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

Define SOP to effect this aim

What standard should be measured?

Audit performance

What is the program aiming to achieve?

Re-audit performance

Improve SOP to effect change

Basic Training
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.
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

Crown-rump length (mm)

NT (mm)

Trisomy 21
How is NT used to adjust risk?
- Have a clear understanding of how the test works

![Graph showing NT (MoM) value distribution for Euploid and Trisomy 21 cases]

- Euploid
- Trisomy 21
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

### What is the effect of bias?

<table>
<thead>
<tr>
<th>Bias (mm)</th>
<th>FPR</th>
<th>DR</th>
</tr>
</thead>
<tbody>
<tr>
<td>-0.4</td>
<td>1.8%</td>
<td>79%</td>
</tr>
<tr>
<td>-0.3</td>
<td>1.9%</td>
<td>80%</td>
</tr>
<tr>
<td>-0.2</td>
<td>2.0%</td>
<td>82%</td>
</tr>
<tr>
<td>-0.1</td>
<td>2.2%</td>
<td>83%</td>
</tr>
<tr>
<td>0</td>
<td>2.6%</td>
<td>85%</td>
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<tr>
<td>0.1</td>
<td>3.1%</td>
<td>86%</td>
</tr>
<tr>
<td>0.2</td>
<td>3.7%</td>
<td>87%</td>
</tr>
<tr>
<td>0.3</td>
<td>4.6%</td>
<td>88%</td>
</tr>
<tr>
<td>0.4</td>
<td>5.7%</td>
<td>90%</td>
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</table>
Nasal bone: Importance of operator experience

Failed exams per group of 20 scans

Groups of 20 scans

120 scans
### Quality assurance of subjective measures

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Caucasian</th>
<th>African</th>
<th>Asian</th>
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<tbody>
<tr>
<td><strong>Absent NB</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trisomy 21</td>
<td>67%</td>
<td>66%</td>
<td>78%</td>
<td>73%</td>
</tr>
<tr>
<td>Normal</td>
<td>2.8%</td>
<td>2.5%</td>
<td>10.4%</td>
<td>6.8%</td>
</tr>
<tr>
<td>CRL 45-54</td>
<td>79%</td>
<td>66%</td>
<td>66%</td>
<td>64%</td>
</tr>
<tr>
<td>CRL 55-64</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CRL 65-84</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NT &lt;95&lt;sup&gt;th&lt;/sup&gt;</td>
<td>61%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>95&lt;sup&gt;th&lt;/sup&gt; – 4.4mm</td>
<td>65%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;4.5 mm</td>
<td>52%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

Assessing the fetal heart: sequential exam / fixed views

Fetal Cardiac Screening

What Are We (and Our Guidelines) Doing Wrong?

Mark Sklansky, MD
Department of Pediatrics
Mattel Children’s Hospital
David Geffen School of Medicine at UCLA
UCLA Children’s Heart Center
Los Angeles, California USA

Greggory R. DeVore, MD
Department of Obstetrics and Gynecology
David Geffen School of Medicine at UCLA
Los Angeles, California USA

Methods of assessing quality

- Qualitative
- Quantitative
- Single Operator
- Local group
- National comparisons
- Training implications
- Frequency / Automation of process
FAS assessment (SPSZN criteria)

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

85 ultrasonographers:

<table>
<thead>
<tr>
<th>Qualitative audit anomaly scan</th>
<th>Perfect</th>
<th>Good</th>
<th>Pass</th>
<th>Failed</th>
</tr>
</thead>
<tbody>
<tr>
<td>N sonographers</td>
<td>2 (2.3%)</td>
<td>46 (54%)</td>
<td>25 (29%)</td>
<td>12 (14%)</td>
</tr>
</tbody>
</table>

Ursem et al. JUM, 2017.
Conclusion: FAS audit

- 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
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