Radiology Clinic

Radiologist, Dr D

A Report by the

Health and Disability Commissioner

(Case 03HDC05925)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Ms A	Consumer
Mr B	Complainant/Consumer's partner
Master C	Consumer's son
Dr D	Provider/Radiologist
Dr E	Provider/Radiologist
Ms F	Provider/Sonographer
A Radiology Clinic	Provider

Complaint

On 24 April 2003 the Commissioner received a complaint from Ms A and Mr B about the services provided to Ms A by Dr D and a radiology clinic during her pregnancy in 2000. The following issues were identified for investigation:

- *The appropriateness and adequacy of scanning procedures and analysis of the results during the pregnancy of Ms A.*

An investigation was commenced on 3 October 2003.

Information reviewed

- A copy of Ms A's medical misadventure claim file from ACC
- Ms A's clinical notes from the first medical centre
- Ms A's clinical notes from the second medical centre
- Ms A's clinical notes from the radiology clinic
- Information from Dr D on behalf of the radiology clinic
- Original ultrasound scan films and video of Ms A's antenatal scans performed by a radiology clinic
- Clinical notes from two Public Hospitals concerning Master C

Independent expert advice was obtained from Dr Robert Sim FRANZCR, diagnostic radiologist (member of Ultrasound subcommittee of the Royal Australian and New Zealand College of Radiologists (RANZCR)).

Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

Information gathered during investigation

Overview
During her pregnancy from November 1999 until July 2000, Ms A attended the radiology clinic for five antenatal ultrasound scans. The first, at approximately 6 weeks' gestation, was to investigate the viability of the pregnancy. The second scan, at 19 weeks, was a routine second trimester screening study. The remaining three scans were to investigate specific clinical concerns, namely fetal growth rate and the possibility of the umbilical cord being near or around Master C's neck. The antenatal ultrasound scans revealed no abnormalities in the baby's anatomy.

Master C was born by emergency Caesarean section on 23 July 2000. On delivery it was discovered that Master C was missing his right leg and testicle.

Background
The radiology clinic is a small private practice providing radiology services, including ultrasound scans. The practice has been owned by Dr D since 1990. Dr D advised me that the radiology clinic performs around 1300 obstetric scans each year.

Dr D is assisted by Ms F, a sonographer who has been working at the radiology clinic since 1997, and Dr E, who works part time at the radiology clinic as a radiologist.

Ms A discovered that she was pregnant with Master C in November 1999. Her clinical notes show that her last menstrual period was recorded as 9 October 1999 and her estimated date of delivery was recorded as 16 July 2000.

First scan – 6 weeks
Ms A experienced some bleeding in the early weeks of her pregnancy and consulted her general practitioner (not involved in this investigation). Ms A was referred to the radiology clinic for an ultrasound scan to verify the viability of the pregnancy. Ms A was approximately six and a half weeks pregnant at the time of the scan.

The scan was performed by Ms F and reviewed by Dr E on 24 November 1999. Dr E recorded in the obstetric ultrasound report:

> "Viable intrauterine [inside the womb] pregnancy confirmed. Fetal heart seen. Crown/rump is approx 6.5mms, this corresponds to a gestational age of around 6 ½ weeks which agrees well with dates. The configuration of the uterus suggests that it is bicornuate [having two horn-shaped branches]. The pregnancy lies in the right cornu [branch]."

Second scan – 19 weeks
Ms A transferred her maternity care to a doctor at the second medical centre on 22 December 1999.

Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

This doctor referred Ms A to the radiology clinic for a routine second trimester ultrasound scan in February 2000. Ms A was approximately 19 weeks pregnant at that time. The scan was performed by Ms F and reported by Dr D on 18 February 2000. Dr D recorded in his obstetric ultrasound report:

> "There is a single live fetus with active heart and body movements. The placenta is posterior [at the back] and clear of the os [opening]. Liquor volume is normal. No anatomical abnormality is detected.
>
> | | | |
> |---|---|---|
> | Measurements: | Biaparietal diameter | 43mms |
> | | Head circumference | 162mms |
> | | Abdominal circumference | 147mms |
> | | Femur length | 29mms |
>
> These measurements are average for a gestation of 19 weeks which matches up nicely with dates and the earlier scan. All appears fine."

Dr D advised me that the 18-20 week scan is one of the more difficult and demanding procedures to perform. A 30 minute appointment is reserved as the examination is time consuming and can be difficult as the fetus is a mobile three- dimensional structure that is being examined in two-dimensional sections.

Dr D explained that multiple windows are used to assess the fetus during this scan. The probe is placed and moved all over the maternal abdomen so that the sonographer can see all of the fetal structures. When a structure cannot be seen from one angle, the angle is changed to get a clearer view. It is uncommon to see both upper and lower limbs in the same image and it is usual to reposition the probe to identify both.

Dr D advised me that the radiology clinic follows the Australasian Society for Ultrasound in Medicine (ASUM) guidelines for the mid trimester (18-20 week) obstetric scan, which includes a requirement that fetal anatomy be checked for malformation.

Third scan – 30 weeks
In April 2000, Ms A transferred her maternity care to a midwife practising in a nearby town.

The midwife referred Ms A for a third ultrasound scan in May 2000 as she was concerned about fetal growth rate and decreased movements. Ms A was approximately 30 weeks pregnant at that time. The scan was performed by Ms F on 5 May 2000. Dr D reviewed the scan and his ultrasound report stated:

> "There is a single live baby in breech [head up] presentation. The placenta is posterior and clear of the os. Liquor volume is normal. Umbilical artery waveform is normal.
>
> | | | |
> |---|---|---|
> | Measurements: | Biaparietal diameter | 74mms |
> | | Head circumference | 272mms |

Abdominal circumference	252mms
Femur length	59mms

Gestation should now be around 30 weeks and today's abdominal measurement lies just below the 50th percentile indicating that growth has been reasonable. Estimated fetal weight is 1460gms. It was noted that the umbilical cord was up by baby's neck and in some views possibly around baby's neck. This is by no means definite, but a specialist opinion and follow up would seem reasonable."

Fourth scan – 32 weeks

It is apparent from the clinical records that the midwife acted on the suggestion that Ms A consult a specialist and an appointment was made with an obstetrician at a city hospital for 19 May 2000, to assess fetal growth and to discuss the implications of the cord possibly being around Master C's neck. The midwife referred Ms A to the radiology clinic for a fourth scan in anticipation of this consultation. Ms A was approximately 32 weeks pregnant at this time.

The fourth scan was performed by Ms F on 18 May 2000. Dr D reviewed the scan and his ultrasound report stated:

"There is a single live baby in cephalic [head down] presentation now with the spine slightly to the right. The placenta is posterior and clear. Liquor volume is very normal. The back of the baby's neck was well seen and there is no sign of any cord in relation to the posterior neck at all. Umbilical artery waveform is normal.

Measurements:	Biaparietal diameter	84mms
	Head circumference	293mms
	Abdominal circumference	266mms
	Femur length	62mms

Gestation should be approaching 32 weeks and there has been growth in all parameters since the previous examination with the abdominal measurement lying midway between 5th and 50th percentile maintaining its position. Estimated fetal weight is 1800gms."

Fifth scan – 39 weeks

Ms A was referred for a fifth and final scan on 10 July 2000 when she was 39 weeks pregnant. The midwife was concerned that Master C's position was high for full term and also queried whether the umbilical cord was around Master C's neck.

Ms F conducted the ultrasound scan on 10 July 2000. Dr D reviewed the scan and his report stated:

"There is a single live baby, head down, back to left. The placenta is posterior and well clear of the os. Liquor volume is very normal and there is good fetal movement.

Measurements:	Biaparietal diameter	93mms
	Head circumference	325mms
	Abdominal circumference	327mms
	Femur length	75mms

Gestation should now be 39 weeks. Today's abdominal measurement lies midway between 5th and 50th percentiles indicating that growth has been reasonable. Estimated fetal weight is 3130gms. Once again umbilical cord is seen around the fetal neck, easily seen posteriorly and with difficulty seen under the fetal chin. Umbilical artery waveform remains very normal. The cord insertion at the placenta is relatively high and it is possible that the cord is stopping the baby's head from engaging. I suggest a second opinion with a scan at the base hospital on whether the cord is around baby's neck."

The radiology clinic also completed a growth chart which recorded the growth developments from the scans at 30, 32 and 39 weeks gestation.

Master C's birth
Ms A and Mr B informed me that an emergency Caesarean section was necessary at 41 weeks' gestation as the umbilical cord was around Master C's neck and causing fetal distress. When Master C was born on 23 July 2000, Ms A and Mr B were shocked to find that their son had been born with his right leg missing (amelia of the right lower limb) and what appeared to be no right testicle.

Dr D and the radiology clinic were notified of Master C's disability in a letter from the public hospital dated 7 August 2000. The paediatrician from the public hospital reported amelia of the right lower limb, an undescended right testis and a single umbilical artery.

Independent advice to Commissioner

The following expert advice was obtained from Dr Robert Sim, radiologist.

"**Review:**
This opinion has included review of the hardcopy of the five ultrasound examinations performed during the second pregnancy of [Ms A], the written reports on these examinations, portions of the photocopied referral forms, and video archive of the last four studies. There appears to be uninterrupted recording of the second trimester study with 13 minutes of footage. The written response from [Dr D] of 19 December 2003 including the attached ASUM Guideline for the Midtrimester Obstetric Scan of October 1999 has been considered.

Is the policy followed by [the radiology clinic] with respect to scans conducted at 18-20 weeks' gestation appropriate?

The guidelines of ASUM for conduct of the second trimester obstetric ultrasound are adhered to widely amongst sonographers and sonologists / radiologists in New Zealand. These guidelines were in fact the subject of a joint statement from ASUM, RANZCR and the Royal Australian and New Zealand Colleges of Obstetrics and Gynaecology (RANZCOG). A radiology clinic's use of these as a guideline, as inferred in [Dr D's] correspondence, is thus appropriate and commended.

The radiologist's ability to supervise and influence the performance and conduct of obstetric ultrasound is a condition of the Ministry of Health s88 Maternity Regulations.

[Dr D] will have signed documentation authorising him to claim payment from the Ministry of Health for provision of obstetric ultrasound and thus would be expected to be familiar with the practical requirements of the notice. What cannot be determined from this review is how [Dr D] does this in practice. He states that '…a sonographer, [Ms F], has been employed and she now scans most of the patients. If there are any queries or abnormalities identified by her I immediately review the patient with her. I dictate a report.' This is how most sonologists / radiologists work, frequently reviewing findings with the sonographer and the patient / woman, with their own hands on the probe and / or slave monitor review of the study in progress. It is always necessary for the radiologist to review the static hardcopy before generating a report.

It is not stated, or apparent from the documentation whether the sonographer and radiologist work with or complete a written checklist derived from the ASUM guidelines. This is common and useful, but not universal practice in a number of ultrasound/radiology workplaces.

Should the scans taken at other stages of [Ms A's] pregnancy have recognised foetal malformation? What was the purpose of these scans?

The formal referral indications provided for the ultrasound scans, as derived from photocopies of portions of the referral forms are as follows (abbreviations have been extended):

24 November 1999 6.5 weeks
Indication: G2P0 Vaginal bleeding one week. Right lower quadrant tenderness

18 February 2000 19 weeks
Indication: LMP 9/10/99. Estimated gestational age 17.5 today. Pregnancy satisfactory

5 May 2000 30 weeks
Indication: 29 weeks. EDD 16 July 2000. Small for dates. Decreased movements

18 May 2000 32 weeks

Indication: 32 weeks. Check growth. For follow up re umbilical cord around baby's neck

10 July 2000 39 weeks
Indication: 39 weeks. High presenting part at term

The scan performed at 19 weeks was a second trimester screening study. The remainder of the scans addressed specific clinical questions and were appropriately tailored to these. The scan at 32 weeks whilst referring to fetal growth was almost certainly also generated by midwife concerns raised by the prior scan suggesting the umbilical cord was around the fetal neck. The clinical questions raised by the referring midwife were addressed on scan and appropriately reported.

The fetal growth parameters, including femoral length were measured at 30, 32 and 39 weeks. It is not usual to repeat a detailed complete anatomic survey at times of fetal growth assessment or when addressing clinical questions when a prior second trimester study has been normal. There is video imaging of the fetal pelvis at 30 weeks that on retrospective review is suspicious of an absent femur.

Decreased fetal movement is a frequent reason for referral for ultrasound scan, and it is usual to confirm gross movements of the limbs and trunk, often as a component of a formal biophysical score in the third trimester. It is sometimes a marker of musculoskeletal, neurological and limb shortening abnormalities such as dwarfism. It may also be attributed to fetal position. It is speculative whether the absent leg would have contributed to this symptom.

Notwithstanding the above comments it still remains somewhat surprising that the absence of one leg was not noticed on the three scans subsequent to the 19 week study.

In your opinion, were the ultrasound scans completed at [the radiology clinic] of a reasonable standard?

Definition of a reasonable standard is based on ASUM guidelines, and personal experience of both secondary / tertiary hospital and community based obstetric ultrasound practice. This judgement is based on the radiology clinic being a community based ultrasound service.

Review of the hardcopy documentation and reporting of all the scans performed throughout the pregnancy would suggest a reasonable standard with the very significant proviso that the examinations were suboptimal at 19, 30, 32 and 39 weeks.

The examinations were suboptimal for the following reasons:

- at the nineteen week scan failure to detect and report the missing limb
- inappropriate labelling of 'lower limbs' on the hard copy
- failure to recognise and report the two vessel umbilical cord documented on the video/hard copy at the [nineteen] week scan and subsequent scans.

In other respects there is appropriate hardcopy documentation and reporting of the findings.

If the scans were completed to a reasonable standard, how is it possible that [Master C's] missing right leg and testicle were overlooked at each scan?

Review of the 19 week scan on the hard copy and video tape in particular shows a very brief review of the fetal 'lower limbs'. The left leg only is demonstrated on the video tape, with no attempt apparently made to extend the examination to demonstrate two legs.

It is usual to confirm the presence of two femora, both tibiae and fibulae and both feet. Many operators customarily document these on hard copy. The single leg shown is labelled 'lower limbs.'

On review of the real time video imaging (which may represent the entire study or only a portion of it): very brief imaging of the fetal pelvis is available, but sufficient to confirm that fetal position and other factors should not have detracted from the ability to detect the limb reduction abnormality.

Thus according to the ASUM guideline only 9 of the 12 long bones were documented. Neither was the presence of both feet confirmed. Thus there has been failure to recognise a significant deviation from the ASUM guideline and document it on the hardcopy. This failure has translated to the radiologist's interpretation of the hard copy images and subsequent report at 19 weeks.

As noted subsequently the two vessel umbilical cord was not identified at the 19 week scan.

Assessment of the scrotum and testes is not part of the usual obstetric ultrasound scan and is not part of the ASUM guideline. Indeed the testes are not in the scrotum at the time of the second trimester scan, and are only sometimes seen by ultrasound in the early third trimester. This is usually a fortuitous imaging finding only. Antenatal detection of undescended, ectopic, absent or hypoplastic testes is not a valid test in the fetus. Failure to detect the right testis by antenatal ultrasound cannot be sustained as a complaint.

Fetal abnormalities are not detected with 100% sensitivity or specificity on ultrasound for a variety of reasons. There is great variation in the sensitivity of ultrasound for detection of fetal anomalies reported from numerous studies. In fact the range of sensitivities in population based studies is reported as 24-61%. The variation is ascribed to selection criteria (screening or targeted / indication based ultrasound), operator expertise (tertiary centres or otherwise), differing severity of abnormalities, gestational age at scanning, variation in post natal ascertainment of abnormalities and the equipment used.

In contrast specificity is good and is close to 99%.

The possibility of false positive and false negative scans is well understood by the ultrasound community but not as well comprehended by prospective parents.

Because of limitations in sensitivity for prenatal ultrasound no parent can be definitely assured that the baby is normal. In reality a normal ultrasound may lower the likelihood of anomalies by as little as 17%. Even in the most experienced hands the likelihood of abnormality is reduced by about 50%, not the level of certainty most parents presume.

Musculoskeletal abnormalities are a large and heterogeneous group of disorders with a prevalence ranging between 2.6 and 14.3 per 1000. As a group, published overall detection rates for musculoskeletal abnormalities have been reported as 23-55%.

Reported numbers for limb reduction defects are small with 43% detected in five published studies (all scans performed before 24 weeks). The largest recent published study from the Euroscan / Eurofetus group has a published sensitivity for detection of lower limb reduction defects of 35.5% (31 lower limb reduction abnormalities in 200,000 women scanned in 14 European countries in 60 hospital ultrasound units between 1990 and 1993).

The overall birth incidence of limb deficiencies and amputations is 1 : 20,000 births. Amelia has a prevalence 0.04-0.15 per 10,000 births.

A structured approach to the mid trimester screening study allows detection of many abnormalities. It is important to acknowledge and express any limitations of the test.

It has become increasingly common practice for reports to state whether any technical difficulties were associated with the examination, which might reduce the accuracy of the study or indicate the need for a return visit to complete anatomic review of the fetus. No such statement was attached to the report at 19 weeks.

Commonly encountered, and identifiable reasons for failure to detect may be attributed to poor quality equipment, operator education, training and scanning experience, difficult fetal position, low amniotic fluid volume and maternal obesity degrading the ultrasound beam. These are not recognised causes in this instance.

It is noted that abnormalities not seen at the mid trimester scan are sometimes seen at subsequent studies. In this instance as no caveats were recorded as to the completeness of the mid trimester scan it would be usual practice to perform fetal biometry for growth evaluation on the subsequent studies and not repeat an anatomic review. It is not usual practice to measure both femora for growth assessment. Hence it is possible to explain how at subsequent scan the missing limb escaped detection.

The standard textbook in obstetric ultrasound by Peter Callen states: 'If the sonographer begins with a specific intent to image a particular fetal part, it is frequently possible to succeed. To accomplish this end, the sonographer must (1) assess the precise fetal position; (2) consider whether the anatomic part of interest is best visualised in planes perpendicular to the fetal long axis or parallel to the fetal long axis; and (3) adjust acoustic imaging parameters, particularly time-gain compensation, and transducer angulation to visualise the area to best advantage.'

[Dr D], in his letter of 19 December 2003, advised that one of the purposes of the 18 to 20 week scan is to "identify, and confirm as normal, the list of structures and measurements required." What is your understanding of the purpose of this scan?

The mid trimester scan is performed at 18-20 weeks. The 'routine' mid trimester scan, as distinct from indication based or targeted scan, has been advocated for detection of fetal anomalies. The vast majority of fetal anomalies are sporadic, cannot be anticipated, and occur in pregnancies of low risk women. Significant structural malformations occur in 2-3% of fetuses.

The other benefits of scanning at this time are: accurate determination of gestational age, diagnosis of multiple gestation, localisation of placental site and assessment of fetal wellbeing. Several randomised studies have confirmed a reduced incidence of labour induction for post date pregnancy when 'routine' rather than 'indicated' ultrasound is used.

Data does suggest that routine second trimester ultrasound does appear to reduce adverse outcomes in fetuses diagnosed with some congenital anomalies. The most sophisticated analyses suggest the cost benefit of routine screening is dependent on sensitivity of detection, cost of the ultrasound examinations, and the rate of pregnancy termination. Demonstration of improvement in perinatal morbidity and mortality from trials of routine scan is more problematic as interventions have not been specified in the trial protocols.

There is also statistical data that indicates a reduction in the number of ad hoc scans during a pregnancy if a routine scan is performed in the second trimester.

There have been concerns regarding the cost benefit of the second trimester scan which are not discussed here.

Other concerns beyond cost are best exemplified by Chervenak's postulate that the omission of an offer to provide ultrasound screening during pregnancy violates patient autonomy by denying information for management decision making.

What is the difference in fetal development between six weeks and eighteen weeks?

There is a significant difference in the ultrasound appearances of the fetus from 6 to eighteen weeks. At six weeks the fetus is only 4mm in length and at 18 weeks has well developed anatomy readily assessable by ultrasound.

Limb buds are first seen by ultrasound at about the eighth week of gestation, the femur and humerus are just seen from nine weeks, with all long bones consistently seen on high resolution ultrasound from about 11 weeks. Body movements are identified from 9 weeks and by 11 weeks limbs move about readily. The length of the humerus, radius/ulna, femur and tibia/fibula are similar at 11-14 weeks and increase linearly with gestation from about 6mm at 11 weeks to 13 mm at 14 weeks. The femur at 18 weeks is 27mm and at term 78mm.

Are there any aspects of the care which you consider warrant either:

- **Further exploration by the investigator?**
- **Additional comment?**

Review of the scan at 19 weeks demonstrates a two vessel umbilical cord, which has also been well demonstrated at 30, 32 and 39 week studies. On review of the video tape, this is confirmed by colour Doppler studies each time. A two vessel cord was confirmed postnatally.

The umbilical cord usually has three vessels, two arteries and a vein. Two vessel cords (also referred to as single umbilical artery, SUA) have an incidence of about 1% and a variable reported association of 30-60% with other fetal abnormalities, chromosomal defects, fetal growth retardation and prematurity. There is no definite correlation between SUA and a specific pattern of anomalies. Not all cases of SUA necessarily share the same embryogenesis. Its ultrasound observation and recognition should generate a particularly attentive anatomic review.

In an analysis of eighteen cases of amelia a 'greater frequency of single umbilical artery… was observed…' Considering the rarity of amelia this association is not commonly known.

Considering the focus and interest in the umbilical cord around the fetal neck and measurement of the umbilical arterial blood flow there is a significant failure of observation to detect and report the two vessel cord on three studies in addition to the 19 week scan.

Included in the sheet of the hard copy images of the study at 39 weeks on 10/07/2000 is a single image labelled 'prostate' with the patient identification [name of another patient]. This image should have been removed/deleted either by the sonographer on review of the images or radiologist at the time of reporting.

It may be worth investigating whether an ASUM guideline based written checklist was/is used by the sonographer.

Summary of opinion:

1. Amelia is a rare abnormality.
2. [the radiology clinic's] stated policy with regard to 18-20 week scans appears appropriate on review.
3. In practical terms there is deficiency by sonographer and radiologist, as there is a failure to observe and document on hard copy and report the missing limb. The level of supervision and influence of the conduct of the examination by the radiologist may have been insufficient.
4. There is failure to image, document and report the absence of three long bones and a foot in the missing fetal leg according to ASUM guidelines and usual practice at the second trimester scan.

5. There is failure to identify a two vessel umbilical cord on four studies, all of which confirm a two vessel cord on video or hardcopy review. This is of concern considering the interest and reporting of the umbilical cord around the fetal neck and reporting of umbilical arterial blood flow.
6. The examinations were conducted with high quality equipment, with no identified or expressed fetal or maternal factors which might have compromised the studies.
7. Cognisance should be taken of the published range of sensitivities for detection of fetal anomalies. In particular the low sensitivities for limb reduction defects are noted, of which amelia is at the extreme end of the spectrum and less likely to be missed. A statistically low sensitivity in the literature does not always translate into failure to detect in a particular instance. Whilst recognising the low sensitivity of detection, the view is formed that in this instance the amelia should have been detected at the 19 week examination.
8. The reasons for failure to detect the missing right leg and two vessel umbilical cord are speculative, but at the 19 week study may be perceptual or systemic. Expertise cannot be assessed from this instance alone, but is also called into question from repeated failure to identify the documented two vessel cord which is not the subject of the complaint. Responsibility may lie with both sonographer and radiologist.
9. Inattention to detail is apparent from the inclusion of a previous patient's prostate image on a sheet of images.

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Addendum

A member of my staff telephoned Dr Sim on 16 August 2004 to follow up on a number of issues raised in his advice.

Dr Sim was asked to give an indication of the seriousness of the error in failing to detect and report on the abnormalities in the 19 week scan. Dr Sim noted that while he was anecdotally aware of a few other cases where abnormalities had been missed, this case was distinctive in that there did not appear to be any complicating factors present that would explain the error. The baby was in a good position and maternal obesity was not a factor. Dr Sim commented that the fact that both the leg and the umbilical cord were missed means that observation skills were "significantly deficient". On that basis, Dr Sim felt this case represented a "serious departure" from reasonable professional standards.

Dr Sim was also asked about the interface between the sonographer and the radiologist. Dr Sim explained that the sonographer usually performs the scans and the radiologist reviews the films and provides the report, although in some cases the radiologist performs the scan himself, as was the case with [Dr E] on the six week scan.

Dr Sim commented that in this case, the review of the lower limbs by the sonographer during the 19 week scan was very brief, as indicated from the time entries recorded on the films. He also noted that the hard copy of the film showing the left leg had been incorrectly labelled in plural "lower limbs". Having said that, Dr Sim explained that, if the radiologist is not satisfied with the quality of the films or any other aspect of the scan, he or she should ask the sonographer to go back and spend more time on a certain area. Dr Sim noted that sometimes a relationship of trust is established over time when a sonographer is usually very skilled but that this case illustrates the need for the radiologist to be vigilant.

Dr Sim was unsure whether the radiologist and sonographer in this case used the ASUM checklist during the scan itself and suggested that this practice may be required in the future.

He also suggested that a period of observation at a tertiary base hospital would be beneficial to refresh skills.

Code of Health and Disability Services Consumers' Rights

The following Rights in the Code of Health and Disability Services Consumers' Rights are applicable to this complaint:

RIGHT 4

Right to Services of an Appropriate Standard

1) *Every consumer has the right to have services provided with reasonable care and skill.*
2) *Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.*

Other Relevant Standards

Australasian Society for Ultrasound in Medicine (ASUM) Guidelines For The Mid Trimester Obstetric Scan (Revised October 1999)

18-20 weeks is the most common time for performing this scan in an otherwise low risk pregnancy but examining the fetal anatomy may be appropriate at other times depending on the clinical situation.

The information gained aims to provide the patient and the doctor involved in her care with as much information as possible about the pregnancy in the safest and most cost-effective manner.

The limitations of ultrasound must be appreciated. Technical factors, such as fetal position and maternal obesity, may make full assessment impossible.

EQUIPMENT
Studies should be performed using high quality real time equipment. The availability of colour Doppler is advisable.

If state of the art equipment is not available both the patient and the referring doctor should be aware that the examination is less complete and the ability to detect fetal abnormality may be reduced.

COMMENT
Each department/practice should decide its own policy on making hard copy images available to the referring doctor and the patient.

THE EXAMINATION CHECKLIST
1. Fetal number
2. Fetal cardiac activity
3. Gestational age
4. Fetal anatomy, including detection of malformation

Head	- Falx	( )
	- Cavum Septum Pellucidum	( )
	- Skull Bones	( )
	- Lateral Ventricles	( )
	- Choroid Plexus	( )
	- Cerebellum/Vermis	( )
	- Nuchal thickness	( )
	- Cisterna Magna	( )
Face	- Orbits	( )
	- Nose	( )
	- Jaw	( )
	- Lips	( )
	- Profile	( )
Diaphragm	- Right	( )
	- Left	( )
Heart	- FHMD	( )
	- Position	( )
	- Axis	( )
	- 4 Chambers	( )
	- Intraventricular Septum	( )
	- Foramen Ovale	( )
	- Mitral Valve	( )
	- Tricuspid Valve	( )
Great Vessels	- Left Ventricular Outflow Tract	( )
	- Right Ventricular Outflow Tract	( )
	- Aortic arch	( )
	- Ductal Arch	( )
Abdomen	- Stomach / Situs	( )
	- Kidney (Left)	( )
	(Right)	( )
	- Bladder	( )
	- Abdominal Wall	( )
Spine	- Ossification Centres	
	Coronal	( )
	Sagittal	( )
	Axial	( )

		- Skin Line	( )
	Extremities	- 12 Long bones	( )
		- Hands/Fingers	( )
		- Feet/Toes	( )
		- Position of joints	( )
	Umbilical Cord	- Insertion	( )
		- 3 Vessels	( )
5. Amniotic Fluid Volume			( )
6. Placenta		- Site	( )
		- Clear of Os	( )
		- Distance from internal os	( ) cm
		- Reaching/Covering os	( )
7. Cervix		- Normal length	( )
		- Open/Closed	( )
8. Maternal anatomy		- Uterus	( )
		- Adnexa	( )

COMMENTS

GESTATIONAL AGE
This should be assessed by the biparietal diameter (BPD), head circumference (HC) and femur length (FL). Abdominal circumference (AC) is normally measured to check fetal proportions.

These values should be reported and a single gestational age assessment given. If the ultrasound due date differs from the menstrual date by more than 2 standard deviations, a revised estimated date of delivery (EDD) together with a predicted range should be given.

The BPD chart distributed by the Australasian Society for Ultrasound in Medicine (ASUM) is recommended.

FETAL ANATOMY INCLUDING THE DETECTION OF ABNORMALITIES
Each practice should develop a protocol on the procedure to be followed when an abnormality is detected. This protocol should include guidelines for the immediate care of the patient and how the referring doctor will be informed.

Careful evaluation of normal fetal anatomy according to the checklist should detect many major anatomical abnormalities.

It is important to remember that an apparently minor defect may be the only pointer to a major chromosomal abnormality.

Some structures may not be demonstrated because of maternal size, fetal position and other factors. Repositioning or rebooking the woman may be necessary to complete the examination.

If the assessment of fetal anatomy is limited, for whatever reason, the report should reflect the limitations of the scan.

Opinion: Breach – Dr D

Ms A and Mr B were understandably shocked when Master C was born with his right leg missing. They had prepared for a normal birth on the basis that everything was fine and would have had whanau and friends present at the birth for support if they had known what to expect.

I can appreciate what an extremely difficult time Ms A and Mr B have been through. Their letter of complaint conveyed a deep sense of grief:

> "The stress and hurt that has been placed on us is extremely difficult to [put] into words. All that we can say is that our freedom of choice was taken from us due to the 'care' we received from the medical practitioners.
>
> We have been thrust into the 'disability world' and were not able to prepare or ready ourselves for this and it has caused problems, obstacles and heartache."

I acknowledge that Dr D has also been deeply affected by the news of Master C's disability. In his response to my investigation, Dr D wrote:

> "We were all horrified when we heard that [Master C] had been born with only one leg. We offer a heartfelt apology to [Ms A] and [Mr B] for not detecting [Master C's] amelia.
>
> …
>
> Not a day goes by when we don't think about this case as every time we perform an obstetric ultrasound we are reminded about [Master C]. [Ms F] and I are very sorry this has occurred and can only strive to be more vigilant in all our work especially antenatal ultrasound."

In attempting to identify the cause for the error, Dr D advised me that the 18-20 week morphology scan is one of the more difficult ultrasound procedures to perform. He stated that staff at the radiology clinic follow the ASUM guidelines for this scan and attempt to identify and confirm the list of structures and measurements listed in the guidelines.

Dr D noted that it is often more difficult to perceive abnormalities when structures are absent rather than abnormal. For example, on a chest X-ray, a missing rib is often more difficult to detect than an abnormal rib. It follows that an abnormal leg is easier to detect than an absent leg. Dr D explained that staff at the radiology clinic seek a second opinion from the public hospital if they have any doubts or concerns about the scans they perform.

Dr D pointed out that in this case he had concerns about the umbilical cord being near Master C's neck and suggested specialist obstetric review on two occasions.

Dr D explained that when an examination is performed, the probe is moved all over the maternal abdomen in order to view the fetal structures. When a structure is not visible from one angle, the probe is moved to a different position to allow a better view. Dr D suggested that in Ms A's case, it is possible that when only one leg was seen, the probe was repositioned and the same leg was identified from a different angle. This could have been perceived as the identification of two legs.

Dr D also noted that complete amelia of a limb is very rare with an incidence rate of only 0.04 to 0.15 per 10,000 births.

My independent advisor confirmed that abnormalities are not detected with 100% accuracy in ultrasound scans for a number of reasons. A normal ultrasound scan may reduce the likelihood that abnormalities will be identified by as little as 17%. Even in the most experienced hands, the likelihood of detecting abnormality through ultrasound scan is only 50%, which is not the level of certainty that most parents assume.

My advisor explained that the mid trimester (18-20 week) scan is a screening study specifically to examine fetal anatomy and that a structured approach to this scan allows detection of many abnormalities. It also allows for an accurate determination of gestational age, diagnosis of multiple gestation, localisation of placental site and assessment of fetal wellbeing. The remainder of the scans performed on Ms A addressed specific clinical questions, namely the viability of the pregnancy (6 weeks) and the growth rate and position of the umbilical cord (30, 32 and 39 weeks).

A failure to detect abnormalities may be attributed to poor quality equipment, operator education, training and scanning experience, difficult fetal position, low amniotic fluid and maternal obesity, but my advisor noted that none of these factors were present in this case.

Despite the rare occurrence of amelia and the difficulties in detecting abnormalities through ultrasound scan, my advisor considered that the 19 week scan was substandard in this case for the following reasons:

- there was only a brief review of the lower limbs
- there was no attempt made to demonstrate two legs during the scan
- the single leg was labelled "lower limbs" on the hard copy of the relevant film
- only 9 of the 12 long bones listed in the ASUM guidelines were documented
- the presence of two femora, both tibiae and fibulae and both feet was not confirmed, and
- the two vessel umbilical cord was not identified.

My expert explained that the umbilical cord usually has three vessels, two arteries and a vein. A two vessel cord is often associated with other fetal abnormalities, chromosomal defects, fetal growth retardation or prematurity. Detection of a two vessel umbilical cord would usually prompt a particularly detailed anatomic review.

Ms A and Mr B have struggled to understand how Master C's amelia of his right leg remained undetected when Ms A underwent three further scans at 30, 32 and 39 weeks. My expert advisor has explained that the scan at 19 weeks was the only screening study where the anatomy of the fetus was specifically checked. The scans at 30, 32 and 39 weeks were tailored to specific clinical questions concerning fetal growth rates and the position of the umbilical cord. It is not usual to measure both femora for growth assessment which is why the missing limb escaped detection in subsequent scans. My advisor did add, however, that he found it somewhat surprising that the absence of one leg was not detected during those subsequent scans. Taking into account the focus on the umbilical cord and the measure of umbilical arterial blood flow in the three scans at 30, 32 and 39 weeks, my expert advised that the failure to detect the two vessel umbilical cord during those scans was significant.

As a health consumer, Ms A was entitled to have services provided with reasonable care and skill and in compliance with professional standards, pursuant to rights 4(1) and 4(2) of the Code.

Although Dr D advised me that all of the staff at the radiology clinic follow the ASUM guidelines for this scan, it is clear that on 18 February 2000 there was a significant departure from these guidelines and from usual practice for the second trimester scan. In particular, Dr D failed to detect and report on the amelia of Master C's right leg and the two vessel umbilical cord. While I accept that ultrasound is not an exact science and that amelia is a very rare disorder, I consider that the 19 week scan was substandard because it did not adequately review Master C's lower limbs and record the structures listed on the ASUM guidelines. I accept the advice of my expert that there was a significant departure from the ASUM guidelines for this scan. In my opinion, this conduct constitutes a breach of rights 4(1) and 4(2) of the Code.

In response to my provisional opinion, Dr D advised me that he has already instituted the formal written checklist based on the ASUM criteria for morphology scans. Dr D took this step after he heard of Master C's case and before my original opinion was issued. Dr D advised me that staff at the clinic have "become much more focussed on attention to detail over completion of the checklist and the recording of details on hard copy images".

I am guided by the advice of my expert that, although the subsequent scans at 30, 32 and 39 weeks were not anatomical reviews, they did focus on the umbilical cord and arterial blood flow. An abnormal umbilical cord will often indicate that other abnormalities are present and prompt a full anatomical review. By failing to detect the two vessel umbilical cord, Dr D was not alerted to the possibility of other abnormalities. In my opinion Dr D also breached right 4(1) of the Code in failing to detect the two vessel umbilical cord when reviewing and reporting on the scans at 30, 32 and 39 weeks.

Opinion: No Breach – The Radiology Clinic

Vicarious liability
The effect of section 72 of the Health and Disability Commissioner Act 1994 is that a breach of the Code by an employee will be treated as being a breach of the Code by his or her employer, unless the employer can show that it took such steps as were reasonably practicable to prevent the breach.

In this case, Dr D advised me that all of the staff at the radiology clinic follow the ASUM guidelines for conduct of the second trimester obstetric ultrasound.

My expert advisor explained that these guidelines are adhered to widely amongst sonographers and radiologists in New Zealand. They are the subject of a joint statement from ASUM, RANZCR and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG). My advisor confirmed that the radiology clinic's use of the ASUM guidelines was appropriate and to be commended.

In my view the failure to detect amelia of the right leg and the two vessel umbilical cord was not attributable to the systems used by the radiology clinic but to individual clinical decisions by Dr D. Accordingly the radiology clinic is not vicariously liable for breaches of the Code by Dr D in this instance.

Direct liability
The radiology clinic was notified of the complaint by Ms A and Mr B on the basis that it could be directly liable as a health care provider.

My expert advisor noted that while a failure to detect abnormalities may be attributed to poor quality equipment, operator education, training and scanning experience, difficult fetal position, low amniotic fluid and maternal obesity, these were not recognised causes in this instance.

I am satisfied that the radiology clinic provided high quality equipment and staff with appropriate training and experience during the scans performed on Ms A during her pregnancy. Accordingly the radiology clinic did not breach the Code.

Other comments

One issue raised by my expert was the role of the sonographer, Ms F , in performing the 19 week scan. My expert felt that, given the time entries recorded on the films, the review of the lower limbs during this scan was too brief and the hard copy of the film was incorrectly labelled 'lower limbs'.

As my investigation focussed on Dr D's overall responsibility for ensuring that the scan was performed with reasonable care and skill and Ms F is not under investigation, I have not formed any view as to whether her actions constitute a breach of the Code. However, I draw my expert's comments to Ms F's attention.

Actions taken

In response to my provisional opinion, Dr D:

- Provided a written apology for Ms A and Mr B.
- Confirmed that he intends to undertake a two week period of obstetric ultrasound observation in a tertiary base hospital.
- Confirmed that he has reviewed his practice in light of my report.

Follow-up actions

- A copy of this report will be sent to the Medical Council of New Zealand and the Royal Australian and New Zealand College of Radiologists.
- A copy of this report, with details identifying the parties removed, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.