ISUOG Basic Training

Quality Control Processes for Operators & Programmes

Learning objectives:

At the end of this lecture you will be able to:

- List the quality control processes that are required to ensure ultrasound operators perform obstetric and/or gynecological examinations safely and to the required standard

- List the quality control processes that are required to ensure obstetric and/or gynecological ultrasound programmes are delivered safely and to the required standard

Key questions

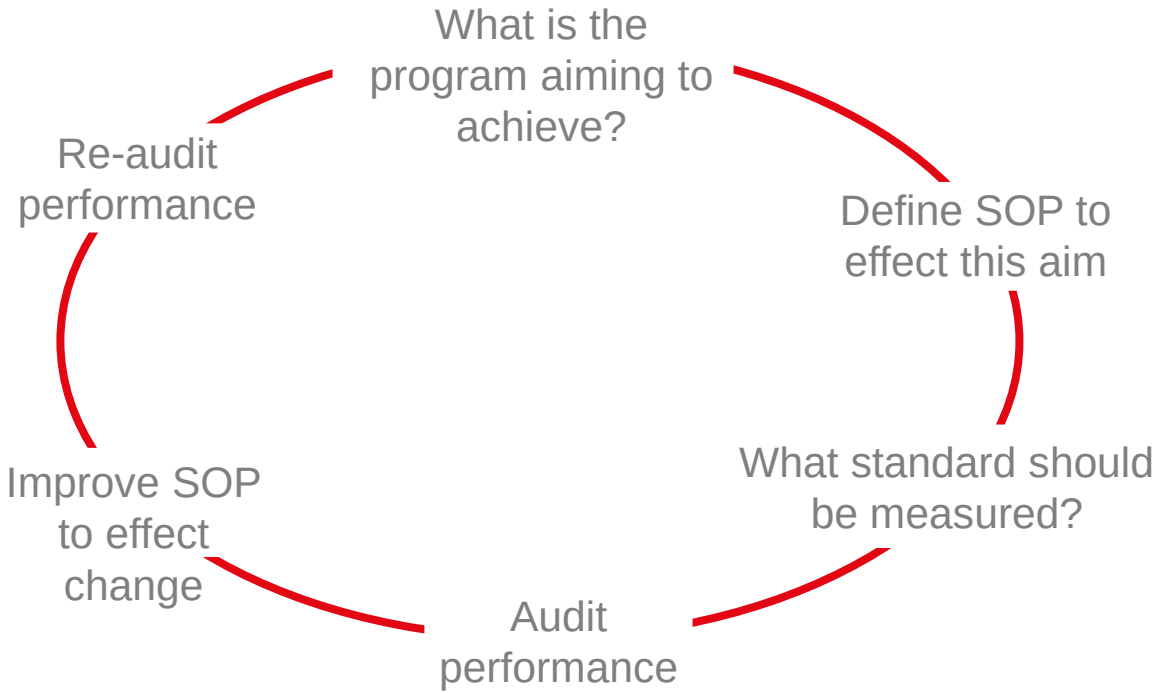
1. What are quality control (QC) processes?
2. What QC processes should be in place to ensure a high quality ultrasound service is being delivered?
3. What contribution does the ultrasound trainee and his/her mentor make to the QC process?

Primum non nocere

Hippocrates '*Of the Epidemics*'
400BC

Establishing QA at a program level

The audit cycle



Defining local standards of care

Down's Syndrome screening failures linked to Y2K bug

150 pregnant women affected

14 Sep 2001 at 12:02, John Leyden

More than 150 pregnant women may have been given incorrect results from a test for Down's Syndrome because of the Y2K software bug.

Between January 4 and May 24 last year, the PathLAN system at Northern General Hospital, which processed results of the screening of mothers at nine hospitals in South Yorkshire, Lincolnshire and the East Midlands, gave potentially incorrect results because of the Millennium bug.

After the year 2000 passed the ages of women were calculated incorrectly, which meant that many patients were informed wrongly that their babies were at low risk of the disease, according to a UK government report.

Four women subsequently gave birth to Down's Syndrome babies and two terminated their pregnancies.

If an error in calculating the women's age correctly had not been made during routine screening they would have been identified as high risk far earlier and offered a more conclusive amniocentesis test for Down's Syndrome far earlier in their pregnancy.

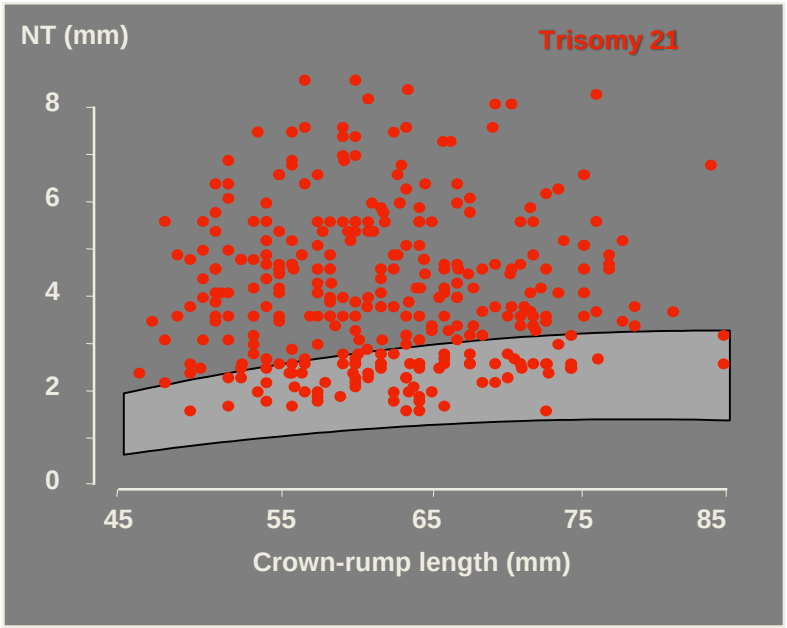
The Register, 14 Sept, 2001.

Providing QA for Down Syndrome screening

Aims of the program:

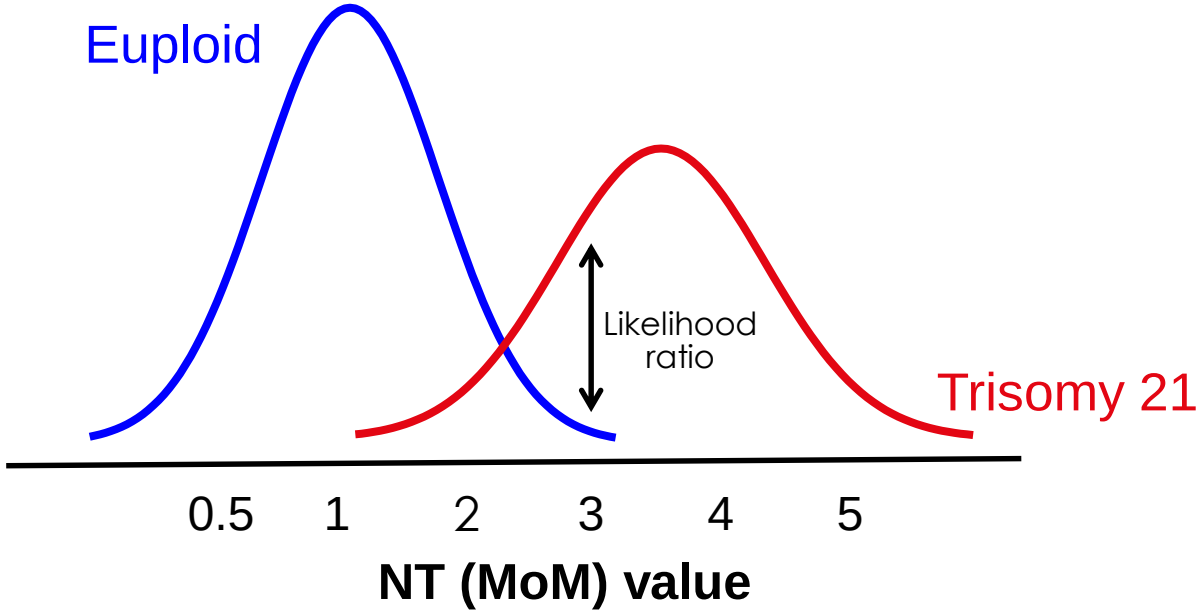
- All women should be offered a screening test
- This should be available in a timely fashion
- Results should be calculated and reported in a timely fashion
- The efficacy of the test should:
  - Limit the false positive rate (FPR) (5%)
  - Detect 90% of cases

Nuchal translucency (NT) & Trisomy 21



How is NT used to adjust risk?

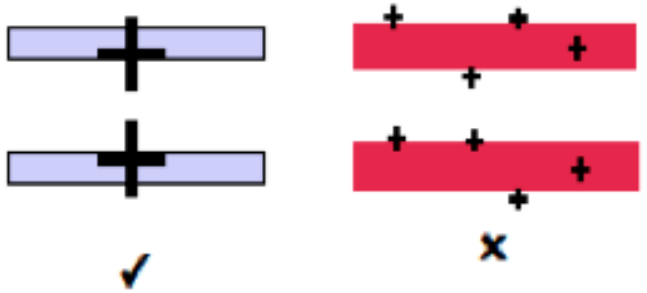
- **Have a clear understanding of how the test works**



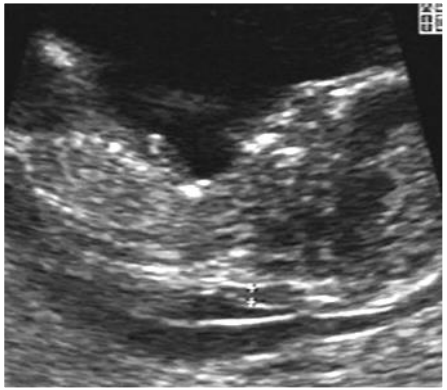
The concept of standardised measurement

- Gestation 11^{+0} to 13^{+6} weeks
- Crown rump length (CRL)

  between 45-84 mm
- Mid-sagittal view
- Large image
- Neutral position
- Away from amnion
- Maximum nuchal lucency
- Callipers ‘on-to-on’

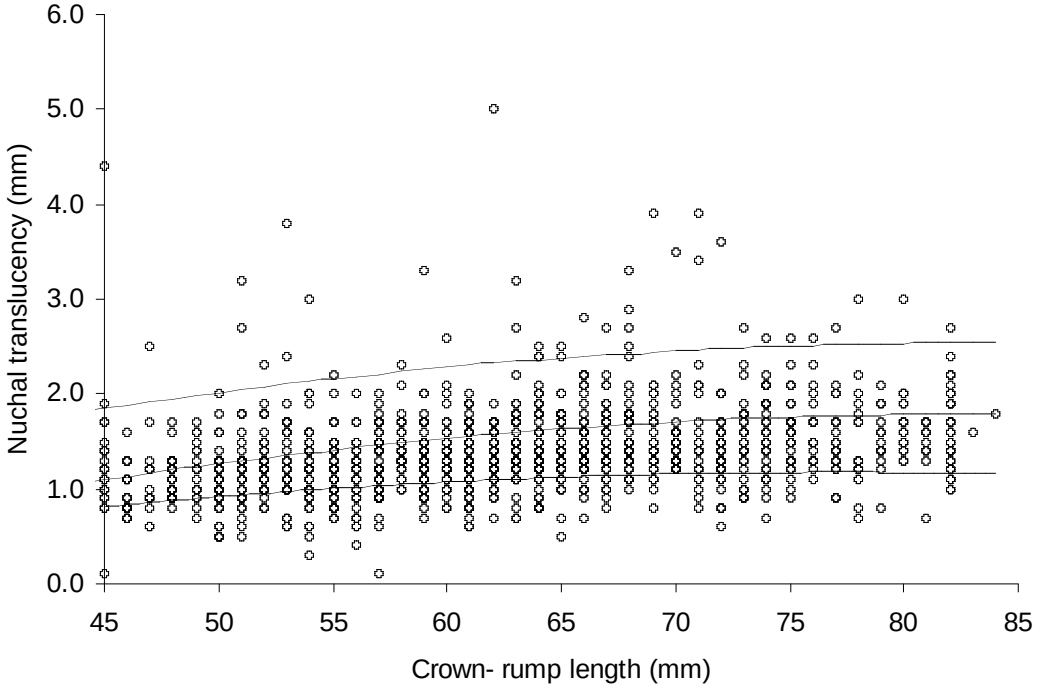




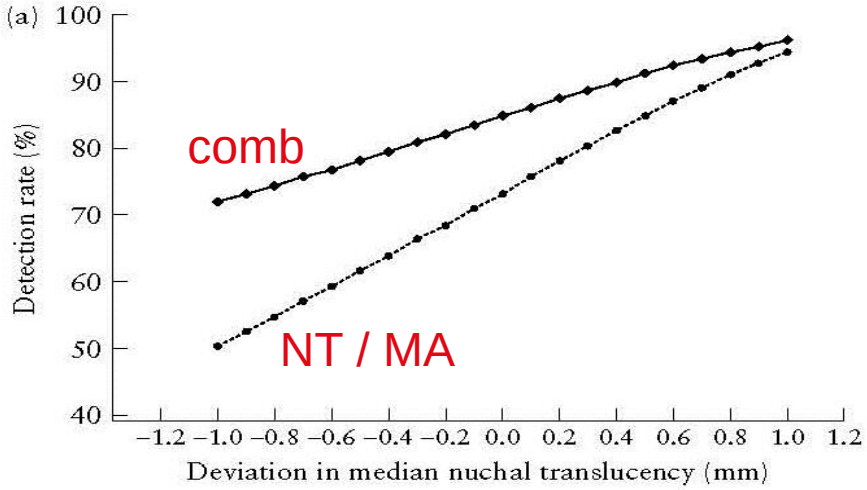


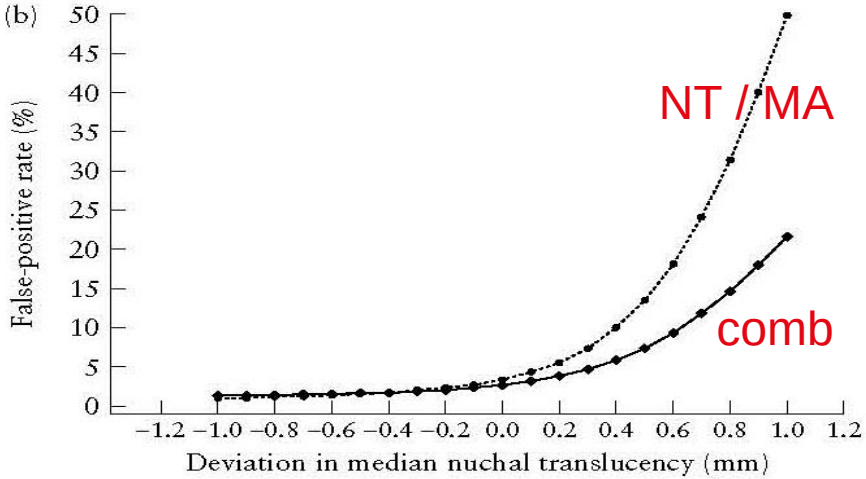

Assessing NT distributions

- Auditing operator measurements



Effect of under measuring or over measuring NT



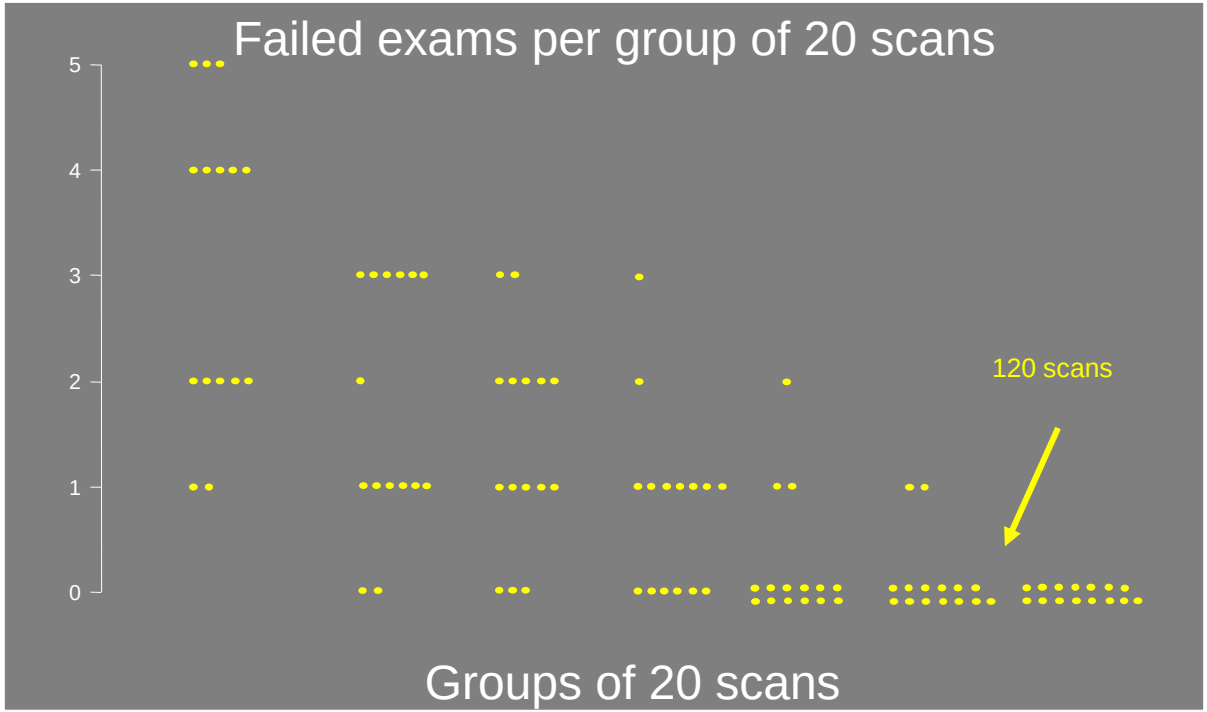


Kagan et al. UOG, 2009.

What is the effect of bias?

Bias (mm)	FPR	DR
-0.4	1.8%	79%
-0.3	1.9%	80%
-0.2	2.0%	82%
-0.1	2.2%	83%
0	**2.6%**	**85%**
0.1	3.1%	86%
0.2	3.7%	87%
0.3	4.6%	88%
0.4	5.7%	90%

Nasal bone:
Importance of operator experience

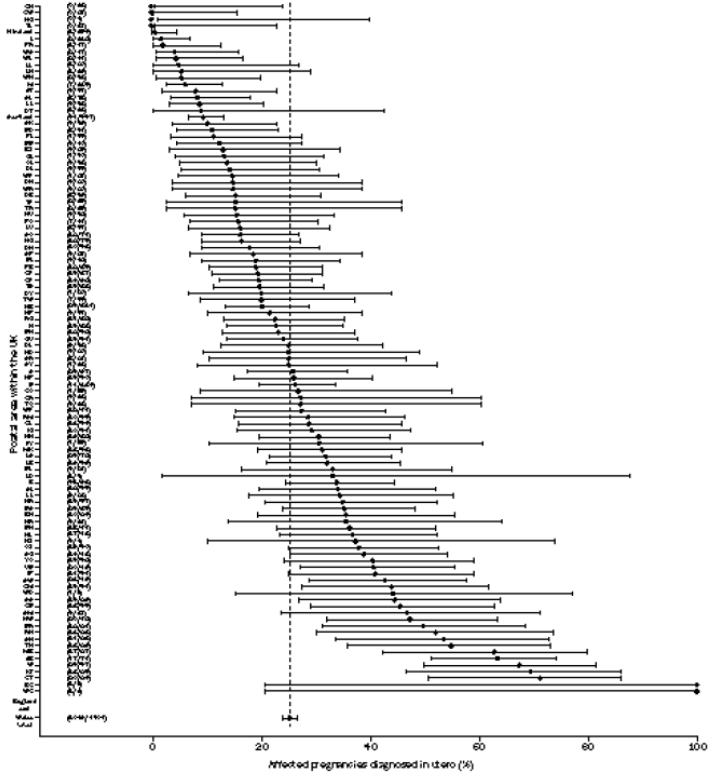


Quality assurance of subjective measures

	Absent NB		
	Trisomy 21	Normal	LR
Total	67%	2.8%	24
Caucasian	66%	2.5%	27
African	78%	10.4%	7
Asian	73%	6.8%	11
CRL 45-54	79%	4.6%	17
CRL 55-64	66%	3.9%	17
CRL 65-84	64%	1.4%	47
NT <95th	61%	1.8%	34
95th – 4.4mm	65%	3.7%	18
>4.5 mm	52%	11.8%	4

Cicero et al. UOG, 2003, 22(1).

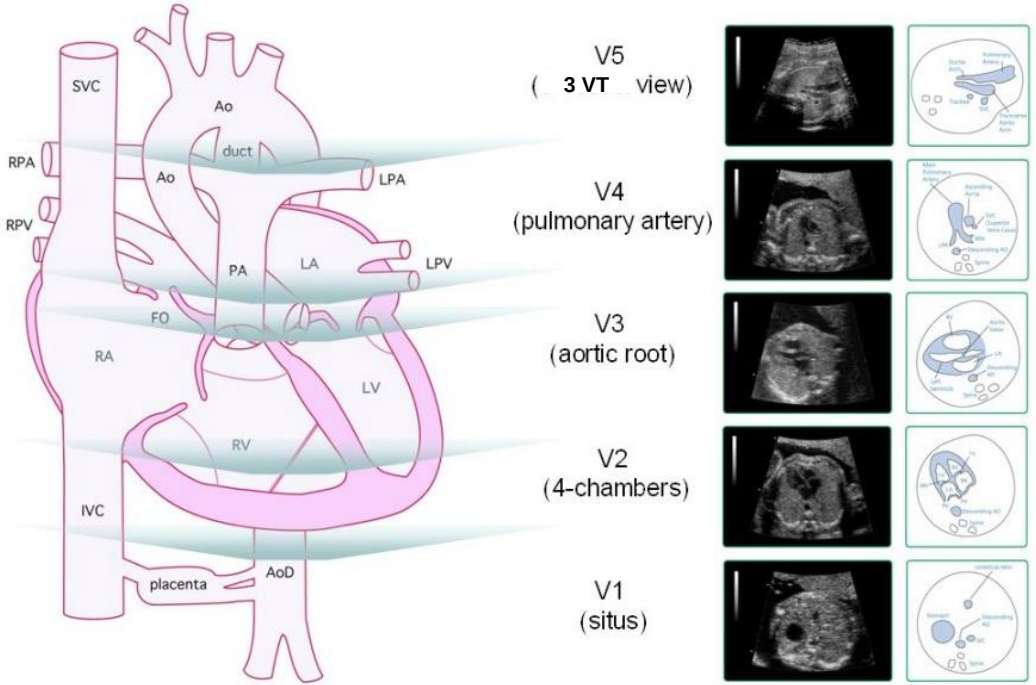
National audit of screening performance



- Collation of outcome data
- Conceal identity of centres
- Define median
- Include confidence intervals

Bull, Lancet, 1999.

Assessing the fetal heart: sequential exam / fixed views



http://www.biomecsrl.it/evaluation-of-the-fetal-heart-using-fetal-echocardiography/

Fetal Cardiac Screening

What Are We (and Our Guidelines) Doing Wrong?

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J Ultrasound Med 2016; 35:679-681.

Methods of assessing quality

- Qualitative
- Quantitative

- Single Operator
- Local group
- National comparisons

- Training implications
- Frequency / Automation of process

FAS assessment (SPSZN criteria)

Stichting Prenatale Screening Zuidwest Nederland

Upload images:	5 cases | 25 images	
Examine	Based on best of three cases	
Criteria:	Image magnification	
	Correct plane	
	Correct calliper placement	
Score:	56 points:	excellent
	50-55 points:	good
	42-50 points:	pass
	<42 points:	fail

Ursem et al. JUM, 2017.

Results:
QA 20 week anomaly scan audit

Stichting Prenatale Screening
Zuidwest Nederland

85 ultrasonographers:

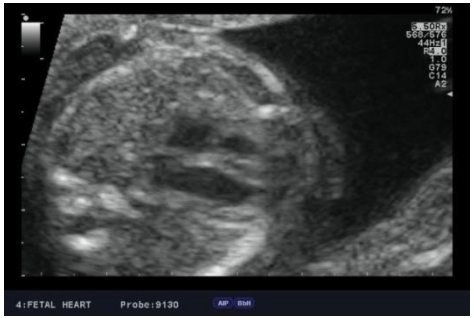
	Qualitative audit anomaly scan			
	Perfect	Good	Pass	Failed
N sonographers	2 (2.3%)	46 (54%)	25 (29%)	12 (14%)

Ursem *et al.* JUM, 2017.

Conclusion: FAS audit

Stichting Prenatale Screening
Zuidwest Nederland

- Fetal structures
  - **Best:** Bladder, umbilical cord vessels, femur
- Fetal structures
  - **Least:** Sagittal profile, placenta –cervix, diaphragm
- Magnification
  - Best: HC
  - Least: 4-chamber view
- Callipers
  - Best: TCD (97% correct)
  - Least: measurement renal pelvis (66% R & 61 % L)



Ursem et al. JUM,

“Study the past if you would define the future.”

Confucius 551 – 479 BC