i)Title:

Quality management of nuchal translucency ultrasound measurement in Australia.

ii)Authors:

Debbie NISBET^{1,2,3}

Ann ROBERTSON⁴

Blessy MANNIL⁴

Vanessa PINCHAM⁵

Andrew MCLENNAN^{5,6}

1. Pauline Gandel Women's Imaging Centre, Ultrasound Department, The Royal Women's Hospital, Parkville, Victoria, Australia.

2. Women's Ultrasound Melbourne, East Melbourne, Victoria, Australia.

3. University of Melbourne, Department of Medicine and Radiology, Melbourne, Victoria, Australia

4. Royal Australian and New Zealand College of Obstetricians and Gynaecologists, East Melbourne, Victoria, Australia

5. Sydney Ultrasound for Women, Sydney, New South Wales, Australia

6. Faculty of Medicine, Sydney University, Sydney, New South Wales, Australia

iiia) Author positions and institutional addresses:

Debbie NISBET

Deputy Director, Ultrasound Department. Pauline Gandel Women's Imaging Centre. The Royal Women's Hospital, Level 1, 20 Flemington Road, Parkville, Victoria 3052, Australia.

Sonologist. Women's Ultrasound Melbourne, 6/320 Victoria Parade, East Melbourne, Victoria, Australia.

Honorary Fellow. University of Melbourne, Department of Medicine and Radiology, Melbourne, Victoria, Australia.

This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the [Version of Record](#). Please cite this article as [doi: 10.1111/ajo.12792](https://doi.org/10.1111/ajo.12792)

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Email: Debbie.Nisbet@thewomens.org.au

Ann ROBERTSON

Manager Women's Health and Special Projects. Royal Australian and New Zealand College of Obstetricians and Gynaecologists, 254 Albert Street, East Melbourne, Victoria, Australia. (Now retired).

Email: grevillia@gmail.com

Blessy MANNIL

Senior Coordinator Nuchal Translucency Ultrasound, Education and Monitoring Program (NTUEMP). Royal Australian and New Zealand College of Obstetricians and Gynaecologists, 254 Albert Street, East Melbourne, Victoria, Australia.

Email: itsbless@gmail.com

Vanessa PINCHAM

Sonographer; Clinical Coordinator Training and Quality Assurance.

Sydney Ultrasound for Women, 47 York Street, Sydney, New South Wales, Australia

Email: vpincham@sufw.com.au

Andrew MCLENNAN

Sonologist. Sydney Ultrasound for Women, 47 York Street, Sydney, New South Wales, Australia

Clinical Associate Professor, Sydney Medical School – Northern, University of Sydney, Sydney, New South Wales, Australia

Email: AMcLennan@sufw.com.au

iii) Corresponding Author:

Dr Debbie NISBET. Ultrasound Department. Pauline Gandel Women's Imaging Centre. The Royal Women's Hospital, Level 1, 20 Flemington Road, Parkville, Victoria 3052, Australia.

Phone: +61 3 8345 2284 Fax: +61 3 8345 2259 Email: Debbie.Nisbet@thewomens.org.au

Optional author for correspondence:

Dr Andrew McLennan. Sydney Ultrasound for Women, 47 York Street, Sydney, New South Wales, Australia.

Phone +61 2 9290 2122 Email: AMcLennan@sufw.com.au

iv) Acknowledgements:

There was no funding for this project.

We would like to acknowledge the administrative support provided by RANZCOG NTUEMP staff.

Article type : Original Manuscript

i) Title:

Quality management of nuchal translucency ultrasound measurement in Australia.

ii) Short Title:

Improving nuchal translucency measurement quality.

iii) Word Count:

Abstract: 249

Main text: 2237

Table and Figure count:

Table: 1

Figures: 2

iv) Keywords:

Ultrasound; nuchal translucency; audit; quality assurance; teleconference

Abstract

Background: Nuchal translucency measurement has an established role in first trimester screening. Accurate measurement requires that technical guidelines are followed. Performance can be monitored by auditing the distribution of measurements obtained in a series of cases.

Aims: The primary aim is to develop an accessible, theory-based educational program for individuals whose distribution of measurements at audit falls outside an acceptable range and assess operator performance following this intervention.

Materials and Methods: Operators whose nuchal translucency measurement distributions fall outside a normal range (38 - 65% above the median) were expected to undergo a teleconference tutorial. Accessible from anywhere in Australia, the 1 hour tutorials were run by a senior sonographer (to explain technical ultrasound aspects) and the audit program manager (to explain the audit process).

Results: In 2011, 83 operators attended the teleconference tutorials. Compared to a random comparison group of operators meeting standard in 2011, teleconference tutorial attendees were significantly more likely to i) operate in rural or regional, rather than metropolitan, centres [$p=0.001$], ii) be less experienced [$p<0.0005$] and iii) have lower annual scan numbers [$p=0.0012$]. Improvement in nuchal translucency measurement quality was seen after one audit cycle and was maintained over subsequent years. The mean percentage of the study cohort reaching standard over the 5-year audit was 77.8% which was not statistically different from the average for the comparison cohort of all other audited operators (79.3%; $p=0.61$).

Conclusions: Teleconference tutorials are a convenient, accessible and effective way to obtain immediate and sustained improvement in operator performance.

Introduction

First trimester combined screening using a combination of ultrasound and biochemistry has an established role in obstetric practice in screening for Down syndrome.¹ To provide accurate information standardised measurement of the nuchal translucency (NT) together with quality control of the biochemical parameters, pregnancy associated protein A (PAPP-A) and free beta human chorionic gonadotrophin (free bHCG) is required.² Central to screening success is training of operators, use of a standardised technique to measure the NT, and continuous audit of clinical practice.³ In Australia the Nuchal Translucency Ultrasound, Education and Monitoring Program (NTUEMP) manages this process, following the principles of the Fetal Medicine Foundation, UK (FMF).

The audit cycle allows for timely interventions and quality improvement when systematic problems exist across a range of industries, including health care.^{4,5} The audit cycle involves defining a standard that can be used as a benchmark, assessment of a practitioner's work against that standard, determining areas of work that need improvement, acting on these findings, and then re-auditing to assess if improvement has occurred.⁶ NT measurement lends itself well to audit as measurements follow a clearly described

distribution⁷ and images are obtained using internationally standardised guidelines allowing for the development of scoring systems.^{8,9}

Certification in NT measurement in Australia follows successful completion of an on-line educational course with tutor support and assessment of NT images. Educational material is available to operators through the NTUEMP and FMF websites and newsletters. Through the supplied FMF software, operators are able to perform self audit to monitor their performance. Operators (sonographers and sonologists performing the NT scan) undergo formal annual audit of the distribution of their NT measurements, and of image quality. For the purpose of audit, the NTUEMP defines an appropriate distribution as 38 – 65% of the measurements being above the gestation-related median. Operators' distributions are not audited if they perform under 30 scans due to the inaccuracy associated with small sample sizes. Operators submit 3 images for audit which are scored by trained assessors using the criteria image size, sagittal section, head position, caliper placement, thickest area of the NT, and nuchal membrane. To pass their image assessment, operators need to pass at least 4 criteria for all images. An operator can fail to reach the auditable standard by failing to have an appropriate distribution of measurements, by failing the image assessment, or both.

Following the lead of the FMF, a decision was made to de-list operators who fail to reach standard from the NTUEMP website, and to ultimately cancel the software licence of operators persistently not reaching an appropriate standard. The goal of the audit cycle is to be educative, rather than punitive, and an intervention to assist these operators improve their performance and maintain their certification was instituted in 2011. Teleconference tutorials (TT) were initiated to provide practical and theoretical education and support. In developing the teleconference tutorial, barriers to operator improvement and to operator attendance at educational workshops were considered. A lack of peer support resulting from operator remoteness and isolation was addressed by making the educational activity an e-learning experience.

The aims of this research are primarily to assess the effectiveness of an intervention in helping under-performing operators to achieve an appropriate standard and secondarily to assess the demographics of the group undergoing TT to identify common themes that may be addressed pro-actively.

Materials and Methods

Study Design:

This was a retrospective, repeated measures, cohort study.

Participants:

Operators performing 30 or more scans and failing to reach the auditable standard (38 – 65% of nuchal translucency measurements above the 50th centile) in consecutive years (2010-2011) were instructed to undertake a teleconference tutorial.

Procedure:

The intervention involved a single 1 hour teleconference tutorial (TT) run by two tutors using desktop-sharing software (GoToMeeting – Citrix).¹⁰ One tutor was a sonographer experienced in NT education, who provided an in-depth technical discussion regarding performance of the NT scan. Practice tips and methods for dealing with difficult imaging or particular clinical situations were discussed and queries addressed. The second tutor was the program manager, who described the concept of audit and how measurement accuracy was crucial to screening efficiency, how performance is measured, and how the first trimester screening software calculates the risk of Down syndrome and other chromosome anomalies. This tutor conducted a demonstration tour of the risk assessment software including data entry, self-audit, and the inbuilt messages available on each screen to address difficulties and provide ongoing support. Tutorials were conducted twice per month and run at flexible times to suit operators needs and allow for time differences within Australia. Discussion was kept informal and supportive, and tutors used positive terminology.

Data collection:

Operator performance and overall program performance from 2011 (the year of the intervention) to 2016 were assessed using the NTUEMP (AUNTs) software developed in collaboration with the Fetal Medicine Foundation, UK (<https://fetalmedicine.org>). Demographic and experiential differences between the group undergoing teleconference tutorial and other operators were considered. Data was collected from the group undergoing the TT and a 2 for 1 comparison group of operators was selected using a random number generator based on the operator ID number.¹¹ Data was transferred to Excel® spreadsheets (Microsoft, Redmond, WA, USA) for management and graphical manipulation.

Statistical Analysis:

Descriptive statistical analysis was conducted on the entire cohort of operators. Separate subgroup analysis was performed on those operators by state, by rural versus urban¹² location, by mean number of annual NT scans, and by prior operator experience. Categorical variables are presented as numbers and percentages. Comparison of proportions using chi squared tests were derived from MedCalc (www.medcalc.org; Ostend, Belgium). A p-value of 0.05 defined the level of significance.

Ethical Clearance:

As this was a clinical audit of operator performance that did not identify patients directly and did not seek pregnancy outcome information, patient consent was not required. The study involved de-identified personnel voluntarily submitting their data for analysis and quality assurance purposes, thus ethical clearance was not required (NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities 2014).¹³

Results

In 2011, there were 1007 certified operators registered with the NTUEMP, working from 313 centres around Australia, who performed 155,768 first trimester nuchal translucency examinations. Of these certified operators, 865 submitted images and data to the NTUEMP for audit and the remainder were exempt (scanning less than 30 patients in the preceding 12 months or on extended leave). From this cohort, 270 operators (31.2%) failed to meet standard, 107 of them for a second consecutive year and the latter group were invited to attend a teleconference tutorial (TT).

The study cohort is comprised of 83 operators who attended a TT in 2011. They represented 9.6% of all audited operators and between them performed 12,985 scans (or 8.3% of all scans in 2011). Of the remaining 24 operators who did not attend a TT in 2011, 18 did so in subsequent years (but do not appear in this study cohort) and 6 ceased to be certified.

The majority (80/83; 96.4%) of the study cohort failed to meet standard due to systematic under-measurement (range 8-37% of NT measurements above the 50th percentile). Compared to a randomly selected control group of 166 operators who reached standard in 2011, the TT attendees were significantly more likely to i) operate in rural or regional, rather than metropolitan, centres [$p=0.001$], ii) be less experienced [$p<0.0005$] and iii) have lower annual scan numbers [$p=0.0012$]. These comparisons are detailed in Table 1.

**** Table 1 here ****

The geographic distribution by State of the study cohort generally reflected the overall distribution of certified operators, other than for Western Australia where 12.0% of the operators practiced but that State only contributed 3.6% of the TT attendees (but the difference did not reach statistical significance [$p=0.65$]). Analysis of the operator NT measurement distributions for this State revealed failure to meet standard in 17/94 (18.1%) in 2011, matching the national average, thus the operators in WA were less likely to attend a TT rather than being superior operators.

The annual audit performance of the study cohort was tracked over the next 5 years. There was a substantial and sustained improvement in overall performance over that time, as depicted in Figure 1.

**** Figure 1 here ****

Importantly, with respect to reducing the false negative risk of screening, the average percentage of the TT attendees with less than 38% of NT measurements above the median continued to fall over the next 5 years (from 20% in 2012, to 7% in 2016). The mean percentage of the study cohort reaching standard over the 5-year audit was 77.8% which was not statistically different from the average for the comparison cohort of all other audited operators (79.3%; $p=0.61$). The biennial comparison of operators reaching standard is depicted in Figure 2. It is important to note that there were subtle differences in the cohort from year to year as some individuals changed status (extended leave or low scan numbers) and were exempt from audit.

**** Figure 2 here ****

A total of 30 (36.1%) operators from the study cohort underwent one or more subsequent TTs, 13 electively despite an appropriate distribution and 17 after failing to reach the auditable standard in a subsequent year(s). In 3 of the 17 cases, improvement to an appropriate distribution was not obtained until after a second TT. In 14 cases at least one further TT was required when an initial improvement in standard was not maintained. Three operators ultimately had their licenses revoked.

Discussion

The main findings of this study are firstly, that the cohort undertaking the intervention were significantly more likely to be rural operators, with shorter prior NT scanning experience, performing fewer NT scans than the comparison group and secondly, that a single targeted teleconference tutorial produced a substantial and sustained improvement in overall NT measurement performance.

Clinical audit is an important component of clinical governance which aims to ensure patients receive optimal care.¹⁴ It should be a transparent process that aims to be educational, supportive and non-judgemental. This program exemplifies these tenets with the intervention being simple, educative and ultimately very successful in improving NT measurement performance. Maintaining standard is vital, as it has been clearly shown that inaccurate NT measurement has a negative impact on screening accuracy. Systematic under-measurement of -0.4mm reduces the trisomy 21 detection rate by 6% and over-measurement of +0.4mm increases the screen positive rate by 4%.¹⁵ One approach to dealing with under-measurement that is in use in some Australian laboratories is to produce operator-specific NT medians.¹⁶ However, this approach of attempting to mathematically correct systematic measurement error has not been demonstrated to improve screening accuracy, supporting adherence to appropriate training and standardized measurement guidelines.¹⁵

The findings from this study highlight the need to provide additional support to newly certified operators and those in regional, rural and remote communities. This support could be in the form of individual mentoring (similar to the Screening Support Sonographer operating in the UK)¹⁷, along with more frequent audit and oversight of screening outcomes. It is important that the program is inclusive, so that operators can be monitored rather than acting alone with no guidance. One-third of Australians live outside a Capital City,¹⁸ as do 32% of the certified operators. Health outcomes are often poorer in rural and remote regions due to a variety of socio-demographic factors.¹⁹ Inequity of access to prenatal screening and diagnosis services has been noted in Western Australia, with those living in remote areas least likely to undergo Down syndrome screening.²⁰ Whilst no formal studies have been conducted in Australia, screening accuracy may be poorer in rural and remote areas (with increased false negative and false positive results), particularly in light of the over-representation of non-urban operators requiring intervention in the current study. Formal annual audit is necessarily a retrospective process that is not geared to early identification of systematic errors. In addition to regular self-audit through the risk assessment program, another useful tool is the cumulative sum control chart as a sequential analysis technique monitoring for change detection, as has been successfully applied to first trimester Doppler measurement of uterine artery pulsatility index, allowing timely intervention to improve operator performance.²¹

The strength of this study is the long follow-up of the cohort and, for the first time in Australia, clear identification of the sub-group of operators most at risk of failing to meet standard and to require more intensive support. There are a number of possible weaknesses that may influence the analysis. One is the variation in composition of the TT cohort as some operators were exempt from audit in subsequent years due to low scan numbers or extended leave. Secondly, there was general improvement in operator performance across the board over that 5-year period and operators who failed to meet standard in 2011 and did not attend a TT may have shown improvement in subsequent years without intervention. Thirdly, some operators in the original TT cohort attended a second TT during this 5-year period and this additional intervention was not analysed separately.

In conclusion, a single, simple teleconference tutorial has been shown to lead to a substantial and sustained improvement in NT measurement quality, which should improve the overall accuracy of first trimester aneuploidy screening. The group of operators at highest risk of systematic measurement error has been identified and increased surveillance and support has been instituted as a result. This model is inexpensive in both monetary terms and time commitments and its utility in other areas of ultrasound quality assurance deserves to be further investigated.

Figure and Table legends

Figure 1: Average annual audit of nuchal translucency measurement distribution from 2011-2016 of the cohort undertaking a teleconference tutorial in 2011.

Figure 2: Biennial comparison of the proportion of operators meeting standard (TT – those attending the teleconference tutorial in 2011; non-TT - all other audited operators)

Table 1: Demographic characteristics of the teleconference tutorial compared with a randomly selected control group of operators.

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Table:

Table 1

Demographic characteristic:	Teleconference tutorial group (n=83):	Comparison group (n=166):	Statistical significance:
Rural or Regional	48 (58%)	53 (32%)	P=0.001
3 Years or less as NT operator	52 (63%)	56 (34%)	P<0.0005
Annual scan numbers 30 - 200	105 (83%)	69 (63%)	P=0.0012

Figure 1:

Figure 2

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Author/s:

Nisbet, D;Robertson, A;Mannil, B;Pincham, V;McLennan, A

Title:

Quality management of nuchal translucency ultrasound measurement in Australia

Date:

2019-02-01

Citation:

Nisbet, D., Robertson, A., Mannil, B., Pincham, V. & McLennan, A. (2019). Quality management of nuchal translucency ultrasound measurement in Australia. AUSTRALIAN & NEW ZEALAND JOURNAL OF OBSTETRICS & GYNAECOLOGY, 59 (1), pp.54-58. <https://doi.org/10.1111/ajo.12792>.

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