinical screen). Ultrasound technique after Graf.	Pathological hips treated using Pavlik harness and monitored for progress and avascular necrosis	Insufficient information about populations studied and possible confounding factors.
Tegnander 1994[47] Norway Historic control	27764 newborns at different hospitals in Norway born between 1980 and 1989.	Group CS (University hospital) (n=15950): General clinical screening (1980-1985). Group US (University hospital) (n=5403): General clinical + ultrasound screening (1986-1987, ultrasound technique after Terjesen). Group CS (District hospitals) (n=6411): General clinical screening (1980-1989).	Method of treatment not reported.	Insufficient information about populations studied and possible confounding factors.
Roovers 2004[46] Netherlands Historic control	7236 children newborns in the catchment areas of Child Health Care centres (CHC) born between 1992 and 1999.	Group CS (n=2066): General clinical screening + plus reference ultrasound examination at the age six months (1992-1993). Group US (n=5170): General ultrasound screening (included clinical screen) at the age of one, two and three months and again for reference at eight months. (1998-1999). Ultrasound technique after Graf.	In the control group the main method of treatment was inpatient traction. For the later intervention group the most common treatment was the Pavlik harness, with traction used only in cases where treatment with the Pavlik harness was unsuccessful.	Possible that not all confounding factors accounted for.

* Ultrasound imaging only if DDH was suspected after clinical screening or if infant had known risk factors for DDH (primarily, breach delivery and family history of DDH).

Table 4: Results of included studies

Study	Outcome	Result	
		Per group	**Difference between groups**
Holen 2002[53]	Overall treatment rate	Group US: 72†/7489 (9.6/1000) Group CS+: 66†/ 7689 (8.6/1000)	US vs. CS+: 1/1000 (95% CI -2.0, 4.1)
	Rate of late diagnosed DDH	Group US: 1/7489 (0.13/1000) Group CS+: 5/7689 (0.65/1000)	US vs. CS+: -0.5/1000 (95% CI -1.4, 0.2)
	Adverse Events	Group US: no reports (0/1000) Group CS+: 1/7689 (0.13/1000)	US vs CS+: -0.13/1000**
Rosendahl 1994[34]	Overall treatment rate	Group US: 123/3613 (34.0/1000) Group CS+: 89/4388 (20.3/1000) Group CS: 71/3924 (18.1/1000)	US vs. CS: 15.9/1000 (95% CI 8.8, 23.4) US vs. CS+: 13.8/1000 (95% CI 6.6, 21.2) CS+: vs. CS: 2.2/1000 (95% CI -3.8, 8.1)
	Rate of late diagnosed DDH	Group US: 5/3613 (1.4/1000) Group CS+: 9/4388 (2.1/1000) Group CS: 10/3924 (2.6/1000)	US vs. CS: -1.2/1000 (95% CI -3.4, 1.0) US vs. CS+: -0.7/1000 (95% CI -2.7, 1.4) CS+: vs. CS: -0.5/1000 (95% CI -2.8, 1.7)
Clegg 1990[52]	Mean number of patients treated surgically per year	Group US: 2.5 Group CS+: 5.4 Group CS: 6.5	US vs. CS: -4.0** US vs. CS+: -2.9** CS+ vs. CS: -1.1**
	Mean age at time of first operation	Group US: 6.7 months Group CS+: 14.2 months Group CS: 12.4 months	US vs. CS: -5.7 US vs. CS+: -7.5 CS+ vs. CS: 1.8
Eggl 1993[50]	Surgical treatment rate	Group US established: 18/23700 (0.8/1000) Group US introducing period: 32/24000 (1.3/1000) Group CS: 86/41500 (2.1/1000)	US established vs. CS: -1.3/1000 (95% CI -1.9, -0.7) US introducing vs. CS period: -0.7/1000 (95% CI -1.4, -0.1) US established vs. US introducing period: -0.6/1000 (95% CI -1.2, 0.0)
Grill 1997[49]	Overall treatment rate	US (1994): 70/1000 CS (1985): 130/1000	US vs. CS: -60/1000**
	Surgery (open reduction) rate	US (1994): 0.24/1000 CS (1991) 0.31/1000	US vs. CS: 0.07/1000**
Krolo 2003[54]	Overall treatment rate (based on numbers with DDH – not stated if actually treated)	Group US: 66†/2010 (32.8/1000) Group CS: 122†/7158 (17.0/1000)	US vs. CS: 15.8/1000 (95% CI 8.1, 24.9)
Maj 1989[51]	Overall treatment rate	Group US: 53/382 (138.7/1000) Group CS1: 64/352 (181/1000) Group CS2: 49/355 (138/1000) Group CS3: 43/333 (129.1/1000)	US vs. CS3: 9.6/1000 (95% CI -41.3, 59.4)
	Duration of treatment ± SD (weeks)	Group US: 7.8 ±3.7 Group CS1 11.5 ±4.6 Group CS2: 10.7 ±4.6 Group CS3 11.6 ±6.5	US vs. CS3: -3.8 (95% CI -4.59, 3.01)
Malkawi 1997[48]**	Overall treatment rate	Group US (12 hours): 85/1823 (46.6/1000) Group US (3 months): 14/1077 (13.0/1000)	US (12 hours) vs Group US (3 months): 33.6/1000 (95% CI 21.3, 45.5)
	Average duration of treatment	Group US (12 hours): 1.16 months (range not reported); Group US (3 months): 2.9 months (range 6 weeks to 4 months)	-1.74 months**
	Adverse Events	No cases of avascular necrosis	
Roovers 2004[46]	Referrals for diagnosis	Group US: 393†/5170 (76/1000) Group CS: 379†/2066 (192/1000)	US vs. CS: -116.1/1000 (95% CI -135.0, -98.1)
	Overall treatment rate	Group US: 269†/5170 (52/1000) Group CS: 72†/2066 (35/1000)	US vs. CS: 17.2/1000 (95% CI 6.7, 26.7)
	Late detected DDH	Group US: 31†/5170 (6/1000) Group CS: 17†/2066 (8/1000)	US vs. CS: -2.2/1000 (95% CI –7.5, 1.7)
	Surgical treatment rate (Inpatient treatment)	Group US: 5†/5170 (1/1000) Group CS: 6†/2066 (3/1000)	US vs. CS: -1.9/1000 (95% CI –5.4, 0.1)
Tegnander 1994[47]	Late detected DDH	Group US (university): 4/5403 (0.7/1000) Group CS (university): 42/15950 (2.6/1000) Group CS (district hospital): 34/6411 (5.3/1000)	US vs. CS (university hospitals): -1.9 (95% CI -2.9, -0.5)

(US=Ultrasound screening; CS+=Clinical screening +selective use of ultrasound (see note table 1); CS= Clinical screening only) * Absolute risk difference for proportions, mean difference for means **CI (confidence interval) not calculated due to lack of information on denominator or variance †numerator calculated from percentage reported in primary study

3.2.4 Findings by reported outcome

Treatment rate

The one RCT[34] that made the comparison found that the treatment rate was statistically significantly higher in the general screening ultrasound population than in those who had clinical screening (difference 15.9/1000 (95% CI: 8.8, 23.4). No effect on treatment rate was seen in the Polish study[51] but those results may not be reliable. Krolo et al,[54] did not report treatment rates but found a significant increase in the incidence of DDH under an ultrasound screening programme compared to an earlier clinical screening programme (difference 15.8/1000 (95% CI: 8.1, 24.9). In the Roovers study[46] the referral rate with ultrasound screening initiated at one month of age was 6.9% compared with a rate of 19.2% with clinical screening and the treatment rates were 5.2% and 3.5% respectively (difference 17.2/1000 (95% CI: 6.7, 26.7). Using the authors' value for clinical screening adjusted for confounding factors of 3.8% the difference was still statistically significant (13.8 (95% CI: 3.0, 23.6). The difference between the treatment rates can be taken as a measure of the rate of over treatment associated with ultrasound screening. The figure of 16 infants treated unnecessarily per 1000 screened identified in the RCT is supported by the results of the two observational studies.

In contrast Grill et al[49] reported a fall in treatment rates associated with ultrasound screening, however as discussed in the quality assessment section these results may not be reliable.

In the one study that compared newborn general screening with later screening[48] the rates were lower in the later screened group, with a treatment difference of -33.6 (95% CI: -45.5, -21.3). The two RCTs that had investigated treatment rates with general versus selective screening reported different results; one found a statistically significant higher rate of treatment with general screening[34] but the other did not.[53]

DDH diagnosed late

The findings of the one RCT[34] that made the comparison indicated that the rate of diagnosis after one month of age rather than earlier is lower with general ultrasound screening than with general clinical screening (difference -1.2/1000 (95% CI -3.4, 1.0). This finding is supported by the large retrospective study[47] in which the treatment difference reached statistical significance (difference -1.9 (95% CI -2.9, -0.5). Two RCTs investigated the difference between universal ultrasound screening and selective ultrasound screening on the rate of late-diagnosed DDH. Both studies reported higher rates with selective screening but in neither study was the difference compared with general screening statistically significant (differences -0.5/1000 (95% CI -1.4, 0.2) and -0.7/1000 (95% CI -2.7, 1.4) respectively). While the evidence indicates that newborn screening with ultrasound can reduce the number of cases of DDH diagnosed after one month of age, the clinical validity of this effect appears to be debatable. DDH identified at one month may not be true disease and even with selective screening most cases were identified by six months and all by 11 months.

In the Roovers' study in which screening did not start until one month of age,[46] the definition of late detected DDH was different: late diagnosis was after eight months of age. The number of cases of DDH missed by the two screening programmes (those identified only at the eight month reference test) was 17 (0.8%, 95% CI: 0.6 –1.3) with clinical screening compared to 31 (0.6%, 95% CI: 0.4 – 0.9) with ultrasound screening (difference -2.2/1000 (95% CI –7.5, 1.7).

Surgery related outcomes

The Roovers study reported a lower rate of in-hospital treatment with ultrasound screening (1/1000 compared with 3/1000 with clinical screening), but the difference was not statistically significant (-1.9/1000 (95% CI –5.4, 0.1) and they do not specify the exact nature of the hospital treatment as surgery.[46]

The number of patients requiring open or closed reduction treatment (which represents the most severely affected or cases resistant to conservative treatment) was compared in only one study.[50] The rate of reduction treatment under a well-established ultrasound screening

program was 0.8 per 1000 compared with 2.1 per 1000 under clinical screening, with a significant difference of -1.3/1000 (95% CI -1.9, -0.7). Interestingly, no cases requiring this treatment were reported in the albeit much smaller study of newborn versus 3-4 month old ultrasound screening.[48] The mean number of patients treated surgically per annum, the number of theatre sessions per case and the percentage of procedures requiring hospital admission were all reported in the UK study.[52] All these parameters were lower in the ultrasound screening period than in the clinical screening period, although the results are difficult to interpret with confidence since the size of the earlier population is not reported and no statistical analysis was conducted. However, the results do suggest a fall in the frequency of the most serious and invasive treatment modalities.

The Polish study[51] compared rates of different modalities and found an apparent increase in broad-diapering and decrease in splinting and overhead extensions that had a temporal association with the introduction of ultrasound screening. It is however, possible that this change in treatment practice was not attributable to ultrasound screening.

Only the UK study[52] reported findings for time to operation. The mean age at the time of first operation was 12.4 months, with clinical screening compared to 6.7 months with general ultrasound screening. The data suggest that the need for an operative intervention is recognised earlier with ultrasound, rather than clinical screening. However, that these percentages are based on only a very small number of cases, with only an average of 6.5 operations per year under clinical screening and 2.5 operations per year under general ultrasound screening.

Duration of treatment

Two studies reported effects on treatment duration. The Polish study[51] reported that there was no change in mean treatment duration over three years of clinical examination, but a fall from 11.6 (SD 6.5) months in 1985-86 to 7.8 (SD 3.7) months in 1986-87 after the introduction of ultrasound in May 1986, although the difference was not statistically significant -3.8 (95% CI -4.59, 3.01). The one study that compared newborn ultrasound screening with later (3 to 4 months) ultrasound screening[48] found that ultrasound screening at birth was associated with a shorter mean treatment duration than was later screening (mean of 1.16 months compared to 2.9 months (range 6 weeks to 4 months).

Both studies indicate that ultrasound screening at birth may be associated with a shorter duration of treatment than either later ultrasound screening or clinical screening. Unfortunately, both studies are of very poor quality and therefore such conclusions can only be tentative.

Adverse effects of screening

Only two of the ten studies reported on adverse effects. One RCT of around 15000 infants screened reported one case of avascular necrosis.[53] No information on the incidence of other adverse events was given. Similarly the smaller non-randomised study by Malkawi,[48] reported only that there were no cases of avascular necrosis. Whilst such reports indicate that avascular necrosis occurs only very rarely under any screening programme for DDH, there is a lack of real data.

Overall conclusions to be drawn from these studies

- General screening using ultrasound appears to be a more sensitive test than clinical screening but this needs to be confirmed in better quality studies.
- General screening of newborns at birth or at one month of age for DDH using ultrasound appears to increase overall treatment rates when compared to clinical screening. This may represent an over treatment rate of approximately 16 infants per 1000 screened. Screening initiated later may result in a lower treatment rate.
- General screening of newborns at birth for DDH using ultrasound reduces the number of cases of DDH diagnosed after one month of age. The clinical significance of this is unclear. In the one study where it was tested the number of cases diagnosed after eight months was not higher in a clinical screening programme.
- The rates of cases of DDH diagnosed after one month of age with selective ultrasound screening are higher, but not statistically significantly higher, than those reported with general ultrasound screening.
- General screening of newborns at birth for DDH using ultrasound produces fewer cases requiring treatment with open or closed reduction or in-hospital treatment than earlier screening programs using clinical examination. General screening of newborns at birth for DDH using ultrasound may be associated with a shorter treatment duration and the need for an operative intervention may be recognised earlier than with clinical screening.
- There are no real data relating to the possible adverse consequences associated with general ultrasound screening of newborns for DDH or any associated treatments.

3.3 Evaluation of the impact of ultrasound in screening of newborns for DDH – clinical experience

A total of 47 papers that described clinical experience of the use of ultrasound in screening of newborns for DDH were identified. These papers could not be included in the main analysis. Although they included the population of interest, that is a general unselected population of newborn infants, they failed to provide information on the utility of ultrasound in the screening of newborns. This was primarily because of a lack of any type of comparator with which the results of the screening program could be compared. They therefore failed meet the inclusion criteria for the review. Furthermore all contained one or more of the following flaws:

- A lack of a clear research question.
- Confusing and apparently selective reporting of the data, with little consistency regarding outcomes across studies
- Reporting of treatment inconsistent and unclear (for example, in some papers it appears that 'broad-diapering' is not considered a treatment whereas in others it is
- Often the description follows only those in whom some abnormality was identified at first screening.
- Treatment algorithms varied widely. Some studies treatment initiated immediately, others it is delayed. In all any sense of the natural course of the disease is lost.

The main findings from these studies are summarised below.

The proportion of immature hips identified by ultrasound screening is usually high (mean around 25 – 30%, with huge range reported 0.5% to 88.9%), whilst the proportion of 'abnormal' hips is much lower, with a range of 0.18% to 13.4% (mean around 4%). Treatment rates quoted vary widely with rates from 0.25% to 9.5% of the whole screened population being reported. It is not always clear what is included as treatment. Higher treatment rates usually appear to include techniques such as broad-diapering, whilst lower rates refer mainly to more invasive interventions. There is only one report of operations being used as a treatment option: this was in a UK centre, although there is some discrepancy between the two reports of the same data.[52, 57]

Two important measure of the success or failure of a screening program for DDH are the proportion of normal hips at the end of follow-up and the number of late cases identified. These outcomes were not well reported in the descriptions of clinical experience. Of the 47

papers, only 15 reported the 'success rates' by the end of their 'follow-up' Almost all of these 15 reported that 100% were normal though the follow-up periods varied from three months to one year. Four papers reported a less than 100% success rate.[57-60] The papers by Falliner 1999[58] reported that all patients were normal after treatment at age three weeks but this was followed by some deterioration. This is perhaps not surprising given the extreme brevity of the follow-up period reported in that paper. Marks et al. 1994[57] reported that following screening and treatment with Pavlik harness three individuals had not responded and required more aggressive forms of treatment. Similarly Riboni et al.[59] reported one unresolved case at one year: this was the single late diagnosed case. Finally Tegander et al.[60] reported that in their series, in which no patient was treated before the age of 4 or 5 months, irrespective of earlier findings, no abnormal radiograph was seen at age 6 or 7 years. However, 12/93 individuals did have a less than normal range of movement.

Generally these papers did not report how many late cases were identified. Four papers stated there had been none,[61-63] One paper reported that 1.6% of all hips (including the hips from the group with infants referred for a diagnostic ultrasound examination) changed from IIa [64] Another very important outcome is the incidence and severity of any adverse effects of screening or treatment. This was hardly reported at all: only four papers actually mentioned complications, one [65] reported there were no complications and the other three stated they had had no cases of avascular necrosis.[64, 66, 67]

Summary of findings from descriptions of clinical experience

1. Ultrasound screening at birth identifies a high number of immature (Graf Type IIa) hips: around 25-30%
2. The number of abnormal hips (Graf Type IIc or worse) is much smaller, around 4%
3. Treatment rates vary greatly depending upon the algorithm adopted
4. Treatment does not appear to be harmful
5. There is little evidence that lack of treatment is harmful

3.4 Cost-effectiveness of ultrasound in screening of newborns for DDH

A total of four economic evaluations were identified for inclusion in the review.[52, 68-70] The structured abstracts of each economic evaluation prepared in accordance with the guidelines developed for the NHS EED database are presented in Appendix 7. The evaluations are based on screening programmes in the UK,[52], the Netherlands[70] and Norway.[68, 69]

UK-based economic evaluation

The UK study[52] was based on a series of screening programmes that included all children born in Coventry between 1976 and 1996. Three time periods were compared:

- 1976 and 1986, when a routine programme of clinical screening for DDH was followed (Group A);
- 1986 and May 1989, when ultrasound plus clinical examination for all infants with risk factors for or clinical signs of DDH (Group B);
- June 1989 and 1996, when routine ultrasound screening in addition to the statutory clinical examination was used (Group C).

Overall there were 65 patients with DDH in Group A, 19 patients in Group B and 19 patients in Group C. The mean number of patients treated surgically per year declined from 6.5 (Group A) to 5.4 (Group B) and 2.5 (Group C). The number of theatre sessions per case fell from 2.8 (Group A) to 2.1 (Group B) and then 1.8 (Group C). The percentage of procedures requiring hospital admission was 47% in Group A, 61% in Group B and 9% in Group C, with only two major procedures performed in the 7.5 years from June 1989 to December 1996.

The main costs considered in this evaluation were direct hospital costs, namely: cost of hospital admission (including fixed costs), surgical implant (Coventry screw and plate), radiological services and contrast material, blood, cost of non-operative treatment using Pavlick harness. The cost of ultrasonographers and equipment for one screening session in the outpatient clinic was also considered. Procedures were assessed in terms of units of

operating theatre time, consumables such as implants and blood. Quantities and costs were analysed separately. Costs were not discounted as they were incurred in a short period of time.

The final overall cost for Group A was £22,188 per year, for Group B it was £21,837 and for Group C, £26,564. The average annual cost of treatment in Group A was £5,110, for Group B it was £3,811, and for Group C, £468 per 1000 live births.

The authors did not provide a summary measure of benefit. As such, the study may be regarded as a cost consequences analysis and the health benefits equate to the health outcomes reported above. Consequently a synthesis of costs and benefits is not applicable due to the cost-consequences approach adopted.

The authors concluded that when the cost of running the screening programme is added to the expense of treating DDH, the overall cost for the management of DDH is comparable for the different screening policies.

Norway-based economic evaluations

Both economic evaluations from Norway[68,69] were prepared by the same research group and drew upon clinical effectiveness data from related sources.

Rosendahl study

The aim of one study [69] was to assess the cost-effectiveness of ultrasound screening using general or selective screening strategies with ultrasound versus routine clinical screening strategy in the diagnosis and treatment of DDH. Routine clinical screening alone was regarded as the comparator.

Effectiveness data were taken from Rosendahl 1994.[34] In a comparison with infants undergoing clinical screening alone, the addition of an ultrasound examination for all infants resulted in a treatment rate of 3.4% compared to 1.8% of early DDH cases. Using ultrasound imaging on high-risk newborns only produced a treatment rate of 2%. The rate of late-diagnosed DDH (late defined as after one month of age) for general ultrasound screening, selective ultrasound screening and for clinical screening alone were 0.3, 0.7 and 1.3 per 1000 respectively. The effectiveness measure used in the economic analysis was late-diagnosed DDH.

The (expected) total costs of screening, follow-up, and treatment for general screening with ultrasound were $27.90, for no screening were $29.20, and for selective screening were $29.60 per child. The average cost of a hypothetical programme involving general screening of all girls and selective screening of 12% of boys with a special risk factor for DDH was $20.70 per infant. The discounting rate for the ultrasound equipment was 5%.

Threshold analysis found that the general screening programme had a net economic benefit if average per diem costs for late treatment exceeded $343.50, or the annual number of deliveries exceeded 3500, or the incidence of late cases exceeded 3.6 per 1000 infants.

The author's concluded that application of costs from other centres to this study's data regarding frequency of clinical outcomes may yield different comparative programme costs. If the findings of this clinical study can be generalised to other centres, a strategy of screening all girls and boys with risk factors for DDH may be the most cost-effective approach.

Geitung study

The second evaluation from Norway[68] aimed to evaluate the cost-effectiveness of ultrasound screening compared to that of conventional clinical screening methods (Ortolani's or Barlow's test).

The study was conducted in a hospital setting in Bergen, Norway. The effectiveness data relate to previous studies conducted between 1989 and 1992, including the same study used in Rosendahl's economic evaluation above) and were derived from a combination of a

review of previous literature, the findings of a single study and authors' assumptions. Cost data for the late-treated group relate to 1984-85, and the cost data for ultrasound screening were derived from a study conducted in 1989 and 1990. The price year was 1993.

As in the previous economic evaluation, the effectiveness outcome was number of late-diagnosed DDH (after one month of age). The effectiveness analysis indicated that by introducing an ultrasound screening programme an estimated 2.6 cases of late-discovered DDH per annum would be avoided. The total cost of ultrasound screening was NOK 1,375,438 (315,562 - 1,690,000), the cost avoided for 2.6 fewer cases of late-discovered DDH). The net cost of detecting 2.6 cases of late-detected DDH would be NOK 275 per new-born baby.

The authors concluded that although ultrasound screening would result in fewer cases of late-detected DDH a general screening programme applied to the total population of new-born infants was not cost-effective. However, screening for those identified as being at greater risk (traumatic birth and family history of DDH) may bring additional benefits and be cost-effective. Moreover, if the screening programme adopted only ultrasound testing and the clinical examinations were eliminated the programme would become cost-effective.

Netherlands-based economic evaluation

The Netherlands study[70] was based on the clinical study by Roovers et al. discussed earlier in this report[46] and a related Decision Model Analysis.[71]

This cost-effectiveness study compared three screening strategies for DDH: general ultrasound screening at the age of 3 months; selective ultrasound screening at the age of 3 months, when only infants with recognised risk factors (breech position or a family history of DDH in first- or second-degree relatives) or abnormal results on physical examination of the hip were screened; and clinical screening as undertaken under the current screening policy for DDH in the Netherlands (repeated physical examination of the infant hip and risk factors in the first months of life, performed as part of the CHC programme). Ultrasound screening at three months was selected rather than at one month because of the risk of overtreatment associated with early screening. The authors hypothesised that, although initially more costly, the implementation of general ultrasound screening could lead to substantial cost-savings due to the significantly lower referral rate than the actual screening strategy. The study was conducted from a societal perspective.

The health outcomes assessed from the primary studies were the incidence of DDH in the Netherlands and the probability values for:

- true cases of DDH (3.1% for general ultrasound screening, 2.4 for selective ultrasound screening and 2.8% for CHC screening);
- missed cases of DDH (0.006 for general ultrasound screening, 0.013 for selective ultrasound screening and 0.009 for CHC screening);
- infants treated by the CHC physician (0.33 for general ultrasound screening, 1 for selective ultrasound screening and 1 for CHC screening);
- infants screened by ultrasound (1 for general ultrasound screening and 0.192 for selective ultrasound screening (NA for CHC screening));
- referral for specialist consultation (0.045 for general ultrasound screening, 0.030 for selective ultrasound screening and 0.192 for CHC screening); and
- early treatment given a positive screening result (0.711 for general ultrasound screening, 0.8 for selective ultrasound screening and 0.146 for CHC screening).

The total cost per child screened was Euro 52.1 with selective ultrasound screening, Euro 82 with CHC screening and Euro 70.6 with general ultrasound screening

Average and incremental cost-effectiveness ratios were calculated to combine the costs and benefits of the screening strategies. The average cost per screen detected case of DDH was Euro 2,171 with selective ultrasound screening, Euro 2,929 with CHC screening and Euro 2,278 with general ultrasound screening. CHC screening was dominated by general ultrasound screening, which in turn offered a cost of Euro 2,646 per additional case of DDH detected.

The sensitivity analysis showed that the ranking of the alternative screening strategy did not change when key inputs were varied; the CHC strategy was always dominated by the general ultrasound strategy. The incremental cost-effectiveness ratio of general versus selective ultrasound screening ranged from Euro 2,388 to Euro 4,526. Only when patient costs were excluded (and a health care system perspective was adopted), was the general ultrasound screening strategy the overall dominant cost-effective option, with an average cost-effectiveness ratio of Euro 1,804 per infant detected

The authors did not make extensive comparisons of their findings with those from other studies and the findings of the study may not be widely generalisable given the uniqueness of the CHC programme in the Netherlands. The rate of participation represented a critical variable, with the authors expecting near complete participation if ultrasound screening were included in the actual CHC programme, however this might be difficult to achieve with screening at three months of age in a different setting.

The authors concluded that general ultrasound screening represented a cost-effective strategy for the detection of developmental dysplasia of the hip (DDH) in the Netherlands. It dominated all other alternative screening options if it were assumed that the patients were willing to pay for the additional time required to attend outpatient visits and screening procedures.

Overall summary of economic evaluations

- The available economic evaluations are limited by the quality of the clinical data available.
- The UK study indicates that because treatment costs are so much lower under a programme of general ultrasound screening of newborns, the overall cost of such a programme is comparable with a clinical screening programme.
- The Norwegian studies were flawed by their use of an effectiveness measure that has doubtful clinical validity: diagnosis of DDH after one month of age.
- The Netherlands study demonstrated the cost-effectiveness of general screening at three months of age but only if it were assumed that participation would be near complete and that the patients would be willing to pay for the additional time required to attend outpatient visits and screening procedures. It is unclear how generalisable these findings would be outside the CHC programme in the Netherlands.

3.5 Evaluation of the method of Graf in screening of newborns for DDH

Only one comparative study of Graf's methodology conducted in the context of general newborn screening for DDH was identified.[48] This study has been described earlier in section 4.2 and further details are given in Appendix 5.

This was not a randomised study and it is unclear whether it was prospective or retrospective. Thus, any findings have to be interpreted with caution. The study report failed to include an adequate description of the study groups and the distribution of prognostic factors, making it difficult to appraise the comparability of the groups. The only demographic detail given was the proportion of female and male patients. The description of the screening processes was adequate, with details of the ultrasound techniques and the equipment. The follow-up period was reported but it was unclear whether it was long enough. The proportion of the screened population followed up was reported.

In this study the infants screened at birth were assigned to either simple sonography (as per Graf) (1823 newborns) or stress sonography (sonography as per Graf, but performed at the same time as a clinical manoeuvre) (1511 newborns). The number of abnormal hips requiring treatment for DDH was 85 (4.7%) in the simple sonography group compared to 88

9 (5.8%) in the stress sonography group. All treatment was given by means of the Pavlik harness and was successful as determined at follow-up at one year.

The findings of this non-randomised study do not indicate any meaningful difference between the utility of the two imaging techniques studied.

4. DISCUSSION

4.1 Limitations of the systematic review

We have attempted to produce a comprehensive and unbiased synthesis of all the available diagnostic and controlled studies of screening programmes of an unselected population of newborns using ultrasound imaging. The review is subject to two main limitations: it was based on published reports of studies only and the authors of this review are not experts in ultrasound imaging or hip dysplasia.

4.2 The evaluation of ultrasound in general screening of newborns for DDH

The importance of conducting good quality studies to evaluate the effectiveness of any screening test or program was outlined in the background to this review (section 2.2). As described there, whilst DDH is the early stage of a disease that fits some of the criteria for a disease for which screening is appropriate, questions over the benefits of ultrasound screening of newborns are still unresolved. These questions are at the heart of the continuing debate over the introduction of general newborn screening. The main issue is whether infants identified with DDH by ultrasound in the first days of life will develop clinical disease that will result in some degree of disability if they are left untreated. The natural course of DDH is still largely unknown and different definitions for when treatment is considered necessary persist and have been tested in very few studies.

Even if the disease and the available treatment are appropriate for a screening program there is no scientific basis for a screening program if the accuracy of the screening test is not known. Accuracy studies done in symptomatic patients are studies of diagnostic tests and those results cannot be used to estimate the accuracy of screening tests. The accuracy of the screening programme could not be determined from the vast majority of the available studies because of their selected populations and selective follow-up; a huge number of studies were excluded from this review because they weren't of the general screening population. Where a general population had been studied it was usual for only those infants with some abnormality to be followed-up, with later follow-up only of those treated. Almost no information on the natural course of the disease was available, and it was unclear how many cases of DDH may have been missed by ultrasound. Thus, for all but one study, the number of true and false positives and true and false negatives could not be calculated, making it impossible to generate any 2x2 tables and to estimate the diagnostic accuracy of ultrasound as a screening test.

The one diagnostic accuracy study performed in an unselected population of newborns provided only limited information due to its use of a flawed reference standard that may not adequately express true disease because children were treated early. By testing infants at one, two, three and eight months the study did demonstrate that a screening test performed only at one month or earlier is likely to miss some cases of DDH. The study by Malkawi[48] hinted that an initial screen at 4 months might prevent this happening, but unfortunately the quality of that study was limited and the results may not be reliable.

Studies that investigated the impact of ultrasound screening were also flawed. The primary failure in the vast majority of the studies reported to date was the lack of any real comparator. Even the few comparative studies identified for this review relied almost exclusively on historical controls, rendering the findings unreliable. The one properly randomised study[53] utilised selective ultrasound screening as the control with which general ultrasound screening of newborns was compared, and therefore, provided only limited information on the benefits or otherwise of general screening.

Data from RCTs indicated that ultrasound screening is associated with an increased rate of treatment compared with clinical screening. However, these RCTs investigated screening conducted in the first few days of life. Data from the most recent observational study by Roovers indicate that ultrasound screening commenced at one month of age is also associated with an increased rate of treatment, but achieved with a greatly reduced referral

rate. Interestingly all studies, RCT or observational, using screening at birth or one month, found similar values for overtreatment of around 16 per 1000 infants screened.

The objective of screening for DDH is to prevent it being diagnosed late when treatment is more invasive and can be less successful. The two best designed and reported studies (i.e. the RCTs[34,53]) did report this as an outcome measure, but, unfortunately both had short follow-up periods and defined a late-detected case as one detected after one month of age. As a basis for assessing the relative benefits of screening programmes this endpoint presumes that it is essential to detect and treat as many cases of DDH as possible within the first month of life. However, the clinical validity of this outcome appears to be debatable since DDH identified at one month is often not true disease.[60] When 'late' was defined as at, or after eight months,[46] there was no difference between the proportion of cases that were detected late with clinical screening compared with ultrasound screening.

There are few data on the impact of ultrasound screening programmes on the types of treatment, the duration and success of treatments for DDH. The use of historical controls in many studies means that the effects of ultrasound cannot be differentiated from the effect of changing treatment practice. Also in most of the studies of screening programmes, treatment outcome was not a reported outcome. There is some evidence that early screening for DDH can reduce the requirement for invasive surgery: the Eggl study[50] reported a lower incidence of open or closed reductions of the hip joint associated with the introduction of ultrasound screening, but we do not know if this was achieved without an increase in the number of infants treated unnecessarily. The best data on surgery related outcomes came from a UK based study, suggesting that number and severity of surgical procedures for the correction of hip dysplasia was reduced under a regime of general ultrasound screening. However, these findings are also difficult to interpret with confidence since the size of the earlier population was not reported and no statistical analysis was conducted. The Roovers study is most promising having reported a lower proportion of hospital treated cases within an overall increase in treatment rate.[46] It must be noted however, that the effect seen in all three studies for these very important outcome measure could have been due to a changing fashion in DDH treatment as well as the impact of ultrasound screening.

Our review has also been unable to provide information on the adverse effects of general ultrasound screening: either of the treatment or of the screening programme as a whole. Of the 10 studies we identified, none properly assessed adverse events and only two mentioned them at all.

Our review did not encompass the effectiveness of the various treatments available for DDH. However, it is acknowledged that the evidence base is not strong.[72] Generally abduction therapy (most commonly abduction splinting in the form of the Pavlik harness) is considered to be an effective and benign intervention. However, a systematic review of English language studies reported that observational studies reported that 20 to 100% of infants who had undergone abduction therapy eventually required operative intervention.[8] Recently published surveillance data collected over 5 years in Germany[73] showed that although the incidence of first operative procedures for DDH was low at 0.26 per 1000 live births, 55% of children undergoing a first operative procedure had been detected by the early ultrasound screening program: these children therefore represent a degree of failure of the available conservative treatment.[73] This experience is reflected in that reported in a UK study[72] that found that all children with abnormal hip radiographs at age two years had started treatment before the age of 8 weeks and overall 12% of all children treated with abduction splinting before the age of 8 weeks subsequently required surgery.[72] These data would suggest some publication bias in observational studies of ultrasound screening in which the reported success rates of treatment are much higher.[74] Furthermore, the potential adverse effects of treatment must be considered. Avascular necrosis has been reported in 1 to 4% of all treated infants.[8] Pressure sores, epiphysitis, femoral nerve palsy, inferior dislocation of the hip and medial instability of the knee joint have also been reported[8] and potential psychological problems must be considered.[7, 9]

Our review has confirmed the conclusions reached by the Canadian Task Force[8] and American Academy of Pediatrics[75] that ultrasound screening cannot as yet be recommended. This is due to the lack of evidence. To date we have a huge body of literature which describes the use of ultrasound imaging as a useful and accurate diagnostic tool for DDH, but which fails to provide clear evidence either for or against its use in the general screening of newborn infants. Studies that address the questions relating to the true course of DDH, the effect of treatment, and the accuracy of ultrasound screening are required.

A recently published decision model acknowledges the lack of evidence to support the implementation of universal screening for DDH in newborns.[76] Values of true and false positives were treated with abduction splinting were calculated using prevalence estimates based on historical data and treatment rates derived from observational studies. This decision model predicts that compared to clinical screening or selective use of ultrasound imaging, universal ultrasound screening would achieve the highest number of favourable outcomes and the lowest number of adverse outcomes (occurrence of avascular necrosis). Another decision model[71] considered three different ultrasound screening strategies: general screening at one, two and three months; general screening at one and three months; and selective screening at one month. These were compared with clinical screening at one month (as currently practised in the Netherlands) and found that overall general screening at three months performed best.

To address the still unanswered questions relating to ultrasound screening in newborns for DDH, a good quality accuracy study should be conducted first, taking, as suggested by the American Academy of Pediatrics,[75] a dislocated hip at one year as the reference standard, with avascular necrosis as the primary complication of DDH treatment to be monitored. Importantly, all infants entered into such a study would be followed-up irrespective of the results of screening tests until it was evident that true disease has developed or not. If such a study demonstrated that ultrasound is an appropriate screening test, then the effectiveness of ultrasound screening for DDH could be assessed. The ideal study would be conducted in an unselected population of newborn infants. All infants would be examined using a standardised, reproducible, but generally accepted technique (Graf's methodology). All ultrasound examinations would be conducted within the first days after birth. All infants would also be examined clinically using the Barlow and Ortolani tests. The ultrasound and clinical examinations would be conducted independently, with no transfer of information between their findings. Furthermore both types of examination would be conducted without knowledge of any risk factors for DDH (except for female gender and obvious physical signs of DDH, knowledge of which cannot be avoided).

All newborns would then be randomised (using cluster randomisation) to one of two management protocols:

1. Follow-up and treatment according to Graf's protocol.
2. Follow-up, with repeat ultrasound (at least at months 1, 3 and 12), with treatment instituted only when there was clear evidence of 'true disease': not before three months and preferably not until one year of age. In this management protocol ultrasound imaging would be used as a diagnostic tool to confirm or otherwise a diagnosis of true DDH requiring intervention.

Both management protocols would include a specified follow-up scheme (which could incorporate standard practice). All infants would be followed-up irrespective of results of screening tests.

The outcome measure would include short term ones such as number treated, duration of treatment, age at which treatment initiated (by type of treatment), type of treatment, adverse effects (all). Data on long term outcomes such as functional disability, gait abnormality, osteoarthritis should also be sought, with as long a follow-up as is possible, for example, at age 10, 20 and 30 years or even later. Within this protocol the optimal timing for the initiation of ultrasound screening could be explored.

Clearly the studies available for review fall short of this ideal study. Unfortunately, ideal studies are usually very difficult to do. Primarily there is the issue of perceived ethics and this in turn is closely entwined with belief in the accepted practice. In Austria, for example it would probably be considered unethical to identify a degree of DDH and then delay treatment. In the USA a similar protocol could perhaps not be followed for fear of future litigation should it transpire that an abnormality had been identified but was not treated. In other countries over-treatment might be considered unethical.

One possible study that could be conducted would be a prospective comparison of the clinical experiences of two different screening programs. For example the experience in Switzerland or Austria could be compared with that of the screening program in Northern Ireland as described by Maxwell.[33] Importantly such a comparison should consist of data from databases describing newborn populations with follow-up data available on all of the original cohorts; both those without any abnormal sonographic findings as well as those with abnormal sonographic findings. That such a study would be conducted prospectively rather than retrospectively would ensure the direct comparability of the data collected. Analysis of the data should be for all relevant outcomes and reporting should be open and unambiguous. Such a study would still fall far short of the ideal, with many differences apart from the screening program itself to account for differences in outcomes.

To date we have a huge body of literature which describes the use of ultrasound imaging as a useful diagnostic tool for DDH, but which fails to provide clear evidence either for or against its use in the general screening of newborn infants. How the available evidence fulfils the ideal characteristics for a screening programme is summarised in Table 5. The current status of the evidence base for the general screening of newborn infants for DDH provides us with a good example of how early acceptance of an intervention or technology can inhibit or even preclude good quality research, resulting in long-term if not permanent uncertainty.

Table 5 Ideal characteristics of disease, test or intervention: evidence for ultrasound in screening of newborns for DDH

	Ideal Characteristics of disease, test or intervention	Evidence to support characteristic for DDH?	
		Proponents' interpretation	**Opponents' interpretation**
Disease:	There is an asymptomatic phase where the disease is undiagnosed but detectable	Yes	Yes
	The natural history of the disease must be known as being associated with a significant burden for the individual patient as well as for the society.	Yes	Unknown
	The prevalence of the disease is known as being high.	Yes	Unknown
Test:	People tested positively develop the disease without an early intervention. That means that the positive predictive value is high.	Yes	Unknown
	The screening must not miss subjects who are at risk of developing the disease.	Yes	Unknown
	All subjects who are at risk of developing the disease are reached by the screening system	Yes	Yes
Intervention:	There is access to early treatment as a result of screening	Yes	Yes
	Early treatment has to be more effective than late treatment. I.e., early treatment must be associated with a reduction of the expected disability when compared to late treatment.	Yes	Uncertain
	Early treatment must be associated with less adverse effects than late treatment.	Yes	Uncertain

5. CONCLUSIONS

- Ultrasound imaging performed initially at age one month appears to be a sensitive diagnostic screening test. However, further better quality diagnostic accuracy studies are required.
- General screening of newborns at birth or at one month of age for DDH using ultrasound rather than clinical examination appears to increase overall treatment rates and may be associated with overtreatment.
- General ultrasound screening of newborns may reduce the severity and invasiveness of the treatments required for DDH.
- There is no evidence that ultrasound screening reduces the number of clinically relevant cases of DDH diagnosed late.
- Limited evidence indicates that general ultrasound screening of newborns offers little, if any increased benefit over selective use of ultrasound imaging.
- There are no reliable data relating to the possible adverse consequences associated with general ultrasound screening of newborns for DDH or any associated treatments. Further research is required.
- Few economic evaluation data are available and these are of limited value due to the quality of the clinical data upon which they are based. Overall the cost of ultrasound screening of newborns for DDH may be comparable to or better than that of other screening programmes.
- There is a lack of evidence. Studies that address the questions relating to the true course of DDH, the effects of treatment, and the accuracy of ultrasound screening are required.

5.1 Implications for practice

The decision on whether or not to implement ultrasound in the general screening of newborns for DDH has to be based on many factors: needs, resources, costs, preferences and evidence of effectiveness and safety. This review highlights the lack of clear evidence in terms of the effectiveness, and to a lesser extent the safety of ultrasound in the general screening of newborns for DDH. However, this reflects a lack of evidence per se rather than any evidence that ultrasound screening is not effective or safe. Thus any decision at the present time will depend on weighting the preferences, needs, costs and lack of evidence.

5.2 Implications for research

Clearly, proper research is required in this field. Suggestions for an ‘ideal study’ and for a re-evaluation of existing screening programmes are described in the review.

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APPENDIX 1: PRELIMINARY MEDLINE SEARCH STRATEGY (SILVERPLATTER/WINSPIRS INTERFACE)

1. (ultrasound or ultrasonography) in ti,ab
2. explode “Ultrasonography”/ all subheadings
3. #1 or #2
4. ((dysplasia or dislocated or dislocation) near (hip or hips)) in ti,ab
5. “Hip-Dislocation-Congenital” / all subheadings
6. #4 or #5
7. #3 and #6
8. (newborn* or neonatal or infant or baby or babies or infants) in ti,ab
9. exact{Infant} in AGE
10. exact{Infant-Newborn} in AGE
11. #8 or #9 or #10
12. #7 and #11
13. #12 and (PY> ”1999”)

APPENDIX 2: FINAL SEARCH STRATEGIES

Medline strategy (SilverPlatter/WinSpirs interface)

1. explode "Ultrasonography"/ all subheadings
2. (ultrasound* or ultrasonogra* or ultra-sound* or ultra-sonogra*) in ti,ab
3. (Sonogram* or sonograph* or echograph* or echogram*) in ti,ab
4. #1 or #2 or #3
5. "Hip-Dislocation-Congenital"/ all subheadings
6. ((dysplasi* or dislocat*) near (hip or hips)) in ti,ab
7. ddh in ti,ab
8. cdh in ti,ab
9. #6 or #7 or #8
10. (neonat* or newborn* or neo-nat* or new-born* or infant* or baby or babies) in ti,ab
11. exact{INFANT} in AGE
12. exact{INFANT-NEWBORN} in AGE
13. #10 or #11 or #12
14. #4 and #9 and #13
15. #14 and (PY = 1975-2002)

Embase strategy (SilverPlatter/WinSpirs interface)

1. "ultrasound"/ all subheadings
2. explode "echography"/ all subheadings
3. (ultrasound* or ultrasonogra* or ultra-sound* or ultra-sonogra*) in ti,ab
4. (Sonogram* or sonograph* or echograph* or echogram*) in ti,ab
5. #1 or #2 or #3 or #4
6. "hip-dysplasia"/ all subheadings
7. ((dysplasi* or dislocat*) near (hip or hips)) in ti,ab
8. ddh in ti,ab
9. cdh in ti,ab
10. #7 or #8 or #9
11. explode "infant"/ all subheadings
12. (neonat* or newborn* or neo-nat* or new-born* or infant* or baby or babies) in ti,ab
13. #11 or #12
14. #5 and #10 and #13
15. #14 and (PY = 1975-2002)

Biosis strategy (Edina interface)

ultrasound* or ultrasonogra* or “ultra sound*” or “ultrasonogra*” or Sonogram* or sonograph* or echograph* or echogram*
AND
(dysplasi* n3 hip) or (dislocat* n3 hips) or (dysplasi* n3 hips) or (dislocat* n3 hip) or ddh or cdh
AND
neonat* or newborn* or “neo nat*” or “new born*” or infant* or baby or babies

Science Citation Index (Web of Science interface)

((ultrasound* or ultrasonogra* or ultra-sound* or ultra-sonogra* or sonogram* or sonograph* or echograph* or echogram*) and (((dysplasi* or dislocat*) same (hip or hips)) or ddh or cdh) and (neonat* or newborn* or neo-nat* or new-born* or infant* or baby or babies)) not (animal or animals or dog or dogs or hamster* or mice or mouse or rat or rats or bovine or sheep or guinea or cat or cats or feline)

Cinahl strategy (SilverPlatter/WinSpirs interface)

1. "Ultrasonography"/ all topical subheadings / all age subheadings
2. (ultrasound* or ultrasonogra* or ultra-sound* or ultra-sonogra*) in ti,ab
3. (Sonogram* or sonograph* or echograph* or echogram*) in ti,ab
4. #1 or #2 or #3
5. "Hip-Dislocation-Congenital"/ all topical subheadings / all age subheadings
6. ((dysplasi* or dislocat*) near (hip or hips)) in ti,ab
7. (ddh or cdh) in ti,ab

8. #5 or #6 or #7
9. (neonat* or newborn* or neo-nat* or new-born* or infant* or baby or babies) in ti,ab
10. explode "Infant"/ all topical subheadings / all age subheadings
11. #9 or #10
12. #4 and #8 and #11
13. #12 and (PY >= "1975")

SIGLE, Econlit & British Nursing Index strategy (SilverPlatter/WinSpirs interface)

1. (ultrasound* or ultrasonogra* or ultra-sound* or ultra-sonogra*) in ti,ab
2. (Sonogram* or sonograph* or echograph* or echogram*) in ti,ab
3. ((dysplasi* or dislocat*) near (hip or hips)) in ti,ab
4. ddh in ti,ab
5. cdh in ti,ab
6. (neonat* or newborn* or neo-nat* or new-born* or infant* or baby or babies) in ti,ab
7. #1 or #2
8. #3 or #4 or #5
9. #7 and #8 and #6

Cochrane Controlled Trials Register strategy (Cochrane Library cd-rom interface)

1. ULTRASONOGRAPHY*:ME
2. (((ULTRASOUND* or ULTRASONOGRA*) or ULTRA-SOUND*) or ULTRA-SONOGRA*)
3. (((SONOGRAM* or SONOGRAPH*) or ECHOGRAPH*) or ECHOGRAM*)
4. ((#1 or #2) or #3)
5. HIP-DISLOCATION-CONGENITAL:ME
6. (DYSPLASI* near HIP) or (DYSPLAS* near HIPS)
7. (DDH:TI or CDH:TI) or (DISLOCAT* near HIP) or (DISLOCAT* near HIPS)
8. ((#5 or #6) or #7)
9. ((((((NEONAT* or NEWBORN*) or NEO-NAT*) or NEW-BORN*) or INFANT*) or BABY) or BABIES)
10. INFANT*:ME
11. (#9 or #10)
12. ((#4 and #8) and #11)

National Research Register strategy (cd-rom interface)

1. ULTRASONOGRAPHY*:ME
2. (((ULTRASOUND* or ULTRASONOGRA*) or ULTRA-SOUND*) or ULTRA-SONOGRA*)
3. (((SONOGRAM* or SONOGRAPH*) or ECHOGRAPH*) or ECHOGRAM*)
4. ((#1 or #2) or #3)
5. HIP-DISLOCATION-CONGENITAL:ME
6. (DYSPLASI* near HIP) or (DYSPLAS* near HIPS)
7. (DDH:TI or CDH:TI) or (DISLOCAT* near HIP) or (DISLOCAT* near HIPS)
8. ((#5 or #6) or #7)
9. ((((((NEONAT* or NEWBORN*) or NEO-NAT*) or NEW-BORN*) or INFANT*) or BABY) or BABIES)
10. INFANT*:ME
11. (#9 or #10)
12. ((#4 and #8) and #11)

DARE, NHS EED & HTA strategy (internal CRD Cairs interface)

1. s ultrasound$ or ultrasonogra$ or ultra(w)sound$ or ultra(w)sonogra$
2. s Sonogram$ or sonograph$ or echograph$ or echogram$
3. s (dislocat$)(w4)(hip or hips)
4. s (dysplasi$)(w4)(hip or hips)
5. s ddh/ttl,ab or cdh/ttl,ab
6. s neonat$ or newborn$ or neo(w)nat$ or new(w)born$ or infant$ or baby or babies
7. s s1 or s2
8. s s3 or s4 or s5
9. s s7 and s8 and s6

PASCAL & Index of Conference Proceedings Index (Dialog interface)

1. S Ultrasonography!/de from 155
2. S (ultrasonography or ultrasound)/de from 144,77
3. S (ultrasound? or ultrasonogra? or ultra(w)sound? or ultra(w)sonogra?)/ti,ab
4. S (Sonogram? or sonograph? or echograph? or echogram?)/ti,ab
5. S s1:s4
6. S Hip Dislocation, Congenital/de
7. S congenital hip dislocation/de from 144,77
8. S (dysplasi? or dislocat?)(3n)(hip or hips)/ab,ti
9. S (ddh or cdh)/ti,ab
10. S s6:s9
11. S (neonat? or newborn? or neo(w)nat? or new(w)born? or infant? or baby or babies)/ti,ab
12. S infant/de
13. S infant, newborn/de
14. S s11:s13
15. S s5 and s10 and s14

APPENDIX 3: WEB ADDRESSES OF INTERNET RESOURCES

The types of keywords used for these internet searches include:
Hip and disclocat*
Hip dysplasia
Dislocate hip
Dislocation hip

- Latin American and Caribbean Health Sciences (LILACS)
  http://www.bireme.br/bvs/I/ibd.htm

- Health Technology Assessment database (HTA), Database of Abstracts of Reviews of Effectiveness (DARE) and NHS Economic Evaluation Database (NHS EED)
  http://agatha.york.ac.uk/welcome.htm

- National Research Register (NRR)
  http://www.update-software.com/National/

- National Technical Information Service (NTIS)
  http://www.ntis.gov/

- MetaRegister of Controlled Trials
  http://www.controlled-trials.com/mrct/

- GrayLit
  http://graylit.osti.gov/

- Organising Medical Networked Information (OMNI)
  http://omni.ac.uk/

- Google
  http://www.google.co.uk/

- Copernic
  http://www.copernic.com

APPENDIX 4:CHECKLIST FOR QUALITY ASSESSMENT OF STUDIES OF DIAGNOSTIC ACCURACY

Quality Assessment of diagnostic accuracy study using the QUADAS checklist[77]

Roovers, E.A., et al., Effectiveness of ultrasound screening for developmental dysplasia of the hip, in Doctoral Thesis 'Post-neonatal ultrasound screening for developmental dysplasia of the hip. A study of cost-effectiveness in the Netherlands'. 2004: University of Twente, Enschede, Netherlands. p. 41-53.			
Item	**Description**	**Yes/No**	**Comments/Further information**
1.	Was the spectrum of patients representative of the patients who will receive the test in practice?	Yes	The population was an unselected population as is appropriate for screening.
2.	Were selection criteria clearly described?	Yes	Inclusion criteria were very general, with no detailed criteria for exclusion.
3.	Is the reference standard likely to correctly classify the target condition?	No	Reference test is end of follow-up but as this encompasses decision to treat at any age, it is very possible that some treated infants would have resolved spontaneously and therefore such cases represent over treatment. Thus the sensitivity of the test will be over estimated.
4.	Is the time period between reference standard and index test short enough to be reasonably sure that the target condition did not change between the two tests?	NA	There is a real possibility that the hip dysplasia will spontaneously resolve between the index text and the reference test if the reference test is conducted at 8 months. This is an important aspect of the reference test and is not a flaw. Unfortunately, because some infants were treated early rather than receiving the reference test at 8 months some information was lost.
5.	Did the whole sample or a random selection of the sample, receive verification using a reference standard of diagnosis?	Yes	It should be noted that as the reference standard was treatment or reference test at 8 months not all children were exposed to the same reference standard.
6.	Did patients receive the same reference standard regardless of the index test result?	No	As above.
7.	Was the reference standard independent of the index test (i.e. the index test did not form part of the reference standard)?	No	
8.	Was the execution of the index test described in sufficient detail to permit replication of the test?	Yes	
9.	Was the execution of the reference standard described in sufficient detail to permit its replication?	Yes	Clinical judgement and various assessments involved so not exactly the same for each infant.
10.	Were the index test results interpreted without knowledge of the results of the reference standard?	Yes	
11.	Were the reference standard results interpreted without knowledge of the results of the index test?	No	
12.	Were the same clinical data available when test results were interpreted as would be available when the test is used in practice?	Yes	
13.	Were uninterpretable/ intermediate test results reported?	Partially Yes	All infants followed up until a definite decision made, however, there may have been some uninterpretable results.
14.	Were withdrawals from the study explained?	Yes	

APPENDIX 5: DATA EXTRACTION TABLES (INCLUDED STUDIES)

Author and reference Clegg J, Bache C E, Raut V V. Financial justification for routine ultrasound screening of the neonatal hip. Journal of Bone & Joint Surgery - British Volume 1999;81B(5):852-857 Note data pertaining to Group C also published as Marks DS, Clegg J, al Chalabi AN. Routine ultrasound screening for neonatal hip instability. Can it abolish late-presenting congenital dislocation of the hip? *J Bone Joint Surg Br* 1994;76(4):534-8. some details taken from that publication **Country:** UK **Study design** Retrospective comparative study **Follow-up:** Not stated **Objective** The objective of the study was to analyse the patterns of management of DDH using three different screening policies: clinical examination alone, introduction of ultrasound screening for infants with known risk factors; and routine ultrasound scanning for all infants at birth.	**Inclusion/exclusion criteria** All children born in Coventry between 1976 and 1996 were included in the analysis. Group A, born between 1976 and 1986, when a routine programme of clinical screening for DDH was followed. Group B, born between 1986 and May 1989, ultrasonograhic assessment of the hip in addition to clinical examination for all infants within the 'at-risk' categories and those with clinical abnormality of the hip. Group C, born between June 1989 and 1996, routine ultrasound screening in addition to the statutory clinical examination. **Number of participants** Not stated except for Group C n=14050 **Mean age (range)** Newborns **Males females** Not stated **Other important demographic factors** Not stated **Other differences between groups** None stated	**Screening test** Clinical screening for DDH was followed, comprising examination at birth by a paediatrician, further examination after discharge by a GP and weekly review in the Orthopaedic Baby Clinic for the babies 'at-risk' Ultrasound by experienced radiographers using Aloaka SSD 500 machine with 7.5 MHz transducer. Technique of Harcke et al. 1984[11] used.and grading system of Terjesen et al. 1989[55]. US initially performed within first few days after birth. Ultrasound used in addition to clinical screening. **Treatment and management** Pavlik harness used if persistent abnormality on US (grade 3 to 5) with or without clinical instability. If inadequate resolution referred for surgery. **Main outcome measure** Mean number of patients treated surgically per annum. Number of theatre sessions per case. Percentage of procedures requiring hospital admission Mean age at time of first operation.	**Statistical methods.** Descriptive only **Withdrawals** No details given – retrospective collection of data **Results for main outcomes** The mean number of patients treated surgically per year declined from 6.5 (group A) to 5.4 (group B) and 2.5 (group C). The number of theatre sessions per case fell from 2.8 (group A) to 2.1 (group B) and then 1.8 (group C).	**Results form main outcomes cont.** The percentage of procedures requiring hospital admission was 47% in group A, 61% in group B and 9% in group C, with only two major procedures performed in the 7.5 years from June 1989 to December 1996. The mean age at the time of first operation was 12.4 months, 14.2 months and 6.7 months in groups A, B, and C respectively. **Comments** This comparative study was conducted primarily to provide data for an economic evaluation.

Author and reference	**Participants' inclusion/exclusion criteria**	**Number of participants**	**Statistical methods.**	**Results for main outcomes cont.**
Eggl, H.; Krismer, M.; Klestil, T.; Frischhut, B. Results of ultrasonographic screening. An epidemiological study. *Orthopade* 1993, 22:277-279 **Also published as** Krismer M, Klestil T, Morscher M, Eggl H. The effect of ultrasonographic screening on the incidence of developmental dislocation of the hip. *Int Orthop* 1996;20(2):80-2. Data taken from Eggl et al because more patients and data up to 1989 included. **Country:** Austria **Study design** Retrospective comparative study **Objective** To assess if the introduction of a hip ultrasound screening programme has reduced the incidence of hip dislocation.	**Inclusion criteria** 89200 newborns born in the Austrian federal state of Tyrol from 1979-1989. Three groups were defined: Group 1:1979-1983. No ultrasound screening. Only clinical screening. Group 2: 1984-1986. Introduction of ultrasound screening. Group 3: 1987-1989. Ultrasound screening established. Subgroups of 3: Regions with different rates of ultrasound examinations. >85% of newborns screened=high rate; <80% screened=low rate **Exclusion criteria:** Patients born outside of Tyrol, but treated in Tyrol. Newborn with hip dislocation due to neurological disorders were excluded.	Group 1: 41500 births. 8300/year Group 2: 24000. 8000/year Group 3: 23700. 7900/year Subgroup "high rate of ultrasound examinations" (n=4800). Subgroup "low rate of ultrasound examinations" (n=3100). **Mean age (range)** Newborns **Males females** Not stated **Other important demographic factors** Not stated **Other differences between groups** **Not stated** **Screening test** Ultrasound examination with Graf`s technique performed within the first few days of life. Ultrasound used in addition to clinical screening. **Treatment and management** Pavlik harness used for dysplasia and instability. Dislocation treated by closed reduction or open surgery followed by plaster cast **Main outcome measure** Number of hip dislocation treated by open or closed reduction.	Wilcoxon and Fisher for differences between the three groups **Withdrawals** No details given (retrospective data collection). **Results for main outcomes** 136 hip locations were treated by open or closed reductions were performed from 1979 to 1989. Group 1: 86 reductions. 2.2/1000 births Group 2: 32 reductions. 1.3/1000 births Group 3: 18 reductions. 0.8/1000 births	p for Differences between Group 1 and 2: 0.03 Group 2 and 3: 0.05 Group 1 and 3: 0.00002 Subgroups of group 3: Difference of number of reductions between "high rate group" and "low rate group": p=0.03: (9 reductions in each group) **Adverse effects of treatment or screening:** There was no reporting or discussion of adverse effects. **Comments** Clinical examination, frequency of examinations and treatments were identical in all three groups (unstable or dysplastic hips were treated identically in all three groups with Pavlik harness) No details on clinical examination and period before introduction of ultrasound. Note: the later publication included fewer patients (data up to 1988 instead of 1989) and this resulted in a reduction rate of 0.7 rather than 0.8 per 1000.

Author and reference Grill F., Mueller D. Hip Screening in Austria. *Orthopaedie* 1997; 26:25-32 **Country:** Austria **Study Design** Comparative retrospective study **Follow-up:** Not Stated **Objective** To assess if the number of conservative treatments and surgical interventions for congenital hip dysplasia has been reduced since the introduction of the Austrian hip screening program.	**Inclusion/exclusion criteria** (All?) newborns in Austria **Number of participants** Not stated **Mean age (range)** Not stated **Males females** Not stated **Other important demographic factors** Not stated **Other differences between groups** Not stated	**Screening test** Newborns screened within first week of life clinically (1985 to 1992) and by ultrasound (1992 to 1994) (Ultrasound used in addition to clinical screening). Data from 1985 to 1992 from insurance companies' form database 1. Data from 1992-1994 from National Health Department form database 2. Total newborns (% screened) 1992: 95302 (58.31%) 1993: 95227 (75.67%) 1994: 92415 (75.29%) **Treatment and management** Conservative or functional therapy used (details not given), followed by surgical reduction if necessary **Main outcome measure** Number of conservative treatments. Number of surgical interventions	**Statistical methods.** Not stated **Withdrawals** Not applicable. **Results for main outcomes** *Conservative treatment:* In 1985, 13.16% of babies were treated opposed to 6.57% in 1994. From 1992 to 1994 there was no further reduction in the rate. *Surgical interventions:* In 1991, 0.31/1000 newborns were treated surgically opposed to 0.24/1000 newborns in 1994.	**Comments** It remains completely unclear if the populations of the two periods were comparable. Two different databases for two different periods. No details about databases. The previous screening regime with which the current practice was compared was not described in any detail. No details about therapeutic strategy. Thus, the reduction of conservative interventions can also be due other reasons than only the ultrasound screening. Denominators used to calculate proportions treated unclear

Author and reference	Inclusion/exclusion criteria	Screening test	Statistical methods.	Results for main outcomes
Author and reference Holen K, Tegander A, T. B, Johansen O, Saether O, Eik-Nes S, et al. Universal or selective screening of the neonatal hip using ultrasound? A prospective, randomised trial of 15529 newborn infants. *Journal Bone Joint Surgery* 2002;84B:886-890. **Study design** RCT, follow-up range 6 to 11 years, mean 8.5 years. **Objective** To evaluate whether universal (all neonates) or selective (neonates belonging to risk groups) ultrasound screening of the hips should be recommended at birth.	**Inclusion/exclusion criteria** All neonates born between 1988 and 1992 at the University Hospital of Trondheim, whose parents consented to their inclusion in the trial. Infants with a permanent address outside the county were excluded. For the group randomised to selective screening infants were screened with ultrasound only if they had risk factors for DDH: neonatal hip instability, doubtful clinical findings (possible instability in the Barlow test), hip dysplasia in the family, breech position birth and foot deformities. **Number of participants** 15529 infants included in study. Universal screen group n= 7840 Selective screen group = 7689 **Mean age (range)** Newborns **Males females** 51% of infants in both groups were male **Other important demographic factors** The number of infants with risk factors for DDH was approximately equal in the two groups.	**Screening test** All infants were clinically examined (Ortolani and Barlow tests) on the first day of life by a senior paediatrician (the same one for almost all infants). The ultrasound examination was performed on the third day after birth. The method used was that of Terjesen[55] and Holen.[78] Mainly based on measurement of the percentage cover of the femoral head by the acetabular roof plus an assessment of hip stability and acetabular anatomy. A 5mHz transducer was used to obtain one longitudinal and one transverse scan. Ultrasound used in addition to clinical screening. **Treatment and management** Frejka pillow if clinical instability and femoral head coverage inadequate. **Main outcome measures** The primary outcome measure was late-detected DDH defined as that diagnosed after one month of age, including dislocation, subluxation, and acetabular dysplasia. Information on possible late-detected cases was sought from all hospitals in Norway. The rate of treatment with a Frejka pillow was also reported. Adverse events (avascular necrosis)	**Statistical methods.** Student's t-test, the Chi-squared test and Fisher's exact test were used. P was significant at the 5% level. The relative risk of detection of late DDH was calculated as the rate in the ultrasound group divided by the rate in the control group (selective screening group). 95% confidence intervals were calculated. **Withdrawals** Of all eligible infants 71 were not included because of a lack of parental consent. Of those randomised to universal screening 351 were not examined by ultrasound due to a lack of complete data.	**Results for main outcomes** Number of late detected cases of DDH was: Universal screening group = 1 diagnosed at age 3 months (rate 0.13 per 1000) Selective screening group = 5 diagnosed between 5 and 11 months (rate 0.65 per 1000) *Note authors state that the one case in the universal screening group should have been avoided as it occurred only because the protocol was not followed correctly.* RR = 0.21 (95% CI: 0.03, 1.45), p=0.22 (Fisher's Exact test) Treatment with Frejka pillow Universal screening group = 0.96% Selective screening group = 0.86% Avascular necrosis occurred in one infant in the selective screening group **Comments** In this RCT randomisation was achieved by assigning each infant a number according to their birth protocol and randomising to screening group by random number tables. There was no blinding of assessors to screening group. 15% (1153) of the selective screening group had at least one risk factor and an ultrasound examination was performed.

Author and reference	**Participants' inclusion/exclusion criteria**	**Number of participants**	**Statistical methods**	**Results for main outcomes**
Krolo I, Viskovic K, Kozic S, Marotti M, Klaric-Custovic R, Banak-Zahtila N, et al. The advancement in the early diagnostics of developmental hip dysplasia in infants--the role of ultrasound screening. *Coll Antropol* 2003;27:627-34. **Country:** Croatia **Study design** Retrospective comparative study, with historical control group. **Objective** To determine the value of continuous ultrasound screening in early diagnosis of DDH.	**Inclusion criteria** 9178 newborns born in the health district of Labin, Croatia from 1968-2001. Two groups were defined: Group 1:1968-1988. Clinical screening. Group 2: 1989-2001. Ultrasound screening. **Exclusion criteria:** Not stated	Group 1: not stated. Calculated as 7158 Group 2: 2010 **Mean age (range)** Newborns **Males females** Not stated **Other important demographic factors** Not stated **Other differences between groups** Not stated **Screening test** Clinical screening: starting with examination at 72 hours, follow-up at one month (Ortolani and Barlow and family history) and radiographic assessment at around 4 months if necessary. Ultrasound examination : with Graf`s technique (not clear at what age: probably at one month). Those with some degree of abnormality followed up after two, then four weeks, then monthly until aged nine months. Ultrasound was used in addition to clinical screening. **Treatment and management** Treatment method not reported. **Main outcome measure** Incidence of DDH. The age when incidence calculated not stated. Diagnostic criteria for DDH not clearly defined except for Graf's classification:	Chi-square test and test for proportional differences used. **Withdrawals** No details given (retrospective data collection).	Incidence of DDH Group 1: 1.7% Group 2: 3.3% Treatment difference p=0.0072 Incidence of dysplasia Group 1: 1% Group 2: 3% Treatment difference p<0.0001. Incidence of subluxation and luxation Group 1: 0.7% Group 2: 0.3% Treatment difference p=0.0422 Graf's classification for those examined by ultrasound: Type Ia: 92.3% Type Ib: 1.62% Type IIa: 5.22% Type IIb: 0.64% Type IIIb: 0.04% Type IV: 0.04% **Adverse effects of treatment or screening:** There was no reporting or discussion of adverse effects. **Comments** It is unknown if the incidence results refer to the findings of the first or final or other ultrasound examination. They do not correspond to the percentages given for the Graf's classification. Authors claim Ultrasound reduced late detected cases but this is not apparent from the data presented.

Author and reference Maj, S.; Sosnierz, A. Evaluation of the program of early diagnosis of congenital hip dislocation by ultrasonographic examination. *Pol Tyg Lek* 1989; 44(43-45):916-917 **Country:** Poland **Study design** Retrospective comparative study **Follow-up:** five years **Objective** To assess if the number of treatment has declined since the introduction of a general ultrasound screening for hip dysplasia in newborns.	**Participants' inclusion/exclusion criteria** Newborns from two hospitals. Group 1: 1983-1984, clinical screening Group 2: 1984-1985, clinical screening Group 3: 1985-1986, clinical screening Group 4: 1986-1987, ultrasound screening **Number of participants** Group 1: 352 Group 2: 355 Group 3: 333 Group 4: 382 **Mean age (range)** Newborns **Males females** Not stated **Other important demographic factors** Not stated **Other differences between groups** Not stated	**Screening test** Introduction of a general ultrasound screening for hip dysplasia in newborns in 05/1986 (group 4). A 5 MHz transducer (Kretztechnik company) was used for the examination with Graf`s technique. Before, i.e. for groups 1-3, newborns were screened clinically (Barlow and Ortolani). **Treatment and management** Broad diapering, splints or overhead extensions. Other details not reported. **Main outcome measures** Number of treatment Number of broad-diapering Number of splintings Number of overhead extensions Duration of treatment (weeks)	**Statistical methods.** Descriptives **Withdrawals** Not applicable **Results for main outcomes** Number of treatment Group 1: 18.1% Group 2: 13.8 Group 3: 12.9 Group 4:13.9 Percentage of treatment with broad-diapering related to all treatments: Group 1: 50% Group 2: 65.3% Group 3: 67.4% Group 4: 90.5% Percentage of treatment with splintings related to all treatments Group 1: 40.6% Group 2: 28.5% Group 3: 11.6% Group 4: 7.5	**Results for main outcomes cont.** Percentage of treatment with overhead extensions related to all treatments Group 1: 9.3% Group 2: 6.2% Group 3: 20.9% Group 4: 1.9% Duration of treatment Group 1: 11.5 ±4.6 Group 2: 10.7 ±4.6 Group 3: 11.6 ±6.5 Group 4: 7.8 ±3.7 **Comments** The number of treatments declined from 1983 to 1985 from 18.1% to 13.8%. It did not change after the introduction of ultrasound screening. The trend to treat the newborn with broad-diapering started before after the introduction of ultrasound screening. There might be other factors that influenced the treatment beside ultrasound screening.

Author and reference	**Participants' inclusion/exclusion criteria**	**Screening test**	**Outcome measure**	**Results for main outcomes cont.**
Malkawi H, Tadros F, Khasawneh Z, AlAsir B. Simple or stress sonographic hip screening in the newborn versus simple hip screening at the age of three to four months. *Saudi Med. J.* 1997;18(5):507-511. **Country:** Jordan **Study design** Retrospective Comparative study **Follow-up:** 3 months **Objective** To ascertain if ultrasound screening is able to detect all abnormal hips and which method (simple or stress sonography) and at what age is the most appropriate.	Newborns delivered at a single hospital (Princess Basma teaching Hospital) One group (Groups 1 and 2) born between August 1988 and February 1989 (n=3334) Another group of unselected infants examined between June 1989 to December 1989 when infants were 3 to 4 months old **Number of participants** Group 1 n=1823 Group 2 n=1511 Group 3 n=1077 **Mean age (range)** Newborns for Group 1 and 2; average of 3.4 months for Group 3 **Males females** Group1 844/1823 females Group2 751/1511 females Group 3 517/1077 females **Other important demographic factors** None stated **Other differences between groups** Not Stated	First group (n=3334) Clinical examination and ultrasound performed within 12 hours of birth. All infants were followed-up (clinical and ultrasound) at three months but in addition, those with risk factors or worse than type II hips (Graf classification) were followed up monthly. This group divided into two Group 1 (n=1823; 844 females and 979 males): simple sonography using 7.5 MHz transducer (method of Graf) Group 2 (n=1511; 751 females and 760 males): stress sonography (sonography performed whilst performing clinical examination manoeuvre). Stress sonography was conducted with the baby and transducer in the same position as in simple sonography. The examiner grasps the infants left leg with his free left hand, positioning his fingers on the slightly flexed and adducted knee and the thumb on the sacrum. When examining the right hip the position of the fingers and thumb is reversed. The femoral head is then pushed in the dorsocentral direction by pushing the knee in this direction while the hip is adducted. From the older group at assessment (Group 3) (n=1077; 517 females and 560 males): simple sonography using 5 MHz transducer (according to Graf) performed at age 3 to 4 months. **Treatment and management** Pathological hips treated using Pavlik harness and monitored for progress and avascular necrosis.	Number of infants requiring treatment **Statistical methods.** Descriptive **Withdrawals** No details **Results for main outcomes** Group 1 Abnormal hips requiring treatment n=85 infants (4.7%). Abnormalities identified or predicted at birth in 64 infants but for remaining 21 initial ultrasound screen did not predict abnormality. Group 2 Abnormal hips requiring treatment n=88 infants (5.8%). Abnormalities identified at birth in 33 infants and remaining 55 diagnosed at one to three months. All of these later diagnoses were being followed-up intensively due to existing risk factors including ultrasound results at birth. Average duration of treatment for Groups 1 and 2 combined was 1.16 months (no SD or range reported)	Group 3 Abnormal hips requiring treatment identified in 14 infants (1.3%). Average duration of treatment 2.9 months (range 6 weeks to 4 months) Where required treatment was given by means of a Pavlik harness and was successful (as determined at one year of age follow-up) in all cases. **Adverse effects of treatment or screening:** There were no cases of avascular necrosis in the treated patients. **Comments** Requirement for treatment not defined. Source of unselected 3 to 4 month olds not described. Had they been referred due to risk factors? Had they been screened previously? Overall impression that delaying screening to 3 to 4 months reduces proportion treated but increases duration of treatment required, but interpret with caution

Author and reference Roovers, E.A., et al., Effectiveness of ultrasound screening for developmental dysplasia of the hip, in Doctoral Thesis 'Post-neonatal ultrasound screening for developmental dysplasia of the hip. A study of cost-effectiveness in the Netherlands'. 2004: University of Twente, Enschede, Netherlands. p. 41-53. **Study design** Prospective cohort study, with historical control group. Follow-up at eight months of age. **Objective** To investigate the value of ultrasound screening for DDH and to determine the best age at which to perform this screening test.	**Inclusion/exclusion criteria** All children born in the catchment areas of two Child Health Care centres (CHC) in Eastern Netherlands between 1 September 1998 and 30 November 1999. These children were screened by ultrasound examination at the age of one, two and three months and again at eight months. The control population comprised all children born in the catchment area of a CHC in Eastern Netherlands between 1 November 1992 and 31 December 1993. These children were screened according to a standardised assessment protocol (identification of risk factors and repeated physical examination (abduction test and Galeazzi test) plus a reference ultrasound examination at the age six months. **Number of participants** Intervention population n= 5170 (82.6% of all children). Control population n= 2066 (98.1%). **Mean age (range)** Newborns **Males females** Not stated but no difference between intervention and control populations for gender distribution. **Other important demographic factors** The number of infants with risk factors for DDH was slightly higher in the intervention group: 47.4% vs. 41.1% were first born and 24.8% vs. 17.8% had affected relatives. No significant difference regarding breech position, foot abnormalities, torticollis or neurological disorders.	**Screening test** Intervention screening: The ultrasound examination was performed using Graf's method. A portable sonograph with realtime imaging was used (Hitachi EUB-405 with linear array transducer operating on an ultrasound frequency of 7.5 or 5 MHz (EUP-L33. A location device and a probe-guiding device were used to standardise the infant positioning and the scanning technique. Hips were classified according to Graf's classifications. At the one month examination only decentred hips (type D) were referred. At the month two or three examination immature (severe type IIIa or worse) and abnormal hips (type IIb or worse) were also referred. The one, two and three month imaging made up the screening programme; the eight month imaging was part of the reference test. In addition these children were also examined under the standardised assessment protocol (see control intervention below). Only children with sustained physical abnormality were referred for further diagnostic work up. **Treatment and management** In the control group the main method of treatment was inpatient traction. For the later intervention group the most common treatment was the Pavlik harness, with traction used only in cases where treatment with the Pavlik harness was unsuccessful	**Main Outcome measure** The primary outcome measure was the sensitivity of the screening test defined as the number of cases DDH identified by the screening program divided by the total number of cases of DDH. The reference standard (gold standard) was the decision to treat made during screening programme or final decision after reference US scan at eight months (US programme) or Reference US scan or radiograph at 6 months (CHC programme). Decision to treat based on clinical examination as well an ultrasound imaging and/or radiograph. Other outcome measure: proportion of population referred for treatment; treated; treated early, detected late (not defined); and inpatient treatment per 1000 treated **Statistical method** Differences in prevalence of risk factors between the two populations were tested using Chi-squared tests and Fisher's exact test. Confounding factors (proportion of firstborn children and those with affected relatives) were controlled for by indirect standardisation. Cases of DDH detected by the end of the study follow-up but who had not been detected by the screening program as such were counted as false negatives. The sensitivity with CI was calculated for each screening program (Ultrasound and clinical). **Withdrawals** Of all eligible infants 1089 from the ultrasound cohort and 39 from the clinical cohort were not included because of a lack of parental consent. In the ultrasound screen group 273 children (5.6%) missed the 8 month reference test as did 4.9% in the clinical screen group.	**Results for Main Outcomes** **Sensitivity:** Ultrasound = 88.5% (95% CI: 84.1%-92.1%) Clinical = 76.4% (95% CI: 64.9% – 85.6%) **Referrals:** Ultrasound = 7.6% (95% CI: 6.9% - 8.3%) Clinical = 19.2% (17.5% – 21.0%) Of those with DDH the proportion referred before 13 weeks was: Ultrasound = 67%; Clinical = 29% **Proportion treated as a result of screening programme:** Ultrasound = 4.6% (95% CI: 4.1% – 5.2%) Clinical = 2.7% (95% CI: 2.0% – 3.5%) **Proportion treated overall:** Ultrasound = 5.2% (95% CI: 3.5% – 7.6%) Clinical = 3.5% (95% CI: 2.7% – 4.4% When treatment rate in Clinical screening group adjusted for some confounding factors rate was 3.8%. **Late detected cases i.e. cases treated but not detected by screening programme.** Ultrasound = 0.6% (95% CI: 0.4% - 0.9%) Clinical = 0.8% (95% CI: 0.6% - 1.3%) **Inpatient treatment per 1000 treated children:** Ultrasound = 1 (95% CI: 0 – 2) Clinical = 3 (95% CI: 1 – 7) **Adverse effects** There was no reporting or discussion of adverse effects. **Comments** Sensitivity of screening programme based on reference standard that included treatment. Number of children referred for treatment at different stages of the screening was not stated so it is not possible to know how many of the treated infants were treated very early and who may have developed normally without treatment. Thus the apparent higher sensitivity of the ultrasound screening programme may simply reflect a higher degree of over treatment. This cannot be discounted from the data as presented. The overall success of the screening programmes in terms of number of infants with normal hips or number who had had to undergo surgery was not reported; the follow-up period of the study was in any case too short for this. Also the standard treatment changed between the assessments of the two screening programmes from traction with the earlier CHC to use of the Pavlik harness with the US programme.

Author and reference Rosendahl K, Markestad T, Lie RT. Ultrasound screening for developmental dysplasia of the hip in the neonate: The effect on treatment rate and prevalence of late cases. *Paediatrics* 1994;94(1):47-52. **Country:** Norway **Follow-up:** a minimum of 27 months (mean =42.4 months) **Study design** Randomised* controlled trial (*Allocation not truly random – see comments) **Objective** To assess the effect of ultrasound screening on primary diagnosis, management, and prevalence of late cases of DDH (defined as after one month after birth)	**Participants' inclusion/exclusion criteria** Infants born between January 1988 and June 1990 in a single hospital. Neonates weighing less than 1500 g or with severe malformation were not included in the study cohort. **Number of participants** 11925 (Group 1 = 3613; Group 2 = 4388; Group 3 = 3924). Three study groups: Group 1: all newborns were investigated using ultrasound Group 2: only infants with defined risk factors for DDH (dislocation, dislocatablity or major instability on the Barlow/Ortolani manoeuvre, breech position, or close family history were screened using ultrasound Group 3: no screening with ultrasound **Mean age (range)** Newborns **Males females** 47.8 to 49.3% females in all three groups **Other important demographic factors** None **Other differences between groups** There is a possibility that there was a higher number of breach presentations (a risk factor for DDH) in the general screening group.	**Screening test** The ultrasound examinations were performed within 24 to 48 hours of delivery, without knowledge of the anamnestic data or preceding clinical findings. Two coronal scans of each hip was obtained for documentation. There was a 90% concordance between two readings. Hips were classified as stable, unstable, dislocatable or dislocated on the basis of sonographic motion during a Barlow manoeuvre. Graf classification used also. Ultrasound was used in addition to clinical screening. **Treatment and management** The decision to treat (with splints) was based on both clinical and sonographic findings. Clinically stable hips were treated only if the sonographic findings indicated pronounced instability. **Main outcome measure** Prevalence of early DDH Prevalence of late discovered cases of DDH (late defined as after the first month after birth)	**Statistical methods.** Sample size based on an assumed prevalence of DHH of 2.6 per 1000 and need to detect a sixfold reduction in prevalence of late DDH in screening group (80% power, 5% significance level). Differences in prevalence rates were tested by Chi-squared test. An exact test for linear trend in the prevalence of late DDH from no screening to general screening was used. All p values reported were two sided. **Withdrawals** Five mothers of full-term babies with normal hips on clinical examination declined to participate. Information on clinical findings was missing for 34 infants in Group 1 and 36 in Group 2. **Results for main outcomes** No statistically significant differences in sex distribution or positive Barlow/Ortolani test between the three groups. The number of breech births and those with family history of DDH significantly higher in Group 1 than in Group 2.	**Results for main outcomes cont.** A significantly higher number of infants subjected to general screening was judged to be in need of treatment than in the other two groups (3.4% vs. 2.0% and 1.8% ($p< 0.0001$) The total number of late diagnosed DDH was 10 in Group 3, 9 in Group 2 and 5 in Group 1, giving respective rates of 2.6, 2.1 and 1.4. The difference was not statistically significant (p for trend =0.11) **Adverse effects of treatment or screening:** There was no reporting or discussion of adverse effects. **Comments** Allocation to treatment groups 1 and 2 was according to which nursery unit the infants were assigned to. This should not have been influenced by other than random factors except that a higher than average number of caesarean births would be expected to be assigned to ward 2. At certain times ultrasound was not available: infants delivered at these times were assigned to Group 3. Thus allocation to group was not truly random.

Author and reference Tegnander A, Terjesen T, Bredland T, Holen KJ. Incidence of Late-Diagnosed Hip-Dysplasia after Different Screening Methods in Newborns. *J. Podiatry. Orthop.- Part B* 1994;3(1):86-88. **Country :** Norway **Study design** Retrospective comparative study. **Follow-up:** Not stated **Objective** To evaluate if screening became more efficient after ultrasonography was introduced (Incidence of late-diagnosed DDH (late defined as after one month of age)).	**Participants' inclusion/exclusion criteria** Newborns at different institutions in Norway Group A (n=15950) (Trondheim University Hospital 1980 to 1985), clinical screening only Group B (n=5403) (Trondheim University Hospital 1986 to 1987), clinical and ultrasound screening Group C (n=6411) (District Hospitals 1980 to 1989) clinical screening only) **Number of participants** 27764 newborns **Mean age (range)** Newborn **Males females** Not stated **Other important demographic factors** **Other differences between groups**	**Screening test** Clinical screening consisted of Barlow/Ortolani tests. Ultrasound screening was performed initially as a dynamic examination only but later the coverage of the femoral head by the bony acetabular roof was also measured. Classification was as dislocation, sublocation or acetabular dysplasia after Terjesen et al[56]. **Treatment and management** Method of treatment not reported. **Main outcome measures** Incidence of late-diagnosed DDH (late defined as after one month of age)	**Statistical methods** Incidences were compared between groups using Chi-squared test of independence, with significance level of 0.05. **Withdrawals** Not stated **Results for main outcomes** Incidence of late diagnosed DDH: Group A = 2.6 per 1000 Group B = 0.7 per 1000 Group C = 5.3 per 1000 In group A all the late diagnoses occurred before the introduction of the measurement of the femoral head by the bony acetabular roof. The difference in incidence between Groups A and B was statistically significant ($p<0.02$). The incidence in Group C was statistically significantly higher than both Groups A and B ($p<0.01$)	**Results for main outcomes cont.** **Adverse effects of treatment or screening:** There was no reporting or discussion of adverse effects. **Comments** No information on whether DDH detected is real DDH or just early DHH that would have resolved without intervention.

APPENDIX 6: DATA EXTRACTION TABLES (DESCRIPTIONS OF CLINICAL EXPERIENCE)

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Andersson JE, Funnemark P-O. Neonatal Hip Instability: Screening with Anterior-Dynamic Ultrasound Method. *Journal of Pediatric Orthopaedics* 1995;15(3):322-324.	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound:** 59 hips/ 44 infants (at birth) (1%) **By clinical exam:** not clear	**Number treated (%)** 5 hips in 4 infants (0.18% treatment rate)
Study design Clinical Experience	**By other**	**Number late diagnosed (%)(define late)** None
Reason for exclusion No comparator		
Population Neonates (n=4430)		**Number normal (hips/patients) at final follow-up(%) (state when)** All treated hips normal at 18 weeks.
		Adverse events Not reported

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Ballerini G, Avanzini A, Colombo T, Crossignani RM, Micucci E, Santucci S. Screening neonatale e follow-up della lussazione congenita dell'anca mediante ecografia. Revisione della letteratura e contributo personale su 1421 neonati. (Neonatal screening and follow-up of congenital hip luxation using echography. Review of the literature and personal contribution on 1421 newborns). *Radiol Med (Torino)* 1990;80(6):814-7.	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 721 (25.4%) IIa hips and 57 IIc or worse (2.0%) within first week of life **By clinical exam:** Not stated **By other**	**Number treated (%)** 109 hips treated
Study design Clinical Experience		**Number late diagnosed (%)(define late)** Not stated
Reason for exclusion No comparator		
Population Full term newborns (n = 1421)		**Number normal (hips/patients) at final follow-up(%) (state when)** Not stated
		Adverse events Not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Baronciani D, Atti G, Andiloro F, Bartesaghi A, Gagliardi L, Passamonti C, et al. Screening for developmental dysplasia of the hip: from theory to practice. Collaborative Group DDH Project. *Pediatrics* 1997;99(2):E5-E55.	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** Abnormal (Graf IIc or worse) = 162 (3.5%) (mix of first week and later scans) **By clinical exam** 233 (5.1%) **By other**	**Number treated (%)** Not stated
Study design Clinical Experience		**Number late diagnosed (%)(define late)** Not stated
Reason for exclusion No comparator		
Population Neonates (n=4648)		**Number normal (hips/patients) at final follow-up(%) (state when)** Not stated
		Adverse events Not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Berman L, Klenerman L. Ultrasound Screening for Hip Abnormalities Preliminary Findings in 1001 Neonates. *BMJ* 1986;293(6549):719-722.	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound:** 5 (0.5%) referred to orthopaedic surgeon **By clinical exam:** 45 (4.5%) referred to orthopaedic surgeon **By other**	**Number treated (%)** Not stated
Study design Clinical Experience		**Number late diagnosed (%)(define late)** Not stated
Reason for exclusion No comparator		
Population Newborn Examined within 48 hours of delivery (n=1001)		**Number normal (hips/patients) at final follow-up(%) (state when)** Not stated
		Adverse events Not reported

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Bialik V, Bialik GM, Wiener F. Prevention of overtreatment of neonatal hip dysplasia by the use of ultrasonography. *J Pediatr Orthop B* 1998;7(1):39-42.	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound:** 457 hips (5.09%) **By clinical exam:** 81 hips (0.54%) **By other**	**Number treated (%)** 54 hips (0.025%)
Study design Clinical experience		**Number late diagnosed (%)(define late)** Not stated
Reason for exclusion No comparator		
Population (n=4321) examined in first 24 hours after birth		**Number normal (hips/patients) at final follow-up(%) (state when)** At age of one year all treated babies had clinically and sonographically normal hips
		Adverse events Not reported

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Bialik V, Bialik GM, Blazer S, Sujov P, Wiener F, Berant M. Developmental dysplasia of the hip: A new approach to incidence. *Pediatrics* 1999;103(1):93-99.	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 995 (5.51%) **By clinical exam** Not stated **By other**	**Number treated (%)** 90 (0.5%)
Study design Clinical Experience		**Number late diagnosed (%)(define late):** Not stated
Reason for exclusion No comparator		
Population 9030 neonates		**Number normal (hips/patients) at final follow-up(%) (state when)** Not stated
		Adverse events Not reported

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Castelein RM, Sauter AJM. Ultrasound Screening for Congenital Dysplasia of the Hip in Newborns Its Value. *Journal of Pediatric Orthopaedics* 1988;8(6):666-670.	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 49 infants (16.0%), 82 hips (13.4%) **By clinical exam** 2 infants (0.5%), 3 hips (0.5%) **By other**	**Number treated (%)** Not stated
Study design Clinical Experience		**Number late diagnosed (%)(define late):** Not stated
Reason for exclusion No comparator		
Population n=307		**Number normal (hips/patients) at final follow-up (%) (state when)** Not stated
		Adverse events Not reported

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Cervone de Martino, M.; Riccardi, G.; Stanzione, P.; di Lena, C.; Riccio, V. Neonatal screening for congenital hip dislocation. Indication of ultrasonography from a systematic study correlating clinical findings and ultrasonography. *Rev Chir Orthop Reparatrice Appar Mot* 1994 80(4):320-323	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 476 (23.8%) IIa and 124 (6.2%) IIc-IIIb **By clinical exam** 150 hips (7.5%) **By other**	**Number treated (%)** Not stated
Study design Clinical experience		**Number late diagnosed (%)(define late)** Not stated
Reason for exclusion No comparator		
Population 1000 neonates (2000 hips), examined within first week of life		**Number normal (hips/patients) at final follow-up (%) (state when)** Not stated
		Adverse events Not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Deimel D., Breuer D., Alaiyan H., Mittelmeier H. Developmental Observations of a Hip Ultrasound Screening program to Early Diagnosis of Hip Dysplasia at the Orthopaedic Department of the University Hospital Homburg/Saar from 19854 to 1990. *Z. Orthop*. 1994; 132: 255-259	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 1229 (26.5%) IIa hips and 104 (2.2%) IIc or worse **By clinical exam:** 754 (32.5%) **By other**	**Number treated (%)** follow-up not complete
Study design Clinical Experience		**Number late diagnosed (%)(define late)** follow-up not complete
Reason for exclusion No comparator		
Population Neonates (n=2317 with 4634 hips).). Exact date of examination not stated.		**Number normal (hips/patients) at final follow-up(%) (state when)** follow-up not complete
		Adverse events Not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Dorn U. Hip Screening in neonates. Clinical and sonographic findings. Wiener Klinische Wochenschrift Supplementum 1990; 102 (181):3-22	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound**: 462 (38.1%) IIa hips and 81 (6.6%) IIc or worse	**Number treated (%)** 115 (9.5%)
Study design Clinical Experience	**By clinical exam** not stated **By other**	**Number late diagnosed (%)(define late)** not stated
Reason for exclusion No comparator		
Population Neonates (n=1210 hips), examined within first 4 days of life.		**Number normal (hips/patients) at final follow-up(%) (state when)** not stated
		Adverse events not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Dziewulski W, Boron Z, Bernatowicz Lojko U. Diagnostyka ultrasonograficzna i organizacja leczenia wrodzonej dysplazji stawow biodrowych w Toruniu. (Ultrasonographic diagnostics and the organization of treating congenital dysplasia of the hip in Torun). *Chir Narzadow Ruchu Ortop Pol* 1994;59(1):9-14. Data not extracted, except for minimal information given in abstract – paper in Polish	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 459 hips **By clinical exam** **By other**	**Number treated (%)** Not extracted
Study design Clinical Experience		**Number late diagnosed (%)(define late):**
Reason for exclusion No comparator		
Population 9348 (18696 hips)		**Number normal (hips/patients) at final follow-up(%) (state when)** Not extracted
		Adverse events Not extracted

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Esparza J, Gonzalez A, Garcia S, Elso J, Cordero JL. The early diagnosis of developmental dysplasia of the hip using ultrasonography. The importance of following up cases with physiological immaturity. *Radiologia* 1999;41(8):557-561.	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 32 (0.92%) **By clinical exam** **By other**	**Number treated (%)**
Study design Clinical Experience		**Number late diagnosed (%)(define late):** One case (defined as not identified by screening)
Reason for exclusion No comparator		
Population Newborns examined by ultrasound at age 1 month		**Number normal (hips/patients) at final follow-up(%) (state when)**
		Adverse events Not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Falliner, A.; Hahne, H.J.; Hassenpflug, J. Ultrasound screening of neonatal hips. *Monatsschrift Kinderheilkunde* 1996, 144:1223-1229	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound:** 1419 **(**14%) IIa hips and 122 (1.2%) IIc or worse (first days after birth) **By clinical exam** 1115 **(**11%) abnormal **By other**	**Number treated (%)** 107 hips (1%)
Study design Clinical Experience		**Number late diagnosed (%)(define late)** not stated
Reason for exclusion No comparator		
Population Neonates (n=5069, 10138 hips). Exact date of examination not stated.		**Number normal (hips/patients) at final follow-up(%) (state when)** not stated
		Adverse events not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Falliner A, Hahne HJ, Hassenpflug J. Sonographic hip screening and early management of developmental dysplasia of the hip. *J Pediatr Orthop B* 1999;8(2):112-7.	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** IIa 1876 (14.3%); IIc or worse 140 (1.1%) **By clinical exam** 288 (2.2%) **By other**	**Number treated (%)** Of the clinically unstable hips 29 (0.44%) were treated (22 (0.33%) with abduction splints and 7 (0.11%) by broad diapering). A further 206 immature hips (ultrasound diagnosis) were treated successfully by broad diapering
Study design Clinical Experience		**Number late diagnosed (%)(define late):**
Reason for exclusion No comparator		
Population 6548 infants between the first and fourth day of life		**Number normal (hips/patients) at final follow-up(%) (state when)** All hips normal at follow-up at three weeks but some indication that the situation worsened after treatment was discontinued (reporting of this unclear)
		Adverse events Not reported

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Ganger R, Grill F, Leodolter S. Ultrasound screening of the hip in newborns: results and experience. *J Pediatr Orthop* 1990;1:45.	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 1237 hips (47.9%) were immature (type IIa) (731 infants (56.6%)); 51 hips type IIc or worse (2%); **By clinical exam** Not stated **By other**	**Number treated (%)** 731 with broad diapering; 110 (10.5%) with Pavlik harness or abduction brace
Study design Clinical Experience		**Number late diagnosed (%)(define late):** Not stated
Reason for exclusion No comparator		
Population **1292 unselected newborns**		**Number normal (hips/patients) at final follow-up(%) (state when)** 100% of those follow-ed up (80.8% of all)
		Adverse events Not reported

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Graf R. Hip sonography--how reliable? Sector scanning versus linear scanning? Dynamic versus static examination? *Clin Orthop* 1992(281):18-21.	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** **By clinical exam** **By other** (whole screening procedure) 1.5 - 3%	**Number treated (%)** Not stated. No surgical treatment needed in any cases
Study design Clinical Experience		**Number late diagnosed (%)(define late):** Not stated
Reason for exclusion No comparator		
Population 8350		**Number normal (hips/patients) at final follow-up(%) (state when)**
		Adverse events No cases of femoral head necrosis (but number of treatments unknown)

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Joller J., Waespe B. Sonographie der Säuglingshüfte- erste Ergebnisse eines Screeningprogrammes im Kanton Uri. In: Angeborene Hüftdysplasie und –luxation vom Neugeborenen bis zum Erwachsenen. Symposium der SGUMB, Zürich 27th of November, 1993. 171-174	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 225 (21.1%) IIa and 40 (3.8%) with IIc or worse **By clinical exam** not stated **By other**	**Number treated (%)** 42 (3.9%)
Study design Clinical experience		**Number late diagnosed (%)(define late)** 0
Reason for exclusion No comparator		
Population Neonates (n=1064)		**Number normal (hips/patients) at final follow-up(%) (state when)** 0
		Adverse events not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Leonhardi, A.; Reither, M. Ultrasound screening of newborn infants. Uses and role in routine diagnosis. *Klin Padiatr* 1999, 205:383-388	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 452 (13.3%) IIa hips and ?? IIc or worse → cannot read numbers because of fax copy **By clinical exam** Not stated **By other**	**Number treated (%)** Not stated
Study design Clinical Experience		**Number late diagnosed (%)(define late)** Not stated
Reason for exclusion No comparator		
Population Neonates (n=3396) at 4th day (mean)		**Number normal (hips/patients) at final follow-up (%) (state when)** Not stated
		Adverse events Not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Malkawi H, Asir B, Tadros F, Khasawneh Z. Sonographic image of the newborn hip with positive Ortolani's sign. *Clin Orthop* 1992(279):138-43.	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** IIa or worse 47 hips (0.53%); D or worse 16 hips (0.18%) **By clinical exam** 73 hips (0.82%) (54 newborns (1.2%) **By other**	**Number treated (%)** Not stated
Study design Clinical Experience		**Number late diagnosed (%)(define late):** Not stated
Reason for exclusion No comparator		
Population 4438 newborn		**Number normal (hips/patients) at final follow-up(%) (state when)** Not stated
		Adverse events Not reported

Description of clinical eExperience – minimal data extraction only		
Study details	**Findings**	
Author and reference Marks DS, Clegg J, al Chalabi AN. Routine ultrasound screening for neonatal hip instability. Can it abolish late-presenting congenital dislocation of the hip? *J Bone Joint Surg Br* 1994;76(4):534-8.	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 847 (6%) **By clinical exam** Not stated **By other**	**Number treated (%)** 34 infats (0.24%) 59 hips (0.21%)
Study design Clinical Experience		**Number late diagnosed (%)(define late):** Not stated
Reason for exclusion No comparator		
Population 14050 newborns		**Number normal (hips/patients) at final follow-up(%) (state when)** Three hips treated with a Pavlik harness failed to respond and require arthrography, closed adductor tenotomy and immobilisation in a hip spica
		Adverse events Not reported

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Merk, H.; Mahlfeld, K.; Wissel, H.; Kayser, R. The congenital dislocation of the hip joint in ultrasound examination--frequency, diagnosis and treatment. *Klin Padiatr* 1999; 211(1):18-21	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 28 (0.47%) hip dislocations **By clinical exam** **By other**	**Number treated (%)** 28 (0.34%) hips
Study design Clinical experience		**Number late diagnosed (%)(define late)** 5%
Reason for exclusion No comparator		
Population Neonates (n=4177)		**Number normal (hips/patients) at final follow-up (%) (state when)** 26 hips (of those treated)
		Adverse events Not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Oberthaler W., Heinzle W., Cziudaj E. Ist die Hüftsonographie als Screening zur Früherkennung von Hüftdysplasien im peripheren Krankenhaus durchführbar? In: Frank W. und Eyb R. Die Sonographie in der Orthopadie. Springer-Verlag 1988. S.111-115	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 41% IIa and 3% with IIc or worse **By clinical exam** 4% **By other**	**Number treated (%)** not stated
Study design Clinical experience		**Number late diagnosed (%)(define late)** not stated
Reason for exclusion No comparator		
Population Neonates (n=1020)		**Number normal (hips/patients) at final follow-up(%) (state when)** not stated
		Adverse events not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Psenner, K.; Ortore, P.; Fodor, G.; Stuefer, J. Echography of the hip of the newborn infant. *Radiol Med (Torino)* 1990, 79:575-581	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 545 (25%) IIa hips and 130 IIc or worse (6%) **By clinical exam** 156 (7.2%) hips **By other**	**Number treated (%)** Not stated
Study design Clinical Experience		**Number late diagnosed (%)(define late)** Not stated
Reason for exclusion No comparator		
Population Neonates (2164 ultrasound examinations, unclear if = 1082 neonates)		**Number normal (hips/patients) at final follow-up (%) (state when)** Not stated
		Adverse events Not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Rabenseifner T., Gohlke F., Feige T. Propektive Studie zur Ätiologie und Frühdiagnostik der Hüftdysplasie. In: Henche HR, Hey W eds. Sonographie in der Orthopadie und Sportmedizen. Uelzen: Med Literatur Verlagsgesellach. 1987. 161-164	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 316 (36.1%) IIa hips and 67 (7.6%) with IIc or worse **By clinical exam** 250 neonates **By other**	**Number treated (%)** Not stated
Study design Clinical experience		**Number late diagnosed (%)(define late)** Not stated
Reason for exclusion No comparator		
Population Neonates (n=873)		**Number normal (hips/patients) at final follow-up(%) (state when)** Not stated
		Adverse events Not stated

Description of clinical eperience – minimal data extraction only		
Study details	**Findings**	
Author and reference Riboni, G.; Serantoni, S.; De Simoni, M.; Bascape, P.; Facchini, R.; Pirovano, G. Echography of the hip in the newborn. 1507 cases. *Radiol Med (Torino)* 1991, 81:53-57	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 493 (32.7%) IIa hips and 15 (1%) IIc or worse **By clinical exam** not stated **By other**	**Number treated (%)** 15 (1%)
Study design Clinical Experience		**Number late diagnosed (%)(define late)** 1 after 1 year of life
Reason for exclusion No comparator		
Population Neonates (n=1507). Examined within first 5 days of life		**Number normal (hips/patients) at final follow-up (%) (state when)** 1506 of 1507 after 1 year of life
		Adverse events not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Riebel, T; Nasir, R; Käding M; Eckart, L. Deterioration of hips during postnatal development as shown sonographically during screening and follow-up observations. *Monatsschrift Kinderheilkunde* 1990, 138:664-669	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 901 (21%) IIa hips and 69 (1.6%) IIc or worse **By clinical exam** not stated **By other**	**Number treated (%)** follow-up not complete
Study design Clinical Experience		**Number late diagnosed (%)(define late)** follow-up not complete
Reason for exclusion No comparator		
Population Neonates (N=4290 hips), examined within first 5 days of life		**Number normal (hips/patients) at final follow-up (%) (state when)** follow-up not complete
		Adverse events not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Riebel T., Herzog N., Nasir R. Neonatales Hüftscreening. *Monatsschr Kindeerheilk* 1995; 143:268-273	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 5060 (28.7%) with IIa hips and 324 (1.8%) IIc or worse **By clinical exam** 130 hips Ortolani positive, 331 with limited abduction **By other**	**Number treated (%)**
Study design Clinical experience		**Number late diagnosed (%)(define late)**
Reason for exclusion No comparator		
Population Neonates (n=8824)		**Number normal (hips/patients) at final follow-up (%) (state when)**
		Adverse events Not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Roelli H.J. Erfahrungen mit dem Neugeborenenscreening der Hüfte. In: Angeborene Hüftdysplasie und –luxation vom Neugeborenen bis zum Erwachsenen. Symposium der SGUMB, Zürich 27th of November 1993. p171-174	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 408 (24%) IIa and 17 (1%) with IIc or worse **By clinical exam** not stated **By other**	**Number treated (%)** 17 at birth pathologic and some at birth immature hips (number not stated)
Study design Clinical experience		**Number late diagnosed (%)(define late)** 0
Reason for exclusion No comparator		
Population Neonates (n=1700)		**Number normal (hips/patients) at final follow-up (%) (state when)** 100% after 5 months
		Adverse events not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Rosenberg N, Bialik V, Norman D, Blazer S. The importance of combined clinical and sonographic examination of instability of the neonatal hip. *Int Orthop* 1998;22(3):185-8.	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 628 newborns (5.5% of hips) **By clinical exam** Not stated **By other**	**Number treated (%)** Not stated
Study design Clinical Experience		**Number late diagnosed (%)(define late):** Not stated
Reason for exclusion No comparator		
Population 9199 newborns		**Number normal (hips/patients) at final follow-up(%) (state when)**Not stated
		Adverse events Not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Rosendahl K, Markestad T, Lie RT. Congenital Dislocation of the Hip a Prospective Study Comparing Ultrasound and Clinical Examination. *Acta Paediatr* 1992;81(2):177-181.	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 436 hips (14.5%) immature; 80 (2.7%) dysplastic **By clinical exam** Not stated **By other**	**Number treated (%)** 117 hips (3.9%)
Study design Clinical Experience		**Number late diagnosed (%)(define late):** Not stated
Reason for exclusion No comparator		
Population 1503 newborns		**Number normal (hips/patients) at final follow-up(%) (state when)** Not stated
		Adverse events Not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Rosendahl K, Markestad T, Lie RT. Developmental dysplasia of the hip. A population-based comparison of ultrasound and clinical findings. *Acta Paediatr* 1996;85(1):64-69.	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** Minor dysplasia or major dysplasia 107 infants (2.97%)	**Number treated (%)** 123 infants (3.4%)
Study design Clinical Experience	**By clinical exam** borderline unstable or dislocated/able 106 20 (2.93%)	**Number late diagnosed (%)(define late):** Not stated
Reason for exclusion No comparator	**By other**	
Population 3613 randomly selected newborns		**Number normal (hips/patients) at final follow-up(%) (state when)**Not stated
		Adverse events Not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Ruhmann, O.; Konermann, W.; Lazovic, D.; Vitek, L.; Bouklas, P. Ultrasound neonatal screening: the effect of anamnestic risk factors on hip dysplasia*. Z Orthop Ihre Grenzgeb* 1998, 136:492-500	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 3825 (57.8%) IIa hips and 217 (3.2%) IIc or worse hips	**Number treated (%)** 220 (3.3%)
Study design Clinical Experience	**By clinical exam** Not stated **By other**	**Number late diagnosed (%)(define late)** Not stated
Reason for exclusion No comparator		
Population Neonates (n=6617). Examined between 1 and 19 days after birth.		**Number normal (hips/patients) at final follow-up (%) (state when)** Not stated
		Adverse events Not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Russo, E.; Cermaria, F.; Sardini, S.; Simeoni, G.; Zanini, F. Ultrasound imaging in the investigation of congenital dislocation of the hip in neonates and infants. Pediatr Med Chir 1989, 11(6): 679-686	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 113 **(**88.9%) IIa hips and no abnormal hips **By clinical exam** not stated **By other**	**Number treated (%)** not stated
Study design Clinical Experience		**Number late diagnosed (%)(define late)** 0 after 7 months
Reason for exclusion No comparator		
Population Neonates and infants between 3 days and 7 months (n=127)		**Number normal (hips/patients) at final follow-up(%) (state when)** 127 (100%) after 7 months
		Adverse events not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Russo Frattasi, C.A.; Blanchietti, E.; Caruso, M.; Favetta, S. Ultrasonic neonatal screening of congenital hip dislocation. *Pediatr Med Chir* 1991; 13(*):299-302	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** not stated **By clinical exam** not stated **By other**	**Number treated (%)** not stated
Study design Clinical experience		**Number late diagnosed (%)(define late)** not stated
Reason for exclusion No comparator		
Population Neonates (n=596)		**Number normal (hips/patients) at final follow-up(%) (state when)** not stated
		Adverse events not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Schilt M. Very early beginning of treatment of edevelopmental dysplasia of the hip (DDH): a consequence of a screening program by hip sonography according to Graf. 4th Congress of ISMUS, Madrid 21st to 24th of October 1998	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 279 (16.1%) with IIa and 24 (1.4%) with IIc or worse **By clinical exam** Not stated **By other**	**Number treated (%)** 22
Study design Clinical experience		**Number late diagnosed (%)(define late)** 0
Reason for exclusion No comparator		
Population Neonates (n=1734)		**Number normal (hips/patients) at final follow-up(%) (state when)** 100%
		Adverse events None

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Schilt, M. Optimal age for screening by hipsonography. *Ultraschall in Der Medizin* 2001; 22:39-47	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 17.7% IIa and 1.6% IIc or worse **By clinical exam** not stated **By other**	**Number treated (%)** 23 (1.12%)
Study design Clinical experience		**Number late diagnosed (%)(define late)** Change from IIa to IIb hips after 3 months: 1.6% of all hips including the hips from the group with infants referred for a diagnostic ultrasound examination.
Reason for exclusion No comparison with another screened population. The other group described in the report are selected infants referred for a diagnostic ultrasound examination		
Population Neonates (n=2054)		**Number normal (hips/patients) at final follow-up (%) (state when)** 100% after 3 months
		Adverse events not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Schlepckow P., Heilige R. Die Wertigkeit der Ultraschalluntersuchung der Neugeborenenhüfte. In: Henche HR, Hey W eds. Sonographie in der Orthopadie und Sportmedizen. Uelzen: Med Literatur Verlagsgesellach. 1987. 165-166	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 124 (4%) IIa and 12 (0.04%) with IIc or worse **By clinical exam not** stated **By other**	**Number treated (%)** Not complete follow up
Study design Clinical experience		**Number late diagnosed (%)(define late)** Not complete follow up
Reason for exclusion No comparator		
Population Neonates (2966 hips), examined in first week of life		**Number normal (hips/patients) at final follow-up(%) (state when)** Not complete follow up
		Adverse events Not complete follow up

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Schule, B.; Wissel, H.; Neumann, W.; Merk, H. Follow-up of ultrasound screening of the hips in newborns. *Ultraschall in Der Medizin* 1999; 20(4):161-164	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 1498 (45.2%) IIa and 84 (2.5%) dysplastic hips **By clinical exam** **By other**	**Number treated (%)** 84 (2.5%) 11.3% of IIa deteriorated until month three to IIb. Not stated if these hips were treated.
Study design Clinical experience		**Number late diagnosed (%)(define late)** 0
Reason for exclusion No comparator		
Population Neonates (N=1656)		**Number normal (hips/patients) at final follow-up(%) (state when)** 100%
		Adverse events Not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Sellier Th., Mutschler B. Erfahrungen und Ergebnisse mit dem sonografischen Hüftscreening von 555 Neugeborenen. In: Frank W. und Eyb R. Die Sonographie in der Orthopadie. Springer-Verlag 1988. S.103-109	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 320 (29.4%) IIa and 28 (2.5%) with IIc or worse **By clinical exam** not stated **By other**	**Number treated (%)** 36 type IIa hips (not complete follow up) 21 pathologic hips (not complete follow up)
Study design Clinical experience		**Number late diagnosed (%)(define late)**
Reason for exclusion No comparator		
Population Neonates (n=555)		**Number normal (hips/patients) at final follow-up(%) (state when)** 100% after 5 months
		Adverse events not stated

Description of clinical experience – minimal Data extraction only		
Study details	**Findings**	
Author and reference Stover B, Bragelmann R, Walther A, Ball F. Development of late congenital hip dysplasia: significance of ultrasound screening. *Pediatr Radiol* 1993;23(1):19-22.	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** **By clinical exam** **By other** combination of ultrasound plus radiographs 163 (3.3%) (unclear of timings of investigations)	**Number treated (%)** Unclear
Study design Clinical Experience		**Number late diagnosed (%)(define late):** 0.61% of 2121 infants reinvestigated after initial screening (late not defined)
Reason for exclusion No comparator		
Population 5970 newborns		**Number normal (hips/patients) at final follow-up(%) (state when)** Not stated
		Adverse events Not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Tegnander A, Holen KJ, Terjesen T. The natural history of hip abnormalities detected by ultrasound in clinically normal newborns: A 6-8 year radiographic follow-up study of 93 children. *Acta Orthop Scand* 1999;70(4):335-337.	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 170 infants (3.4%) had abnormal ultrasound but normal clinical findings **By clinical exam** Not stated **By other**	**Number treated (%)** None were treated before 4-5 months when 10 infants required treatment with an abduction orthoasis and developed normally.
Study design Clinical Experience		**Number late diagnosed (%)(define late):** Not stated
Reason for exclusion No comparator		
Population 4973 newborns (1988-1990)		**Number normal (hips/patients) at final follow-up(%) (state when)** Follow-up of 93 children at age 6-7 years. 12 had a reduced range of motion compared to the normal population. None had abnormal radiograph findings.
		Adverse events Not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Terjesen T, Bredland T, Berg V. Ultrasound for Hip Assessment in the Newborn. *Journal of Bone and Joint Surgery British* 1989;71(5):767-773.	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 36 (3.6%) **By clinical exam** 7 (0.7%) **By other**	**Number treated (%)** 7 (0.7%) with Frejika pillow) and one with double-diapering
Study design Clinical Experience		**Number late diagnosed (%)(define late):** 1 (0.1%) at three months
Reason for exclusion No comparator		
Population 1000 consecutive births at University Hospital ,Trondheim		**Number normal (hips/patients) at final follow-up(%) (state when)** Unclear, but appears to be 100%
		Adverse events Not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Terjesen T, Holen KJ, Tegnander A. Hip abnormalities detected by ultrasound in clinically normal newborn infants. *J Bone Joint Surg Br* 1996;78(4):636-40.	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 306 (3.1%) abnormal ultrasound but normal clinical findings **By clinical exam** **By other**	**Number treated (%)** No treatment initiated before 2-3 month follow-up. Overall one infant treated at age 3 months, and 16 from age 4-5 months
Study design Clinical Experience		**Number late diagnosed (%)(define late):**
Reason for exclusion No comparator and only selected follow-up		
Population 9952 newborns (1987 to 1992)		**Number normal (hips/patients) at final follow-up(%) (state when)** All treated normal at follow-up (timing unclear)
		Adverse events No avascular necrosis or other complications found

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Toennis D, Storch K, Ulbrich H. Results of Newborn Screening for CDH with and without Sonography and Correlation of Risk Factors. *Journal of Pediatric Orthopaedics* 1990;10(2):145-152.	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** Type IIc or worse 2.64% **By clinical exam** **By other**	**Number treated (%)** 14.9% broad diapering 4.2% abduction pillow 0.2% Pavlik's
Study design Clinical Experience		**Number late diagnosed (%)(define late):** Not stated
Reason for exclusion No comparator		
Population 1310 newborns		**Number normal (hips/patients) at final follow-up(%) (state when)** Not stated
		Adverse events Not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Ulveczki E. Ultrasound Screening for Congenital Dysplasia of the Hip. *Orv Hetil* 1992;133(24):1481-1483. (Data extraction from abstract only – language)	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** 30 hips (2.5%) **By clinical exam** Approximately 18 (1.5%) **By other**	**Number treated (%)** 30 hips (2.5%)
Study design Clinical Experience		**Number late diagnosed (%)(define late):** Not stated
Reason for exclusion No comparator		
Population 1200 neonatal hips		**Number normal (hips/patients) at final follow-up(%) (state when)**Not stated
		Adverse events Not stated

Description of clinical experience – minimal data extraction only		
Study details	**Findings**	
Author and reference Vekonj Fajka G, Vekonj N. Primarna ultrazvucna dijagnostika razvojnog poremecaja kuka novorodenceta u bolnici Senta. (Primary ultrasonic diagnosis of congenital hip dysplasia in neonates at the Senta Hospital). *Med Pregl* 1999;52(6-8):247-252.	**Number diagnosed as DDH at first screening (%)(state when):** **By ultrasound** (4912) 34.2% hips with IIa and 199 (1.39%) with IIc or worse **By clinical exam** 12.85% **By other**	**Number treated (%)** Language restrictions
Study design Clinical Experience		**Number late diagnosed (%)(define late):** Language restrictions
Reason for exclusion No comparator		
Population Newborns (n=7189)		**Number normal (hips/patients) at final follow-up(%) (state when)**Language restrictions
		Adverse events Language restrictions

<table>
<tr><td colspan="3">Description of clinical experience – minimal data extraction only</td></tr>
<tr><td>Study details</td><td colspan="2">Findings</td></tr>
<tr><td>Author and reference
Venbrocks R, Verhestraeten B, Fuhrmann R. The importance of sonography and radiography in diagnosis and treatment of congenital dislocation of the hip. Acta Orthop Belg 1990;56(1 (Pt A)):79-87.</td><td rowspan="4">Number diagnosed as DDH at first screening (%)(state when):
By ultrasound Type IIa 380 (34.5%); Type IIg or worse 83 infants (7.7%)
By clinical exam
By other</td><td>Number treated (%)
All type IIa and worse treated giving a total treated of 463 (42.2%).</td></tr>
<tr><td>Study design
Clinical Experience</td><td rowspan="2">Number late diagnosed (%)(define late):
Not stated</td></tr>
<tr><td>Reason for exclusion
No comparator</td></tr>
<tr><td>Population
1100 newborns</td><td>Number normal (hips/patients) at final follow-up(%) (state when)
Not stated</td></tr>
<tr><td></td><td></td><td>Adverse events
No osteonecrosis</td></tr>
</table>

APPENDIX 7: ECONOMIC EVALUATIONS – STRUCTURED ABSTRACTS FROM NHS EED

These records were compiled by CRD commissioned reviewers according to a set of guidelines developed in collaboration with a group of leading health economists.

Cost-effectiveness of ultrasonographic screening for congenital hip dysplasia in new-borns
Geitung J T, Rosendahl K, Sudmann E. Skeletal Radiology 1996;25(3):251-254.

Health technology
Ultrasonographic screening for congenital hip dysplasia (CDH) in new-borns.

Disease
Musculoskeletal diseases.

Type of intervention
Screening.

Hypothesis/study question
To evaluate the cost-effectiveness of a programme which utilises ultrasonographic screening to detect congenital hip dysplasia in new-born infants. Ultrasonographic screening has been shown to reduce the number of late-discovered CDH. The comparator was that of conventional clinical screening methods (Ortolani's or Barlow's test).

Economic study type
Cost-effectiveness analysis.

Study population
The study population, for the purposes of assessing ultrasonographic screening, consisted of a hypothetical cohort of all new-born infants in the hospital in which the study was conducted. A second population consisted of patients who had been treated for late-diagnosed CDH with the following characteristics: Age when discovered = 11.9 months (mean), 5 months(median); Number of operations = 0.7 (mean), 0 (median); Age at last visit = 3.8 years (mean), 4 years (median).

Setting
Secondary care (hospital). The study was conducted in Bergen, Norway.

Dates to which data relate
The effectiveness data relate to previous studies conducted between 1989 and 1992. Cost data for the late-treated group relate to 1984-85, and the cost data for ultrasonographic screening were derived from a study conducted in 1989 and 1990. The price year was 1993.

Source of effectiveness data
The effectiveness data were derived from a combination of a review of previous literature, the findings of a single study and authors' assumptions.

Links between effectiveness and cost data
For the purposes of the ultrasonographic sample the cost and effectiveness data were derived prospectively from the same hypothetical cohort. The effectiveness and cost of the comparator were derived from the relevant study sample. For the latter group, the costing was conducted retrospectively.

Single study

Study sample
The late-detected (comparator) group consisted of 26 children who had been referred for

specialist consultation and were diagnosed as having CDH. Power calculations were not used in determining sample size.

Study design
The study design for the late-detected group was case series and was conducted on a single site. The duration of follow-up was not specified. The loss to follow-up was not specified.

Analysis of effectiveness
The analysis of effectiveness was based on intention to treat. The measure of effectiveness adopted was the sensitivity and specificity of the screening test in terms of the number of late-detected cases of CDH avoided per annum and the number of false-positives after ultrasonographic screening.

Effectiveness results
The sensitivity and specificity of current screening practice resulted in an incidence of late-detected CDH of 2.6 cases in 5,000 live births.

Clinical conclusions
The number of late-discovered cases of CDH was higher in ultrasonographic versus clinical screening. The ultrasonographic screening would have produced 57.5 false-positive diagnoses.

Review/synthesis of previously published studies

Outcomes assessed in the review
The outcomes assessed in the review were the sensitivity and specificity of ultrasonographic screening and the number of late-discovered CDH cases in Norway.

Study designs and other criteria for inclusion in the review
No specific study designs were stipulated by the authors as inclusion criteria. The authors emphasised the value of a double-blinded study used to assess the detection rate of ultrasonographic screening.

Sources searched to identify primary studies
Not stated.

Criteria used to ensure the validity of primary studies
Not stated.

Methods used to judge relevance and validity, and for extracting data
Not stated.

Number of primary studies included
The authors examined approximately three studies in determining the effectiveness of ultrasonographic screening.

Method of combination of primary studies
Not stated.

Investigation of differences between studies
Not stated.

Results of the review
The sensitivity and specificity of ultrasonographic screening for all live births in Norway would result in the avoidance of 2 cases of late-detected CDH per annum over 1,000 live births.

Estimates of effectiveness based on opinion

Methods used to derive estimates of effectiveness

Authors' assumptions were also used to supply estimates of effectiveness.

Estimates of effectiveness and key assumptions
The number of investigators needed was based upon the assumption of an even distribution of investigators throughout the country.

Economic analysis

Measure of benefits used in the economic analysis
The benefit measure was the number of late-detected cases of CDH avoided per annum.

Direct costs
Direct costs were derived from hospital accounts and estimates based on resource usage and time and included: the cost of treating late-detected cases of CDH; the cost of ultrasonographic investigation which also included training costs, equipment, personnel time and cost accounting; and the cost of the utilization of hospital facilities. The costs of unnecessary treatment due to false positive results of screening were also included. Costs and quantities were analysed separately. The quantity/cost boundary adopted was the hospital. Discounting was not relevant due to the time scale of the study. Direct costs would be met by the Norwegian NHS and the price year was 1993.

Indirect costs
Not carried out.

Currency
Norwegian Kroner (NOK). The conversion rate adopted was 1 US$ = 6 NOK.

Statistical analysis of costs
Not undertaken.

Sensitivity analysis
Sensitivity analysis was not carried out.

Estimated benefits used in the economic analysis
By introducing an ultrasonographic screening programme an estimated 2.6 cases oflate-discovered CDH per annum would be avoided. The cost avoided for 2.6 fewer cases of late-discovered CHD was NOK 315,562.

Cost results
The total average cost of treatment per case of late-detected CDH was NOK 121,370. The extra cost of exchanging one clinical examination for one ultrasound examination was NOK 60. The total cost of screening plus one clinical examination was estimated to be NOK 1,650,000 and the cost of false positive over treatment was estimated to be NOK 40,000 for a total cost of NOK 1,690,000. If the clinical examinations were eliminated the extra cost of ultrasound would be NOK 285,000. Discounting was not applied. The total cost of ultrasonographic screening was NOK 1,375,438 (1,690,000 - 315,562, the cost avoided for 2.6 fewer cases of late-discovered CDH).

Synthesis of costs and benefits
The costs and benefits were combined by estimating the cost per child screened in order to avoid late-detected cases of CDH. The net cost of detecting 2.6 cases of late-detected CDH would be NOK 275 per new-born baby. As such an incremental analysis was carried out. The authors also presented the findings in terms of total screening costs minus late-detected treatment costs in monetary terms to produce an incremental cost-benefit measure.

Conclusions, commentary and implications

Author's Conclusions
The authors concluded that although ultrasonographic screening would result in fewer cases of late-detected CDH a general screening programme applied to the total population of new-born infants was not cost-effective. However, screening for those identified as being at greater risk (traumatic birth and family history of CDH) may bring additional benefits and be cost-effective. Moreover, if the screening programme adopted only ultrasonographic testing and the clinical examinations were eliminated the programme would become cost-effective.

CRD commentary
Selection of comparators:

The reason for the choice of the comparator is clear. The ultrasonographic option is a widely used screening technology. You, as a user of this database, should consider whether these are widely used health technologies in your own setting.

Validity of estimate of measure of benefit:

The estimate of measure of benefit used in the economic analysis is likely not to be internally valid. The data have not been used selectively.

Validity of estimate of costs:

Resources and costs were reported separately. Adequate details of methods of quantity/cost estimation were given. Important cost items do not appear to have been omitted.

Other issues:

The authors' conclusions are likely to be justified given the uncertainties in the data. Some confusion was evident concerning the sample size of the late-detected treatment group as the text refers to a figure of 26 but is reported in table 1 as n=16. As costings for this group were calculated on the basis of 26 patients the total figures would have been different if 16 were, in fact, the true figure. Clearly, this would have created a different outcome in terms of the comparison made with alternative screening costs. The issue of generalisability to other setting was addressed in terms of a national screening programme. For purposes of clarity the study would have benefited from presenting values for sensitivity and specificity explicitly, although it is recognised that the figures for clinical examinations would have wide variations due to differing levels of expertise. The authors argued for a centralisation of screening within large hospitals to overcome this limitation. Appropriate comparisons were made with other studies and the results were not presented selectively.

Implications of the study
The authors recommend further study to assess quality of life deterioration in cases of late-detected CDH and in patients in later stages of their lives when the condition would become more costly to treat.

Subject index terms
Subject indexing assigned by NLM:
Cost-Benefit-Analysis; Costs-and-Cost-Analysis; Health-Care-Costs; Hip-Dislocation,-Congenital/ec (economics); Hip-Dislocation,-Congenital/pc (prevention-and-control); Hip-Dislocation,-Congenital/th (therapy); Hospital-Costs; Infant; Infant,-Newborn; Norway; Referral-and-Consultation; Risk-Factors; Sensitivity-and-Specificity; Hip-Dislocation,-Congenital/us (ultrasonography); Neonatal-Screening/ec (economics) Human

Country code
Norway

Review funding body
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Address for correspondence
Dr J T Geitung MD, Department of Radiology, Ulleval University Hospital, N-0407 Oslo, Norway.

Accession number and database entry date
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Cost-effectiveness of alternative screening strategies for developmental dysplasia of the hip
Rosendahl K, Markestad T, Lie R T, Sudmann E, Geitung J T. Archives of Pediatrics & Adolescent Medicine 1995;149(6):643-648.

Health technology
Using general screening (clinical screening combined with ultrasound screening of all infants) or selective screening (clinical screening plus an ultrasound screening of infants at high risk of developing developmental dysplasia of the hip (DDH)) in the diagnosis and treatment of DDH.

Disease
Musculoskeletal diseases; Neonatal diseases and abnormalities.

Type of intervention
Screening, diagnosis and treatment.

Hypothesis/study question
The aim of the study was to assess the cost-effectiveness of using general or selective screening strategies versus routine clinical screening strategy in the diagnosis and treatment of DDH. No screening (routine clinical screening alone) was regarded as the comparator.

Economic study type
Cost-effectiveness analysis.

Study population
Newborn babies.

Setting
Hospital. The economic study was carried out in Norway.

Dates to which data relate
Effectiveness data were derived from a study published in 1994. The date to which the resource use data referred was not specified. All costs were converted to 1993 US dollars.

Source of effectiveness data
Effectiveness data were derived from a single study.

Links between effectiveness and cost data
Costing was undertaken (retrospectively) on the same patient sample as that used in the effectiveness analysis.

Single study

Study sample
There was no report of the use of power calculations to determine the sample size. 11,925 newborn babies were studied in general (n=3,613), and selective (n=4,388) ultrasound screening programmes compared with clinical screening (n=3,924) alone, to compare differences in the rates of early, borderline, and late cases of DDH. Note: members of the selective group could only undergo ultrasound examination if they had high-risk factors (e.g. breech position, close DDH family history, and dislocated/dislocatable/unstable hips upon examination).

Study design
Single-centre randomised controlled trial. Duration of follow-up was a minimum of 27 months (mean 42.4 months). Loss to follow up was not reported.

Analysis of effectiveness
The principle (intention to treat or treatment completers only) used in the analysis of effectiveness was not explicitly specified. Timing of and rates of treatment for DDH were the primary health outcomes assessed in the analysis. The rate of late subluxation and dislocation was also reported.

Effectiveness results
In comparison with infants undergoing clinical screening alone, the addition of an ultrasound examination for all infants resulted in a treatment rate of 3.4% compared to 1.8% of early DDH cases. Using ultrasound treatment on high-risk newborns only produced a treatment rate of 2%. The rate of late subluxation and dislocation for general and selective screening were 0.3 and 0.7 respectively. The corresponding rate for clinical screening alone was 1.3 per 1000 infants.

Clinical conclusions
In contrast to other investigators, this study found a higher treatment rate for those subjected to general ultrasound screening than for those subjected to selective or no screening.

Economic analysis

Measure of benefits used in the economic analysis
The benefit measure was late treatments for DDH.

Direct costs
Costs generally were not discounted (a discount rate was applied for the depreciation of ultrasound equipment). Quantities were partially reported separately from the costs. Direct health service costs were used, which included screening costs (personnel, training, equipment), with ultrasound and clinical examination time(s) obtained from a 1 month average of time sheet entries. Overhead costs (hospital administration costs, housekeeping, laundry, heat, inter-departmental resource use) were obtained from hospital accounts. Overhead costs were assumed to be the same for all three treatments. Early treatment and follow-up personnel costs were obtained from pediatric outpatient clinic time sheets. Hip ultrasound and x-ray examination costs were obtained from the department of pediatric radiology. Late diagnosis treatment costs were obtained from 24 similar cases at Hagavik Orthopaedic Hospital, as was the average patient cost of hospitalisation (from the 1991 accounts, converted into 1993 Norwegian kroner and US dollars). Retrospective personnel time was obtained from the same source. Outpatient contact costs (personnel time, departmental administration, hospital facilities) were also considered. The perspective adopted in the cost analysis was that of a health care system. All costs were expressed in 1993 dollars.

Indirect costs
Not considered.

Currency
Norwegian kroner (NKr). A conversion to US dollars was performed based on an exchange rate of $1 = Nkr7.57.

Sensitivity analysis
One-way sensitivity analysis was carried out on the discount rate for ultrasound equipment lifetime, overhead costs, hospitalisation costs, screening numbers, and the incidence of late cases of DDH. Threshold analysis was performed to identify the cut-off points.

Estimated benefits used in the economic analysis
The number of late treatments for DDH was reduced from 2.6 cases per 1000 with clinical screening to 2.1 per 1000 for selective and 1.4 per 1000 for general screening.

Cost results
The (expected) total costs of screening, follow-up, and treatment for general screening were $27.90, for no screening were $29.20, and for selective screening were $29.60 per child. The average cost of a hypothetical programme involving general screening of all girls and selective screening of 12% of boys with a special risk factor for DDH was $20.70 per infant. The discounting rate for the ultrasound equipment was 5%.

Synthesis of costs and benefits
Threshold analysis found that the general screening programme had a net economic benefit if average per diem costs for late treatment exceeded $343.50, or the annual number of deliveries exceeded 3500, or the incidence of late cases exceeded 3.6 per 1000 infants.

Conclusions, commentary and implications

Author's Conclusions
Application of costs from other centres to this study's data regarding frequency of clinical outcomes may yield different comparative programme costs. If the findings of this clinical study can be generalised to other centres, a strategy of screening all girls and boys with risk factors for DDH may be the most cost-effective approach.

CRD commentary
Selection of comparators:

The reason for the choice of the comparator is clear.

Validity of estimate of measure of benefit:

The estimate of benefit is likely to be internally valid given the use of a randomised controlled trial.

Validity of estimate of costs:

Resource use data were partially reported separately from the costs and adequate details of methods of cost estimation were given.

Subject index terms
Subject indexing assigned by NLM:
Follow-Up-Studies; Infant,-Newborn; Cost-Benefit-Analysis; Health-Care-Costs; Hip-Dislocation,-Congenital/di (diagnosis); Hip-Dislocation,-Congenital/su (surgery); Ultrasonography/ec (economics); Comparative-Study; Female; Human; Male; Support,-Non-U.S.-Gov't

Country code
Norway

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Address for correspondence
Dr K Rosendahl MD, Department of Pediatric Radiology, Haukeland Sykehus, 5021 Bergen, Norway.

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Financial justification for routine ultrasound screening of the neonatal hip
Clegg J, Bache C E, Raut V V. Journal of Bone & Joint Surgery - British Volume 1999;81B(5):852-857.

Health technology
Routine ultrasound screening for developmental dysplasia of the hip (DDH).

Disease
Musculoskeletal diseases; Neonatal diseases and abnormalities.

Type of intervention
Screening.

Hypothesis/study question
The objective of the study was to analyse the patterns of management of DDH using three different screening policies: clinical examination alone, introduction of ultrasound screening for infants with known risk factors; and routine ultrasound scanning for all infants at birth. The reason for the choice of the comparators is clear, as these screening policies were widely used in the authors' setting.

Economic study type
Cost-effectiveness analysis.

Study population
New-born babies.

Setting
Secondary care. The economic study was conducted in Coventry, UK.

Dates to which data relate
Effectiveness and cost data were collected between 1976 and 1996. The authors stated that all costs were estimated at present-date prices, but the price date was not reported.

Source of effectiveness data
Effectiveness data were derived from a single study.

Links between effectiveness and cost data
Costing was undertaken retrospectively on the same patient sample as that used in the effectiveness analysis.

Single study

Study sample
All children born in Coventry between 1976 and 1996 were included in the analysis. The following groups were investigated:

group A, born between 1976 and 1986, when a routine programme of clinical screening for DDH was followed, comprising examination at birth by a paediatrician, further examination after discharge by a GP and weekly review in the Orthopaedic Baby Clinic for the babies 'at-risk';

group B, born between 1986 and May 1989, ultrasonograhic assessment of the hip in addition to clinical examination for all infants within the 'at-risk' categories and those with clinical abnormality of the hip; and

group C, born between June 1989 and 1996, routine ultrasound screening in addition to the statutory clinical examination.

Power calculations were not used to determine sample size.

Study design
This was a non-randomised trial with historical controls, carried out in Coventry. Neither the length of follow up nor any loss to follow up was reported.

Analysis of effectiveness
The analysis appears to have been based on treatment completers only. The main health outcomes used in the analysis were: incidence of abnormality, success rate for treatment with Pavlick harness, number of patients treated surgically, number of theatre sessions per case and percentage of procedures requiring hospital admission.

Effectiveness results
There were 65 patients with DDH in group A, 19 patients in group B and 19 patients in group C.

After the introduction of routine screening (group C), the incidence of abnormality in first scans was 7.3%. The rate decreased to 0.4% by six weeks, which equates to 129 patients in the 7.5 year period until the end of 1996. In all but 19 patients (0.06% of the total), subsequent treatment in a Pavlick harness was successful.

The mean number of patients treated surgically per year declined from 6.5 (group A) to 5.4 (group B) and 2.5 (group C).

The number of theatre sessions per case fell from 2.8 (group A) to 2.1 (group B) and then 1.8 (group C).

The percentage of procedures requiring hospital admission was 47% in group A, 61% in group B and 9% in group C, with only two major procedures performed in the 7.5 years from June 1989 to December 1996.

Clinical conclusions
If DDH is identified early it can be treated conservatively by gentle abduction of the hips by a simple brace. If the diagnosis is delayed, the infant will usually require surgical treatment. Routine scanning for DDH of infants at birth resulted in earlier detection of DDH and fewer children needing surgery.

Economic analysis

Measure of benefits used in the economic analysis
The authors did not provide a summary measure of benefit. As such, the study may be regarded as a cost consequences analysis and the health benefits equate to the health outcomes reported above.

Direct costs
Direct hospital costs were considered namely: cost of hospital admission (including fixed costs), surgical implant (Coventry screw and plate), radiological services and contrast material, blood, cost of non-operative treatment using Pavlick harness. The cost of ultrasonographers and equipment for one screening session in the outpatient clinic was also considered. Procedures were assessed in terms of units of operating theatre time, consumables such as implants and blood. Quantities and costs were analysed separately. Costs were not discounted as they were incurred in a short period of time.

Indirect costs
Not considered.

Currency
UK pounds sterling (£).

Statistical analysis of costs
Not performed.

Sensitivity analysis
Not performed.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The final overall cost for group A was £22,188 per year, for group B it was £21,837 and for group C, £26,564. The average annual cost of treatment in group A was £5,110, for group B it was £3,811, and for group C, £468 per 1000 live births.

Synthesis of costs and benefits
This was not applicable due to the cost-consequences approach adopted.

Conclusions, commentary and implications

Author's Conclusions
When the cost of running the screening programme is added to the expense of treating DDH, the overall cost for the management of DDH is comparable for the different screening policies.

CRD commentary
Selection of comparators:

The reason for the choice of the comparators is clear as all three screening policies (clinical examination alone, introduction of ultrasound screening for infants with known risk factors and routine ultrasound scanning for all infants at birth) were used in the authors' setting. You, as a database user, should consider if this applies to your own setting.

Validity of estimate of measure of benefit:

The authors did not provide a summary measure of benefit and hence, conducted a cost consequences analysis. The retrospective nature of the study design may have introduced biases. With the exception of age, groups were not shown to be comparable in terms of baseline characteristics. No power calculations related to the sample size were reported.

Validity of estimate of costs:

The analysis of costs is presented in detail, but costs were not analysed statistically. Indirect costs were not considered in the analysis.

Other issues:

Costs may not be generalisable outside the UK NHS. Appropriate comparisons with costs from other NHS centres and other health systems were made.

Implications of the study
Further investigation is needed in order to assess the long-term savings which would occur by reducing the risk of developing arthritis secondary to acetabular dysplasia or the cost of litigation from missed cases.

Subject index terms
Subject indexing assigned by NLM:
Blood-Transfusion/ec (economics); Bone-Screws/ec (economics); Contrast-Media/ec (economics); Cost-Control; Great-Britain; Hip-Dislocation,-Congenital/th (therapy); Hospitalization/ec (economics); Infant,-Newborn; Osteotomy/ec (economics); Hip-Dislocation,-Congenital/ec (economics); Hip-Dislocation,-Congenital/us (ultrasonography); Neonatal-Screening/ec (economics); Ultrasonography/ec (economics); Human

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Address for correspondence
Mr C E Bache, 109 Wood Lane, Harborne, Birmingham B17 9AY, UK.

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Cost-effectiveness of ultrasound screening for developmental dysplasia of the hip
Roovers E A, Boere-Boonekamp M M, Adang E M, Castelein R M, Zielhuis G A, Kerkhoff A H. Enschede, The Netherlands: University of Twente 200468-77.

This record was compiled by CRD commissioned reviewers according to a set of guidelines developed in collaboration with a group of leading health economists.

Health technology
Three screening strategies for developmental dysplasia of the hip (DDH) were examined:

general ultrasound screening at the age of 3 months;

selective ultrasound screening at the age of 3 months, when only infants with recognised risk factors (breech position or a family history of DDH in first- or second-degree relatives) or abnormal results on physical examination of the hip were screened; and

current screening policy for DDH in the Netherlands. This was based on repeated physical examination of the infant hip and risk factors in the first months of life, and was performed as part of the child health care (CHC) programme.

Both ultrasound screening strategies used the Graf's sonographic method.

Disease
Neonatal diseases and abnormalities; Musculoskeletal diseases.

Type of intervention
Screening.

Hypothesis/study question
The objective of the study was to compare the cost-effectiveness of general ultrasound screening, selective ultrasound screening, and current screening for DDH in the Netherlands. On the basis of prior results the authors hypothesised that, although initially more costly, the implementation of general ultrasound screening could lead to substantial cost-savings due to the significantly lower referral rate than the actual screening strategy. The study was conducted from a societal perspective.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised the general cohort of infants in their first months of life.

Setting
The setting was CHC centres (primary care). The economic study was carried out in the Netherlands.

Dates to which data relate
The dates to which the effectiveness and resource use data related were not reported. The price year was 2002.

Source of effectiveness data
The effectiveness evidence was derived from completed studies.

Modelling
A decision tree model was used to evaluate the costs and clinical outcomes of the three screening strategies. Details of the model were not reported.

Review/synthesis of previously published studies

Outcomes assessed in the review
The health outcomes assessed from the primary studies were the incidence of DDH in the Netherlands and the probability values for:

true cases of DDH,

missed cases,

infants treated by the CHC physician,

infants screened by ultrasound,

referral for specialist consultation, and

early treatment given a positive screening result.

Study designs and other criteria for inclusion in the review
A formal review of the literature was not carried out. The authors stated that one of the primary studies was a large prospective study (the Soundchec study) that involved 5,170 infants screened by ultrasound.

Sources searched to identify primary studies
Not stated.

Criteria used to ensure the validity of primary studies
Not stated.

Methods used to judge relevance and validity, and for extracting data
Not stated.

Number of primary studies included
The effectiveness evidence came from 2 primary studies.

Method of combination of primary studies
Not stated.

Investigation of differences between studies
Not stated.

Results of the review
The incidence of DDH in the Netherlands was 3.7%.

The probability values were:

for true cases of DDH, 3.1% for general ultrasound screening, 2.4 for selective ultrasound screening and 2.8% for CHC screening;

for missed cases of DDH, 0.006 for general ultrasound screening, 0.013 for selective ultrasound screening and 0.009 for CHC screening;

for infants treated by the CHC physician, 0.33 for general ultrasound screening, 1 for selective ultrasound screening and 1 for CHC screening;

for infants screened by ultrasound, 1 for general ultrasound screening and 0.192 for selective ultrasound screening (NA for CHC screening);

for referral for specialist consultation, 0.045 for general ultrasound screening, 0.030 for selective ultrasound screening and 0.192 for CHC screening; and

for early treatment given a positive screening result, 0.711 for general ultrasound screening,

0.8 for selective ultrasound screening and 0.146 for CHC screening.

Economic analysis

Measure of benefits used in the economic analysis

The summary benefit measure used in the economic evaluation was the proportion of screen-detected cases of DDH. This was obtained from the decision tree.

Direct costs

Discounting was irrelevant since the costs per patient were incurred during a short time. The unit costs were presented separately from the quantities of resources used. The health services included in the economic evaluation were ultrasound examination (personnel, training, equipment and consumables), medical costs (diagnostic imaging and treatment of DDH) and travel expenses. A breakdown of the costs was provided. The cost/resource boundary adopted in the study reflected the societal perspective. The equipment costs were calculated using a depreciation method based on annuities with a discount rate of 4.5%. It was assumed that the equipment had an economic lifetime of 5 years and the costs of maintenance were 8% of the purchase price. Most of the resource use and cost data came from the Soundchec study and authors' and experts' assumptions. The Dutch guideline prices were also used for medical costs and travel expenses. Distances were based on prior studies. All the costs were adjusted to 2002 values using the consumer price index.

Indirect costs

The indirect costs were included in the economic evaluation to reflect the societal perspective adopted in the study. The unit costs were not reported, although the authors stated that the patients' time was valued according to Dutch guidelines. However, the method used was not reported. The quantity of time spent for screening examination, visits and overnight hospitalisation was estimated using authors' assumptions. The price year was likely to have been 2002.

Currency

Euro (Euro).

Statistical analysis of costs

The costs were treated deterministically.

Sensitivity analysis

One-way sensitivity analyses were carried out. These assessed the impact of changes in the costs of ultrasound screening, CHC screening and diagnostic imaging in hospital, treatment costs of true-positive infants, patient costs, and the incidence of DDH. The authors stated that plausible changes were made.

Estimated benefits used in the economic analysis

The proportion of screen-detected cases of DDH was 2.4% for selective ultrasound screening, 2.8% for CHC screening and 3.1% for general ultrasound screening.

Cost results

The total cost per child screened was Euro 52.1 with selective ultrasound screening, Euro 82 with CHC screening and Euro 70.6 with general ultrasound screening.

Synthesis of costs and benefits

Average and incremental cost-effectiveness ratios were calculated to combine the costs and benefits of the screening strategies. The average cost per screen detected case of DDH was Euro 2,171 with selective ultrasound screening, Euro 2,929 with CHC screening and Euro 2,278 with general ultrasound screening. CHC screening was dominated by general ultrasound screening, which in turn offered a cost of Euro 2,646 per additional case of DDH detected.

The sensitivity analysis showed that the ranking of the alternative screening strategy did not change when key inputs were varied, the CHC strategy was always dominated by the general ultrasound strategy. The incremental cost-effectiveness ratio of general versus

selective ultrasound screening ranged from Euro 2,388 to Euro 4,526. Only when patient costs were excluded (and a health care system perspective was adopted), was the general ultrasound screening strategy the overall dominant cost-effective option, with an average cost-effectiveness ratio of Euro 1,804 per infant detected.

Conclusions, commentary and implications

Author's Conclusions
General ultrasound screening represented a cost-effective strategy for the detection of developmental dysplasia of the hip (DDH) in the Netherlands. It dominated all other alternative screening options if it were assumed that the patients were willing to pay for the additional time required to attend outpatient visits and screening procedures.

CRD commentary
Selection of comparators:

The authors justified their choice of the comparators. Universal ultrasound screening was the strategy under evaluation, which had been shown to be cost-effective in other countries such as Austria, Germany and Switzerland. CHC screening represented the strategy currently implemented in the Netherlands. Selective ultrasound screening was considered as a further comparator because it was unclear from earlier analyses whether it could be more efficient than universal screening. Overall, it appears that all feasible screening alternatives have been considered in the study. You should decide whether they represent valid comparators in your own setting.

Validity of estimate of measure of effectiveness:

The analysis of effectiveness used data derived from published studies, but it is unclear whether a systematic review of the literature was carried out. Details of the primary studies were not provided and it is not obvious whether the authors also made some assumptions. Therefore, since the sources of the effectiveness evidence were not reported satisfactorily, it is difficult to assess the validity and reliability of the data used in the analysis.

Validity of estimate of measure of benefit:

The benefit measure used in the analysis represents a disease-specific measure that was calculated using a decision tree model. The model was not described and the structure of the tree was not depicted. Hence, the patterns of care under each strategy were unclear. The use of the number of detected cases does nothing to facilitate comparisons with the benefit measure used for other health care interventions.

Validity of estimate of costs:

The perspective adopted in the study was explicitly stated. It was the most appropriate as it also included patient costs. A breakdown of the costs was provided, and both resource use and unit cost data were reported for most of the direct costs included in the economic evaluation. The indirect costs were estimated from Dutch guidelines, which were also used to estimate some other medical costs. The price year was reported, thus simplifying reflation exercises in other settings. The cost estimates were specific to the study setting, but the transferability of the results was enhanced by the sensitivity analyses conducted on most key economic parameters. Experts' assumptions were also used for resource use data.

Other issues:

The authors did not make extensive comparisons of their findings with those from other studies. In terms of the generalisability of the study results to other settings, the authors stated that their conclusions were applicable only to countries with characteristics similar to those observed in the Netherlands. However, the CHC programme represented quite a unique system with nearly complete attendance of all infants. Sensitivity analyses were carried out to assess the robustness of the study results to variations in the parameters

used. Some limitations to the validity of the study were reported. The long-term costs and effects were not considered and the authors stated that their inclusion would have favoured the general ultrasound screening strategy. The rate of participation represented a critical variable, but the authors expected near complete participation if ultrasound screening were included in the actual CHC programme.

Implications of the study
The study results suggested that general ultrasound screening for DDH represents a cost-effective strategy. Policy-makers should devote more attention to the identification of effective and efficient screening options for infants.

Subject index terms
Subject indexing assigned by CRD:
Hip-Dislocation,-Congenital/us (ultrasonography); Hip-Dislocation,-Congenital/ep (epidemiology); Hip-Dislocation,-Congenital/ec (economics); Hip-Joint/us (ultrasonography); Mass-Screening; Costs-and-Cost-Analysis; Human; Infant

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APPENDIX 8: LIST OF EXCLUDED REFERENCES

REFERENCE/STUDY	REASON FOR EXCLUSION
Abril JC, Berjano P, Diaz A. Concordance between hip ultrasonography and hip arthrography in the assessment of developmental dysplasia of the hip. *J Pediatr Orthop B* 1999;8(4):264-7.	Not general newborn screening
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Anderssen SH, Silberg IE, Soukup M, Andersen AE. Medfodt hofteleddsdysplasi i ostfold 1990 96. (Congenital hip dysplasia in Ostfold 1990-96. *Tidsskr Nor Laegeforen* 2000;120(29):3530-3.	Not general newborn screening
Ang KC, Lee EH, Lee PYC, Tan KL. An epidemiological study of developmental dysplasia of the hip in infants in Singapore. *Annals Academy of Medicine Singapore* 1997;26(4):456-458.	Not general newborn screening
Bennet GC. Screening for congenital dislocation of the hip. *J-Bone-Jt-Surg-Ser-B* 1992;74(5):643-644.	Editorial
Benez C, Lechevallier J, Abuamara S, Durand C, Cunin V, Lefort J, et al. Failure of primary management of developmental dislocation of the hip: 31 years experience in Normandy. *Rev Chir Orthop Reparatrice Appar Mot* 2003;89:228-233.	Not general newborn screening
Bensahel H, Themar Noel C, Legmann P, Bourillon A, Levesque M, De Pailleres F. (Etude del'echographie de hanches dans la maladie luxante du nouveau-ne et du nourrisson) Ultrasound imaging of hip in neonates and infants with congenital dislocation of hip. *Chirurgie* 1985;111(8):688 691.	Technical report of ultrasound techniques only
Bialik V, Berant M. "Immunity" of Ethiopian Jews to developmental dysplasia of the hip: a preliminary sonographic study. *J Pediatr Orthop B* 1997;6(4):253-4.	Not relevant
Bialik V, Reuveni A, Pery M, Fishman J. Ultrasonography in developmental displacement of the hip: a critical analysis of our results. *J Pediatr Orthop* 1989;9(2):154-6.	Not general newborn screening
Bialik V, Reuveni A, Pery M, Fishman J. Ultrasonography and screening in developmental displacement of the hip. *J Pedaitr orthop B* 1992;1:51 54.	Not general screening population
Bialik V, Wiener F. Sonography of Suspected Developmental Dysplasia of the Hip - a Description of 3,624 Hips. *J. Pediatr. Orthop.-Part B* 1993;2(2):152-155.	Not general newborn screening
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Boeree NR, Clarke NM. Ultrasound imaging and secondary screening for congenital dislocation of the hip. *J Bone Joint Surg Br* 1994;76(4):525 33.	Not general newborn screening
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Bossi MC, Merlo M, Fusco U. Sonographic examination in the infant hip dysplasia. Method and results. *Minerva-Ortop-Traumatol* 1991;42(78):337-341.	Not general newborn screening
Bowe JLEJ. Ultrasonography helpful in diagnosing developmental hip dysplasia. *J Fam Pract* 2003;52:355	Not original puplication.
Bralic I, Vrdoljak J, Kovacic L. Ultrasound screening of the neonatal hip: Cost-benefit analysis. *Croatian Medical Journal* 2001;42(2):171-174.	Cost study not economic evaluation
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Burger BJ, Burger JD, Bos CFA, Obermann WR, Rozing PM, Vandenbroucke JP. Neonatal Screening and Staggered Early Treatment for Congenital Dislocation or Dysplasia of the Hip. *The Lancet* 1990;336(8730):1549-1553.	No ultrasound
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Davids JR, Benson LJ, Mubarak SJ, McNeil N. Ultrasonography and Developmental Dysplasia of the Hip: A Cost-Benefit Analysis of Three Delivery Systems. *Journal of Pediatric Orthopaedics* 1995;15(3):325 329.	Economic but not of screening
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APPENDIX 9: GRAF'S CLASSIFICATION OF ULTRASONOGRAPHIC HIP TYPES

Graf's classification of ultrasonographic hip types (Taken from[1])

HIP TYPE	OSSEOUS ROOF CONTOUR	SUPERIOR OSSEOUS RIM	CARTILAGINOUS RIM	OSSEOUS ROOF: α ANGLE (degrees)	CARTILAGINOUS ROOF: β ANGLE (degrees)
Fully mature (any age)					
Ia	Good	Angular	Narrow: triangular; covers femoral head	≥ 60	< 55
Ib	Good	Usually slightly rounded (blunt)	Wide-based: short; covers femoral head	≥ 60	> 55
IIa+: physiological delay of ossification appropriate for age (before age of 3 mos.)	Adequate	Round	Wide: covers femoral head	50-59	> 55
IIa: physiological delay of ossification with maturity deficit (before age of 3 mos.)	Deficient	Round	Wide: covers femoral head	50-59	
IIb: delay of ossification after age of 3 mos.	Deficient	Round	Wide: covers femoral head	50-59	> 55
IIc: critical range (any age)		Round to flat	Wide: still covers femoral head	43-49 (critical range)	70-77
D: decentering (any age)	Severely deficient	Round to flat	Displaced	43-49 (critical range)	> 77 (decentering range)
Eccentric IIIa	Poor	Flat	Displaced, without structural alteration	< 43	> 77
IIIb	Poor	Flat	Displaced, with structural alteration	< 43	> 77
IV	Poor	Flat	Displaced inferomedially	< 43	> 77