

The accuracy of antenatal ultrasound screening in Malta: a population-based study

✉ Jeremy Borg Myatt¹, ✉ Miriam Gatt², ✉ Mark Cordina³, ✉ Victor Grech¹, ✉ Simon Attard-Montalto¹

¹Department of Pediatrics, Mater Dei Hospital, Msida, Malta

²Malta Congenital Anomalies Registry, Directorate of Health Information and Research, Gwardamanga, Malta

³Department of Obstetrics and Gynaecology, Mater Dei Hospital, Msida, Malta

Abstract

Objective: To analyse the accuracy of antenatal ultrasound screening in Malta, comparing detection rates within the private and public sectors, and with the rest of Europe. To assess local trends in accuracy for each organ system.

Material and Methods: Ethics approval was obtained to gather routinely collected data from the national congenital anomalies registry between 2016 and 2018. This was analysed to determine local antenatal ultrasound accuracy rates and trends. Electronic medical appointment record data was also used to indirectly determine whether a significant difference existed in the detection of antenatal anomalies in mothers scanned privately and those scanned within the public sector. χ^2 -for-trend was used to analyse changes in the accuracy rates. European Surveillance of Congenital Anomalies (EUROCAT) data was used to compare scanning accuracy in Malta and other EUROCAT centres.

Results: The local rate of undetected congenital anomalies was 62.0% for public scans and 83.9% for private scans. Local trends over the three-year period showed an improvement in accuracy rates in detecting isolated syndromes ($p=0.05$), anomalies of the renal system ($p=0.02$) and craniofacial anomalies ($p=0.05$). Malta's overall performance was similar to other EUROCAT centres.

Conclusion: Scans carried out within the public sector are more accurate than private scans, and Malta's overall performance was similar to other EUROCAT centres. (J Turk Ger Gynecol Assoc 2022; 23: 222-32)

Keywords: Prenatal diagnosis, ultrasonography, pregnancy outcome, maternal health services

Received: 09 May, 2022 **Accepted:** 06 September, 2022

Introduction

Congenital anomalies are relatively common, occurring in 2-3% of all births. Anomalies constitute a major cause of perinatal morbidity and mortality, with lasting effects on those who survive, as well as on their families, in the form of physical and emotional trauma (1). Ultrasound is the ideal modality for the antenatal detection of many anomalies, since it is safe and highly effective, albeit user and equipment-grade dependent (1).

Antenatal ultrasound scanning has now become a routine procedure and an integral part of antenatal care universally. In most countries worldwide, screening is carried out in all pregnancies as the great majority of abnormal foetuses are

born to mothers with no apparent risk factors (2). Ultrasound is also used to monitor foetal growth, multiple pregnancies, and so on (3).

A nuchal scan is carried out at 12 weeks of gestation since, at this time, the majority of the foetal organs are well developed and may be visualised (4). In Malta, the nuchal scan is the earliest routine antenatal ultrasound scan, typically carried out at 10 to 14⁺⁶ weeks gestation. Foetal organs are scrutinised for anomalies and foetal growth measured (5). This scan may also be used in conjunction with other antenatal tests to confirm an antenatal diagnosis of trisomy 21 (Down syndrome) (4).

The anomaly scan is a later ultrasound scan, performed routinely at around 20 weeks of gestation (5). In all studies, the



Address for Correspondence: Jeremy Borg Myatt

e.mail: jeremy.borg-myatt@gov.mt ORCID: orcid.org/0000-0002-7227-9237

© Copyright 2022 by the Turkish-German Gynecological Education and Research Foundation - Available online at www.jtgga.org
Journal of the Turkish-German Gynecological Association published by Galenos Publishing House.

DOI: [10.4274/jtgga.galenos.2022.2022-4-1](https://doi.org/10.4274/jtgga.galenos.2022.2022-4-1)

ability to detect anomalies depends on many factors, such as operator ability, the ultrasound machine being used, the foetal organ being analysed, and even the body mass index (BMI) of the mother (6).

Benefits of antenatal ultrasound scanning include promoting improved antenatal practice and perhaps further encourage expectant mothers to attend their routine antenatal clinics. Psychological benefits, in the form of maternal-fetal connection, have also been adduced, albeit in higher-income countries (7). It has also been suggested that seeing one's child via ultrasound may help promote healthy behaviour, such as smoking cessation (7). Antenatal diagnosis may also allow expectant parents to prepare for the eventual birth of a disabled child (8). In addition, the early diagnoses of foetal anomalies may allow paediatricians, paediatric surgeons, and neonatologists, as well as the obstetric specialists, to prepare for the eventual medical and surgical needs at birth. It can also trigger a more detailed screening of the foetus as well as genetically related family members. Furthermore, the method and timing of delivery can be optimised.

Malta is an independent archipelago located south of Sicily in the Mediterranean Sea with a population of approximately half a million. Malta has only one main public hospital, giving the authors the unique opportunity to carry out a population study. Free National Health Care is available, modelled on the British system, but patients may also elect to attend private, fee-paying clinics. Antenatal ultrasound scans are no exception and can be carried out in private obstetric clinics, or in the country's regional centre. All mothers whose foetus is found to have an abnormality on an ultrasound scan carried out in the private sector are referred to the state hospital for a second ultrasound scan. This is carried out by the obstetrics and gynaecology outpatient department and further follow-up is organised as necessary. Termination of pregnancy is currently illegal in Malta.

This study was carried out to analyse the accuracy of the antenatal ultrasound services provided in Malta.

Material and Methods

The study was approved by Ethics Committee of Malta Faculty of Medicine and Surgery Research Ethics Committee (approval number: FRECMDS_1819_100).

Case recruitment

Recruitment of local cases

Cases recruited for this study included all cases of babies diagnosed with congenital anomalies detectable by antenatal ultrasound screening, born between January 2016 and December 2018. This list of cases was based on inclusion

criteria adopted by the country's local congenital anomalies registry. This data is routinely collected by the registry and was complete up to the end of this period. The variables used from the registry dataset were gender, gestation, date of birth, whether antenatal ultrasound scanning was done, what anomalies were found postnatally, whether said anomalies were detected antenatally, and which type of antenatal test was positive first.

EUROCAT data

The EUROCAT network is a European network of population-based registries for the epidemiological surveillance of congenital anomalies. Data obtained included all cases of babies with congenital anomalies detectable by antenatal ultrasound screening, born between January 2015 and December 2019. This was done by accessing the publicly available EUROCAT website (9). EUROCAT data extract started from 2015 through to 2019 and it was thus decided to use all data available. The EUROCAT centres from which data was obtained were as follows: Cork and Kerry, French West Indies, Hainaut, Malta, Netherlands, Northern England, Odense, Plevin, Saxony-Anhalt, Tuscany, Valencian Region, Vaud, Wessex and Zagreb.

Inclusion and exclusion criteria

Inclusion and exclusion criteria for local congenital anomalies registry cases

All cases of registered anomalies were collected, irrespective of maternal nationality, gender of child and whether assisted conception was used or not. Cases excluded from the data set included those in which pre-natal ultrasound scans were not done, or in cases where this could not be traced. Cases in which a scan was logged as performed, but the results were not available, were also excluded. Cases where any anomaly found postnatally could not have been detectable on antenatal ultrasound or would have been considered part of the normal foetal anatomy [e.g., patent ductus arteriosus (PDA)] at the time of antenatal scanning were also excluded. Furthermore, cases in which the first positive pre-natal test showing an anomaly was identified by other methods and not by ultrasound were also excluded (e.g., chromosomal defect picked by chromosomal analysis following amniocentesis before an ultrasound scan detected an abnormality).

Inclusion and exclusion criteria for EUROCAT data

Cases excluded were those in which the patient was diagnosed with a condition in which no children with the same pathology were born in Malta. This was done because this data was specifically collected for the purpose of accuracy comparison between Malta and the other EUROCAT centres.

Local data collection

Ultrasound machines in the Maltese state service

To-date, there is no central electronic record system available for storing data obtained from antenatal ultrasound, apart from the data recorded and stored on the ultrasound machines themselves, which is eventually overwritten once the machine hard-drives reach maximum data capacity. Nevertheless, electronic attendance records are created on the hospital electronic medical record software (iSoft Clinical Manager, <https://dxc.com/us/en/industries/healthcare>), whenever a patient attends an appointment for an ultrasound at the state hospital. This information was utilised to ascertain whether a patient actually attended the state hospital gynaecology outpatients department. Scans performed for the purposes of the antenatal nuchal and anomaly scans as provided by the state hospital, were carried out using one of two General Electric (<https://www.ge.com/>) Voluson S10 BT18 ultrasound machines, capable of carrying out 3D and 4D ultrasounds (10). Each machine is equipped with three different transducer probes:

1. General Electric RAB6-RS broadband electronic curved array transducer running at 2-8 MHz.
2. General Electric C1-5-RS wide band convex array probe running at 2-5 MHz.
3. General Electric RIC5-9A-RS endocavity probe running at 4-10 MHz.

A Philips IE33 echo machine, with the Philips C5-1 PureWave probe/transducer, was available for foetal echocardiograms (<https://www.philips.com/global>).

Ultrasound machines in the private sector

The ultrasound units and probes utilised in private clinics vary widely and information relating to the make and models of these ultrasound scanners was not available. Since data from ultrasound records in private sector was not directly available, an indirect method of data calculation was employed. State hospital electronic medical records were accessed via iSoft Clinical Manager software, and a list of mothers within the local congenital anomaly registry dataset who presented within the gestational period for an outpatient antenatal obstetric ultrasound scan at the state hospital was created. The remaining mothers in the local congenital anomaly registry dataset who had not presented for a state hospital ultrasound, but did have an ultrasound done at some point during the pregnancy (as per the congenital anomaly registry information), were thus assumed to have done their ultrasound privately. Some bias may have occurred due to differences in the case mix of mothers attending private and state hospital clinics.

Local ultrasound accuracy data collection

Once all the required ethical and data protection approvals were obtained, data was obtained from the local congenital anomalies registry that contained data on each baby born with a list of their congenital anomaly(s). Using data from this registry, for each anomaly listed, data on whether an antenatal ultrasound diagnosis was made for each anomaly was collected and, if so, whether the diagnosis was partially correct or completely correct. For the purposes of this study, anomalies that were marked as partially correct and completely correct were taken as successfully detected.

Assessment of where local scans were performed

The attendance of gravid mothers for an antenatal ultrasound scan at the state hospital obstetrics and gynecology outpatient department was determined by accessing the electronic public hospital medical record system. This made it possible to identify whether an anomaly was missed by a non-state hospital clinic or by the state hospital antenatal ultrasound clinic. This methodology was based on the assumption that any one mother either had her scans done privately or within the public sector. If the local congenital anomalies registry were to list a congenital anomaly as not detected during antenatal ultrasound screening, and the mother did not have an episode registered at the state hospital, then the case must have been missed at a non-state hospital clinic. On the other hand, if the local congenital anomalies registry listed a congenital anomaly as not detected during antenatal ultrasound screening and the mother had confirmed attendance at the state hospital antenatal ultrasound clinic as per her electronic medical record, then the anomaly must have been missed during state hospital screening. As per typical local practice protocols, abnormal scans in private practice typically result in a referral to the state hospital for a second follow-up scan, and for the purposes of this study, such mothers were considered to have had a scan only at the state hospital. In view of this limitation, results were represented as percentage of cases not detected, rather than detected, in order to minimise the risk of under-estimating the performance of private clinics. This was done because babies with anomalies that were not detected privately would not have been referred to the state hospital for a follow up scan.

EUROCAT data

Data pertaining to the antenatal ultrasound detection rates is openly available on the EUROCAT website (9). The anomalies analysed for antenatal detection by EUROCAT were anencephaly and similar defects, spina bifida, hydrocephalus, transposition of the great arteries (TGA), hypoplastic left heart, cleft lip with or without cleft palate, diaphragmatic hernia,

gastroschisis, omphalocele, bilateral renal agenesis and Potter's syndrome, posterior urethral valves and/or prune belly, limb reduction defects, club foot, chromosomal abnormalities in general, Down syndrome, Patau syndrome and Edwards syndrome.

Statistical analysis

Local accuracy by organ system was assessed as follows. The data on accuracy rates for antenatal ultrasound screening was classified by organ system. The percentage of congenital anomalies missed by antenatal ultrasound for congenital malformations involving the central nervous system (CNS), face, lung, heart, musculoskeletal system, craniofacial system, gastrointestinal system, the renal system, and syndromes were subsequently analysed separately. χ^2 -for-trend testing was carried out to elucidate any statistically significant trends in scan accuracy for each organ system over the 3-year period. This was done using formulae made by the authors within Microsoft Excel software (<https://www.microsoft.com/en-mt>).

Local accuracy trend by organ system

The overall trend in antenatal ultrasound screening detection over the three study years, 2016, 2017 and 2018, was also noted for each organ system and for syndromes.

Public vs. private sector accuracy was calculated and expressed as a percentage.

EUROCAT data

The number of cases detected on ultrasound antenatally within the EUROCAT database and the percentage that this represented was retrieved and compared with the local figures for the same three-year period. Simple proportion was utilised to calculate the total number of postnatal cases that were found, and subsequently, the number of cases that were not detected. This was carried out for each group according to the underlying pathology.

Results

A total of 335 mothers were obtained from the local congenital anomalies registry, which included births affected by congenital anomalies from the beginning of 2016 to the end of 2018. The maternal age ranged from 16 to 46 years. A total of 338 babies were delivered with congenital anomalies during this period, 202 of which were male and 136 of which were female. Gestational lengths ranged from 26 weeks up to 41 weeks. The local birth rate decreased over the 3-year period, with a rate of 9.90 per 1,000 persons in 2016, 9.25 in 2017 and 9.15 in 2018.

Local exclusions

Twelve patients were removed in view of incomplete data. Another 6 patients were removed since their reported anomalies were deemed to be normal foetal findings. These were isolated patent foramen ovale and PDA. Another 30 cases labelled atrial septal defect (ASD) were also removed from the analysis, since it is nearly impossible to differentiate an ASD from the physiological foramen ovale on antenatal scans (11). Single cases of Crigler-Najjar syndrome, Bartter syndrome, gangliosidosis and two cases of cutis aplasia, three cases of congenital hypothyroidism and one case of severe hearing loss were excluded, since these conditions cannot be antenatally detected by ultrasound.

EUROCAT exclusions

Patau syndrome and bilateral renal agenesis plus Potter's syndrome were not analysed as Malta did not have any cases of these pathologies during the period, 2015-2019.

Local accuracy overall (public and private)

Antenatally detected cardiac anomalies (Table 1) included TGA, tetralogy of Fallot, tricuspid atresia, cor triatriatum, pulmonary valve stenosis, congenital hypertrophic cardiomyopathy, perimembranous and muscular ventricular septal defect, hypoplastic left heart, Ebstein anomaly, coarctation of the aorta, hypoplastic abdominal aorta, atrioventricular septal defect, truncus arteriosus, aortic valve stenosis, pulmonary atresia, total anomalous pulmonary venous drainage, bicuspid aortic valve, double outlet left ventricle, mitral valve regurgitation, hypoplastic aortic arch, ASD, dysplastic aortic valve, right sided aortic arch, atrial isomerism, vascular ring around the trachea and congenital dilated cardiomyopathy. There were no significant trends in antenatal cardiac anomaly diagnosis rates during the 3-year period.

Renal defects detected included were penoscrotal, proximal shaft, midshaft, distal shaft, glanular, perineal and subcoronal hypospadias, fused renal ectopia, hydronephrosis, pulviureteric junction stenosis, webbed penis, pelvic kidney, duplex kidneys, chordee, atrophic kidneys, horseshoe kidney, renal agenesis, webbed scrotum, hydroureter, micropenis, renal cystic dysplasia, bifid scrotum, and posterior urethral valves. A statistically significant negative trend in the percentage of cases missed was observed (Table 1).

Musculoskeletal defects included congenital hip dislocation, duplication of various digits, structural talipes equinovarus, myopathies, achondroplasia, hamartomata involving the digits, hypoplastic digits, congenital dislocation of the knee, natal teeth, asymmetrical limb shortening, arthrogryposis, overriding digits, abnormalities of the vertebrae, clinodactyly, dysplastic hands, dysplastic/bifid ribs, brachydactyly, thoracic dystrophy,

Sprengel deformity, scoliosis, fixed knee flexion, and rotated hip (Table 1) and there were no significant trends in diagnosis rates.

With regards to craniofacial defects, a significant negative trend in the percentage of cases missed was detected (Table 1). Facial abnormalities included cleft lip and palate of various grades, facial dysmorphism, micrognathia, high arched palate, microtia, low set ears, accessory auricles, choanal atresia, facial hypertelorism, microphthalmia, mid-facial hypoplasia, and coloboma.

There were no significant trends in the antenatal detection rate of CNS defects (Table 1) and congenital anomalies identified were hydrocephalus, myelomeningocele, anencephaly, microcephaly, severe holoprosencephaly, partial and complete agenesis of the corpus callosum, plagiocephaly, turriccephaly (due to maternal bicornuate uterus), colpocephaly, subependymal cysts, craniosynostosis, Dandy-Walker variant, pontine and cerebellar hypoplasia, neurofibromatosis type-1, Chiari-1 malformation, hypoplasia of the anterior pituitary and bilateral choroid plexus cysts.

With regards to defects affecting the lungs and thorax, no significant trends were identified, and these defects were lung aplasia, a cystic lesion in the sub-cutaneous layers of the right side of the chest, a cystic mass in the right upper lung lobe, and premature hypoplastic lung (one of which was associated with a left sided severe pulmonary artery malformation).

There were no significant trends in gastrointestinal cases either (Table 1) and the anomalies included gastroschisis, Hirschsprung disease, congenital hepatomegaly with hepatic fibrosis, diaphragmatic hernia, omphalocele, displaced anus, oesophageal atresia, trachea-oesophageal fistula, imperforate anus, congenital volvulus, duodenal stenosis, jejunal-ileal atresia, and obstruction secondary to an annular pancreas.

With regard to syndromes, a significant negative trend in the percentage of cases missed was noted, indicating an improvement in the antenatal US detection of certain syndromes (Table 1). The syndromes were: Down, DiGeorge, Edwards, Poland syndrome with characteristic absent right pectoralis, 3p deletion, dextrocardia with complete situs inversus, Pentalogy of Cantrell, Neu Laxova, and CHARGE syndrome.

Local accuracy of out of hospital scans

A total of 199 anomalies were present in patients who did not have an antenatal ultrasound appointment logged at the local state hospital. The trend in the miss rate over the three-year period was not significant (Table 2A).

Local accuracy of hospital scans

A total of 284 anomalies were present in patients who did have an antenatal ultrasound appointment logged at the local state

hospital. The trend in the not detected rate over the three-year period was not significant (Table 2B).

Hospital vs. private

Private sector scans had a higher non-detection rate than the state hospital scans (Table 3).

Malta vs. EUROCAT

There were no statistically significant differences in the number of antenatal anomalies detected and not detected between Malta and the rest of the EUROCAT centres (Table 4).

Discussion

Timely antenatal diagnosis and appropriate, repeated parental counselling is associated with lower levels of parental anxiety at birth (12). Early diagnoses and appropriate preparation may at least soften the blow dealt by such a turbulent and upsetting period in parents' lives.

Private vs. hospital scan accuracy

A notable discrepancy existed between the accuracy rates obtained in non-state hospital clinics and state hospital clinics (Table 3). This may be due to the use of ultrasound machines in some non-state hospital clinics, which perhaps do not meet the same specifications as those used in the state hospital. It may also be due to the use of machines which may not be equipped with the ideal set of ultrasound probes needed to perform a range of antenatal ultrasound scans. Finally, it may also be due to more rigorous maintenance of the ultrasound equipment used within state hospital clinics as opposed to equipment used in some non-state hospital clinics. It is also possible that obstetricians carrying out antenatal ultrasound scans within the state hospital have more experience than some of those carrying out scans solely in the private sector. They may also have more training pertaining specifically to carrying out effective antenatal ultrasound scans.

Malta vs. EUROCAT

Accuracy rates were not significantly different on comparing Malta and the other EUROCAT centres. This suggests that at least some of the factors that hinder ultrasound accuracy locally may also be present in other antenatal clinics abroad.

Declining congenital anomaly rates

The total number of postnatally detected cases decreased over the three-year period under study. This suggests that the incidence of various congenital anomalies was decreasing. Another possibility is that parents may in fact be notified of a serious antenatal anomaly during a routine antenatal anomaly

Table 1. Local trends in scan accuracy for each organ system

	Heart			Renal			Musculoskeletal					
	2016	2017	2018	Overall	2016	2017	2018	Overall	2016	2017	2018	Overall
Not detected	41	42	24	107	31	15	18	64	27	14	20	61
Detected	14	14	14	42	12	11	20	43	6	4	2	12
Total	55	56	38	149	43	26	38	107	33	18	22	73
(%) not detected	74.5	75	63.2	71.8	72.1	57.7	47.4	59.8	81.8	77.8	90.9	83.6
Upper 95% CI for overall (%) not detected	78.7				69.0				90.9			
Lower 95% CI for overall (%) not detected	63.8				49.9				72.7			
χ^2 -for-trend	2.52				5.16				0.66			
p	0.11				0.02				0.42			
	Craniofacial			Central nervous system			Lung					
	2016	2017	2018	Overall	2016	2017	2018	Overall	2016	2017	2018	Overall
Not detected	23	14	4	41	3	10	5	18	2	1	0	3
Detected	1	2	2	5	9	4	3	16	0	2	0	2
Total	24	16	6	46	12	14	8	34	2	3	0	5
(%) not detected	95.8	87.5	66.7	89.1	25.0	71.4	62.5	52.9	100	33.3	-	60.0
Upper 95% CI for overall (%) not detected	95.9				69.8				92.7			
Lower 95% CI for overall (%) not detected	76.5				35.4				17.0			
χ^2 -for-trend	3.93				3.48				2.22			
p	0.05				0.06				0.14			
	Gastrointestinal tract			Isolated syndrome								
	2016	2017	2018	Overall	2016	2017	2018	Overall				
Not detected	3	3	7	13	16	12	8	36				
Detected	7	2	5	14	1	1	4	6				
Total	10	5	12	27	17	13	12	42				
(%) not detected	30	60	58.3	48.2	94.1	92.3	66.7	85.7				
Upper 95% CI for overall (%) not detected	67.7				94.1							
Lower 95% CI for overall (%) not detected	29.2				85.7							
χ^2 -for-trend	1.69				3.97							
p	0.19				0.05							
CI: Confidence interval												

Table 2A. The accuracy rates of antenatal ultrasound screening in non-state hospital clinics between 2016 and 2018, including trend analysis

Non-state hospital clinics	2016	2017	2018	Overall	Trend analysis
Not detected	93	35	39	167	χ^2 -for-trend=2.52 p=0.11
Detected	15	4	13	32	
Total	108	39	52	199	
(%) not detected	86.1	89.7	75.0	83.9	
Upper 95% CI for overall (%) not detected	88.6				
Lower 95% CI for overall (%) not detected	77.9				
CI: Confidence interval					

Table 2B. The accuracy rates of antenatal ultrasound screening in state hospital clinics between 2016 and 2018, including trend analysis

State hospital clinics	2016	2017	2018	Overall	Trend analysis
Not detected	53	76	47	176	χ^2 -for-trend=0.30 p=0.58
Detected	35	36	37	108	
Total	88	112	84	284	
(%) not detected	60.2	67.9	56.0	62.0	
Upper 95% CI for overall (%) not detected	67.6				
Lower 95% CI for overall (%) not detected	56.0				
CI: Confidence interval					

Table 3. Comparing the accuracy of state hospital scans and non-state hospital scans

	Not detected overall	Detected overall	(%) not detected
State hospital	176	108	62.0
Non-state hospital	167	32	83.9

scan, at which point they may decide to travel overseas, as abortion is illegal in Malta, and proceed with termination of the pregnancy of their own accord. This would result in a decrease in the total number of postnatally detected congenital anomalies listed within the local congenital anomalies registry per annum since a baby is only listed in said registry upon being born. According to the non-profit organisation *Doctors for Choice Malta*, it is possible for people residing in Malta to carry out termination of pregnancy by either travelling overseas to Italy, the Netherlands or the United Kingdom and having the procedure done at a dedicated abortion clinic, or by purchasing abortifacient tablets over the internet (13).

Accurate statistics pertaining to the number of people residing in Malta who carry out termination of pregnancy at the time of writing were unavailable. It may be reasonable to assume that a proportion of abortions are carried out solely in view of the successful detection of a severe congenital anomaly, which is known to be associated with high degrees of morbidity, mortality, and reduction in quality of life. With this assumption in mind, such abortions could lead to an underestimation of

the total number of babies born in Malta with severe congenital anomalies. If this were the case, this may also result in an overestimation of the percentage of anomalies not detected by antenatal ultrasonography, as in cases such as these, antenatal ultrasound would have indeed made a correct diagnosis, but this would never be recorded in the local congenital anomalies registry. According to data published by the country’s local directorate of health and research information, a decline in birth rate in Malta occurred during the three-year period under study (14,15). If a significant decline in the national birth rate were to be caused mainly by increased rates of abortion secondary to the detection of severe congenital anomalies on ultrasound and such events would most likely be under-reported, this would most likely hinder the ability of the local congenital anomaly registry to provide accurate representations pertaining to the incidence of congenital anomalies occurring during births in Malta. Subsequently, any attempt to calculate the accuracy of antenatal screening programs in Malta would be less representative of the true situation.

Maternal BMI and scan accuracy

Maternal obesity can be detrimental to ultrasound accuracy. Malta is known to have some of the highest obesity rates in Europe, with 35.65% of the Maltese population classified as overweight and 34.10% classified as obese from 2014 to 2016 (16). In 2015, 23.8% of pregnant women were noted to be overweight, and 13.7% were noted to be obese (17). According

to this data, in 2015, over a third of the population of pregnant women in Malta were above the normal range for healthy body weight. Thus, it may be possible that this factor heavily impacted the local performance of antenatal ultrasound screening.

It has also been shown that obese pregnant women are more likely to give birth to children with congenital anomalies, such as neural tube defects, cardiac defects, gastrointestinal defects, hypospadias, and limb reduction defects. It has been postulated that the typical metabolic disturbances that come with obesity, which include increased serum triglycerides, uric acid, oestrogens, and serum insulin, may have their own teratogenic effects (18). It is well known that performing

antenatal ultrasound scans on obese women is technically challenging. It has been suggested that foetal component visualisation rates drop by 14.5% if the maternal BMI is higher than the 90th centile, with the heart and spine being the most difficult to visualise. A linear correlation has been established between the rate of hindered sonographic visualisation and increasing degrees of maternal obesity (18). Carrying out the anomaly scan at a later date than usual in cases of maternal obesity was seen to improve visualisation rates, but not significantly. It has thus been suggested that significant maternal obesity as a specific indication for dedicated foetal echocardiography and possibly even early transvaginal

Table 4. EUROCAT data on the number of cases not detected and detected for the various congenital anomalies

	Anencephaly		Spina bifida		Hydrocephalus	
	Malta	Rest of EUROCAT	Malta	Rest of EUROCAT	Malta	Rest of EUROCAT
Number detected	4	567	3	572	9	519
Number not detected	0	440	1	560	3	535
Observed χ^2	3.09		0.95		3.15	
p	0.08		0.33		0.08	
	Transposition of the great arteries		Hypoplastic left heart		Cleft palate	
	Malta	Rest of EUROCAT	Malta	Rest of EUROCAT	Malta	Rest of EUROCAT
Number detected	1	383	3	294	7	801
Number not detected	4	486	0	328	3	1034
Observed χ^2	1.17		3.33		2.81	
p	0.28		0.07		0.09	
	Congenital diaphragmatic hernia		Gastroschisis		Omphalocele	
	Malta	Rest of EUROCAT	Malta	Rest of EUROCAT	Malta	Rest of EUROCAT
Number detected	4	272	2	286	2	285
Number not detected	1	409	1	297	2	280
Observed χ^2	3.31		0.37		0.00	
p	0.07		0.54		0.99	
	Posterior urethral valve/prune belly syndrome		Limb reduction		Club foot	
	Malta	Rest of EUROCAT	Malta	Rest of EUROCAT	Malta	Rest of EUROCAT
Number detected	3	164	5	393	11	1144
Number not detected	0	144	4	622	17	1583
Observed χ^2	2.61		1.06		0.08	
p	0.11		0.30		0.78	
	Chromosomal		Trisomy 21		All anomalies	
	Malta	Rest of EUROCAT	Malta	Rest of EUROCAT	Malta	Rest of EUROCAT
Number detected	7	2890	7	1331	131	13239
Number not detected	36	8786	30	4849	307	37256
Observed χ^2	1.64		0.15		3.05	
p	0.20		0.70		0.08	

EUROCAT: European Surveillance of Congenital Anomalies

anomaly scanning. This would of course be difficult in view of the high numbers of mothers that are obese. It would also mean that each mother with a high BMI would require more time for her scan, with resultant longer waiting lists and higher costs (18). The greater the distance over which the ultrasound waves must travel (increased in maternal obesity), the higher the degree of energy absorption and dispersion of ultrasound wave energy into the surrounding tissues. This results in weaker ultrasound wave signals and a greater degree of backscatter (18).

It would appear that it is worth using high-end ultrasound machines, especially in light of the high proportion of mothers with high BMI in Malta. Nevertheless, such sophisticated machinery would need to be operated correctly, highlighting the importance of operator experience and skill.

Another factor that complicates further the performance of antenatal ultrasound in obese mothers, is the increasing incidence of multiple pregnancies, especially in those who opt to use assisted reproductive methods. Multiple pregnancies hinder the availability of useful acoustic windows via which one may assess the foetus. Furthermore, infertility secondary to hormonal and metabolic issues is more common in obese mothers and having to manage a mother with high BMI with multiple pregnancy is not uncommon (18).

The high acoustic impedance of the foetal skeletal structures means that the gross visualisation of the foetal skeleton is typically possible in spite of maternal obesity. However, low impedance foetal structures, such as the cerebellum, extremities, lips, kidneys, and heart, are not as easy to visualise. It is recommended that the extremities are best visualised during a transvaginal scan at 12 to 15 weeks' gestation. It may sometimes even be possible to visualise the heart during this scan (18).

Challenges

In Malta in 2016-18, there was currently no IT data record system in place to allow publication of ultrasound reports online, unlike other medical investigation results that are all online. Data collection was thus challenging. Antenatal ultrasound reports and/or images could only be found on the ultrasound machines themselves, or on printed reports within the patient's paper-based file. Clearly, there is room for improvement in this regard.

Recommendations

It may be beneficial to have an IT-based system on which all antenatal scan data, whether carried out privately or within Mata's State Hospital, could be published and accessed by relevant healthcare professionals. Having all the data on one unified database archiving and communications system

would provide the caring obstetrician or paediatrician secure, password protected access to any relevant images or measurements pertaining to the foetus. The use of this system could be extended as part of the formation of a dedicated foeto-maternal unit. Apart from the advantages that this would provide to the obstetric, neonatal, and paediatric teams, this would also streamline the data collection process required for future audits, research, and local congenital anomaly registry data collection. A similar system is already in place for imaging used in other departments of medicine and surgery.

With regards to privately run clinics which offer antenatal ultrasound scans, it may prove beneficial to ensure effective regulation of such services by ensuring that personnel operating the ultrasound units are experienced and certified, and that the machines and probes themselves are updated according to internationally recognised standards and designed for obstetric use.

It would be useful to repeat this study in the future, perhaps once data collection sources become more streamlined as highlighted above, over a longer period of time. This would allow further accuracy rate trending to be carried out, providing more information regarding the quality of the local antenatal screening service moving forward.

Study limitations

Due to the fact that Malta has a relatively small population, data pertaining to rare diseases and their incidence within the Maltese islands was not as abundant as data relating to such conditions in larger EUROCAT centres. For the rarer subset of congenital anomalies, this made it difficult to judge Malta's antenatal ultrasound screening performance against that of overseas centres.

In view of the data available, it was not possible to obtain a list of every type of private clinic each mother attended during the antenatal period, and these were thus analysed "collectively". During the data collection process, it was assumed that if a mother attended an appointment for an antenatal scan with the state hospital, as per her electronic medical record, then it may be assumed that she did not attend a non-state hospital (private) clinic for an antenatal scan. Thus, if a mother was logged as having attended a scan within the state hospital, and anomalies affecting her foetus were logged as detected antenatally, then the credit for the positive antenatal diagnosis was given to the state hospital clinic. Nevertheless, it may be that the mother was indeed referred for a scan within the state hospital in the first place because an anomaly was successfully detected during a scan at a non-state hospital obstetrics clinic. In this case, it followed that the non-state hospital clinic may also have been credited as having successfully picked up the anomaly antenatally. This would risk underestimating the

accuracy of antenatal scans performed privately. However, the opposite is also true, in that if a patient was logged as having attended an appointment within the state hospital, and the anomaly was not detected, that same patient may have still attended a non-state hospital clinic, which also did not detect the anomaly. It was therefore decided to collect and process data in terms of anomalies not detected rather than anomalies detected. Subsequently, the overall risk would be of underestimating the number of anomalies not detected by non-state hospital clinics. This is because if an anomaly was not detected in a non-state hospital clinic, then that patient will not be referred to the state hospital for further scanning anyway. In spite of this, a significant difference in accuracy rates was still detected when comparing state hospital and non-state hospital scans, with non-state hospital clinics underperforming in comparison to state hospital clinics.

Finally, there exists a lacuna in the research data collected in view of the fact that the local congenital anomaly registry only registers babies who are delivered from 22 weeks gestation onwards. This means that data pertaining to fetuses who may have been diagnosed antenatally prior to 22 weeks gestation with a serious congenital anomaly and then aborted overseas, was missing from the registry.

Conclusion

The difference between the performance of private and state hospital sectors in terms of antenatal ultrasound screening in Malta was significant. In this study, for major congenital anomalies, Malta's antenatal ultrasound screening service performed similarly to antenatal ultrasound screening centres contributing to EUROCAT. Overall trends do not indicate a reduction in the miss rate over the three-year period for non-state hospital or state hospital clinics, although the detection of isolated syndromes, craniofacial anomalies and renal anomalies was seen to improve significantly during the study period. The three organ systems that had the best accuracy rates were the gastrointestinal system, the CNS, and the renal system. The congenital anomalies that had the worst accuracy rates were those associated with the musculoskeletal system, the craniofacial system and those related to congenital syndromes, although miss rates were seen to be significantly down-trending for craniofacial anomalies and syndromes.

Ethical Committee Approval: *The study was approved by the University of Malta Faculty of Medicine and Surgery Research Ethics Committee (approval number: FRECMDS_1819_100).*

Informed Consent: *It wasn't obtained.*

Peer-review: *Externally and internally peer-reviewed.*

Author Contributions: *Surgical and Medical Practices: M.C.; Concept: V.G., M.C., J.B.M.; Design: V.G., M.C., J.B.M.; Data Collection or Processing: J.B.M., M.G., V.G.; Analysis or Interpretation: S.A.M., M.G.; Literature Search: J.B.M.; Writing: J.B.M.*

Conflict of Interest: *No conflict of interest is declared by the authors.*

Financial Disclosure: *The authors declared that this study received no financial support.*

References

1. Munim S, Nadeem S, Ali Khuwaja NA. The accuracy of ultrasound in the diagnosis of congenital abnormalities. *J Pak Med Assoc* 2006; 56: 16-8.
2. Wood SL, Owen J, Jenkins SM, Harper LM. The utility of repeat midtrimester anatomy ultrasound for anomaly detection. *Am J Perinatol* 2018; 35: 1346-51.
3. Whitworth M, Bricker L, Mullan C. Ultrasound for fetal assessment in early pregnancy. *Cochrane Database Syst Rev* 2015; 2015: CD007058.
4. Chen M, Lee CP, Lam YH, Tang RY, Chan BC, Wong SF, et al. Comparison of nuchal and detailed morphology ultrasound examinations in early pregnancy for fetal structural abnormality screening: a randomized controlled trial. *Ultrasound Obstet Gynecol* 2008; 31: 136-46.
5. Impey L, Child T. *Obstetrics and gynaecology*. 5th edition. John Wiley and Sons, Ltd; 2017.
6. Baldwin A, Hjelde N, Goumalatsou C, Myers G. *Oxford Handbook of Clinical Specialties*. 10th edition. Oxford University Press; 2016.
7. Richter L, Slemming W, Norris SA, Stein A, Poston L, Pasupathy D. Health Pregnancy, Healthy Baby: Testing the added benefits of pregnancy ultrasound scan for child development in a randomised control trial. *Trials* 2020; 21: 1-11.
8. Boyd PA, Wellesley DG, De Walle HE, Tenconi R, Garcia-Minaur S, Zandwijken GR, et al. Evaluation of the prenatal diagnosis of neural tube defects by fetal ultrasonographic examination in different centres across Europe. *J Med Screen* 2000; 7: 169-74.
9. Prenatal detection rates charts and tables. EU RD Platform; 2022.
10. Voluson S10 | OB/GYN Ultrasound Machine | GE Healthcare (United States) n.d. (accessed: December 20, 2021). Available from: <https://www.gehealthcare.com/products/ultrasound/voluson/voluson-s10-ultrasound>
11. Bravo-Valenzuela NJ, Peixoto AB, Araujo Júnior E. Prenatal diagnosis of congenital heart disease: A review of current knowledge. *Indian Heart J* 2018; 70: 150-64.
12. Aite L, Trucchi PA, Nahom A, Zaccara A, La Sala E, Bagolan P. Antenatal diagnosis of surgically correctable anomalies: effects of repeated consultations on parental anxiety. *J Perinatol* 2003; 23: 652-4.
13. Abortion Statistics | Doctors for Choice Malta 2021. (accessed: September 27, 2021). Available from: <https://www.doctorsforchoice.mt/abortion-statistics>
14. Gatt M, Borg K. NOIS National Obstetric Information System Annual Report 2017. Directorate for Health Information and Research; 2017.
15. Gatt M, Cardona T. NOIS National Obstetric Information System Annual Report 2018. Directorate for Health Information and Research; 2018.

16. Cuschieri S, Vassallo J, Calleja N, Camilleri R, Borg A, Bonnici G, et al. Prevalence of obesity in Malta. *Obes Sci Pract* 2016; 2: 466-70.
17. European Perinatal Health Report 2015 - Euro-Peristat n.d. (accessed: January 11, 2022). Available from: <https://www.europeristat.com/index.php/reports/european-perinatal-health-report-2015.html>
18. Paladini D. Sonography in obese and overweight pregnant women: Clinical, medicolegal and technical issues. *Ultrasound Obstet Gynecol* 2009; 33: 720-9.