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## Quality Control Processes for Operators & Programmes

Jon Hyett, Australia



### 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 gynaecological examinations safely and to the required standard
- list the quality control processes that are required to ensure obstetric and/or gynaecological ultrasound **programmes** are delivered safely and to the required standard

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## Key questions

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

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**primum non nocere**  
Hippocrates 'Of the Epidemics' 400BC

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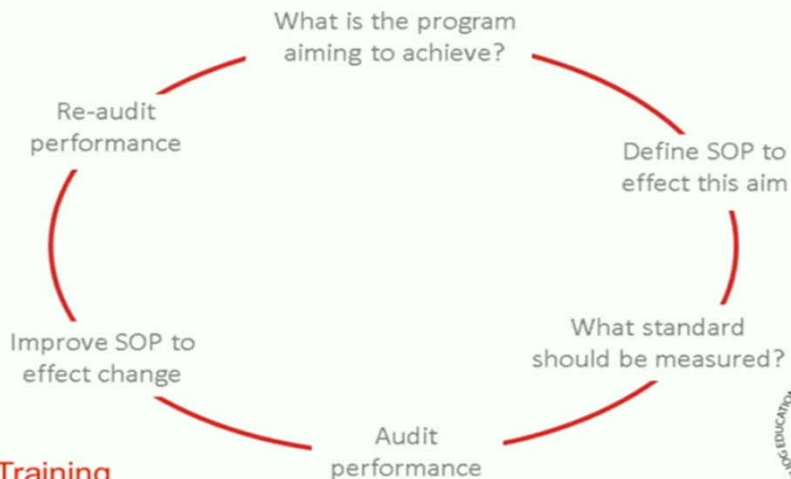


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# Establishing QA at a program level

## The audit cycle



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# Defining local standards of care



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## 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

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## 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 FPR (5%)
  - Detect 90% of cases

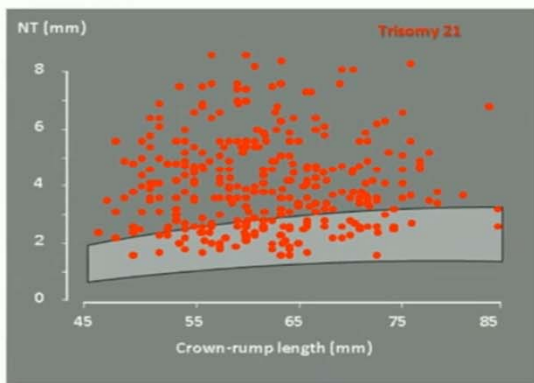
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## Nuchal translucency | Trisomy 21



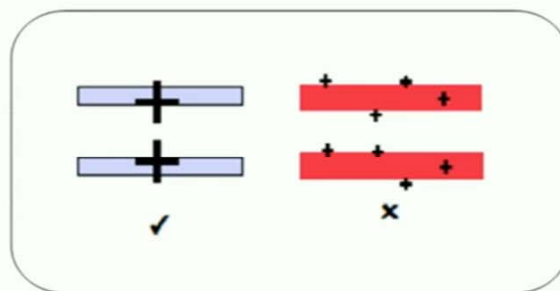
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## The concept of standardised measurement

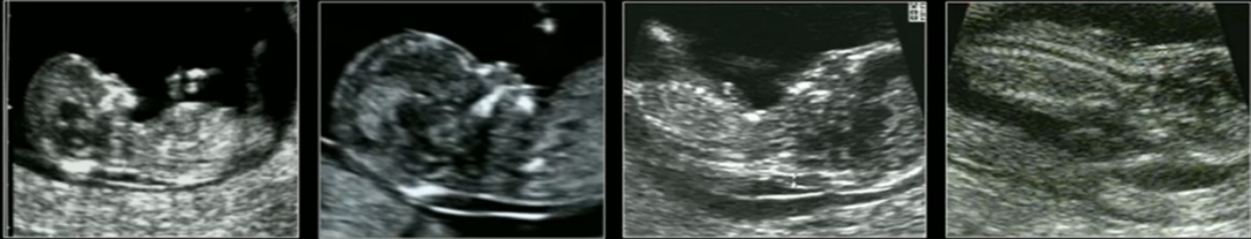
- Gestation 11<sup>+0</sup> to 13<sup>+6</sup> weeks
- CRL 45-84 mm
- Mid-sagittal view
- Large image
- Neutral position
- Away from amnion
- Maximum nuchal lucency
- Callipers 'on-to-on'



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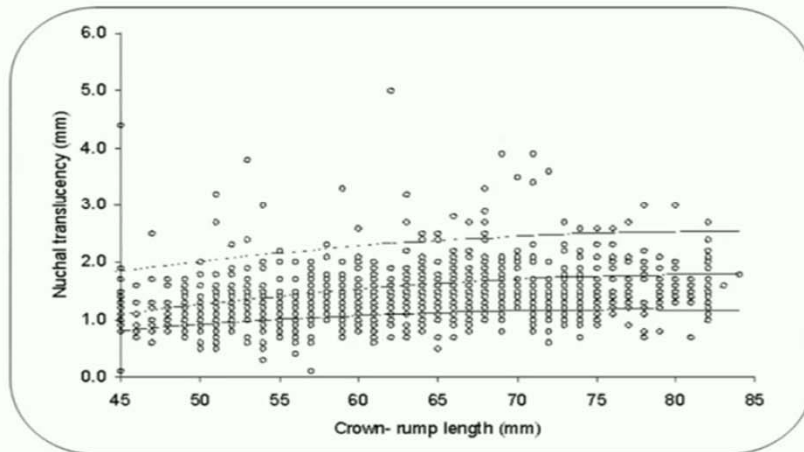


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## Assessing NT distributions

- auditing operator measurements



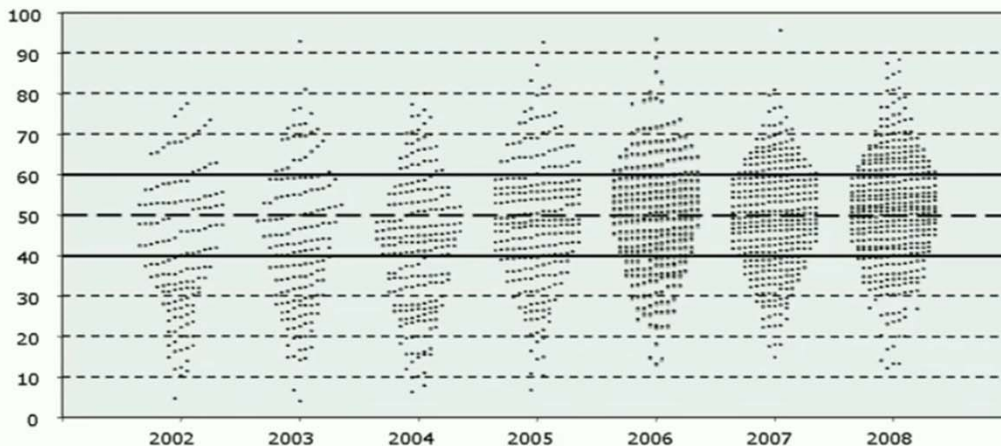
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# Assessing NT distributions

- all australian operators



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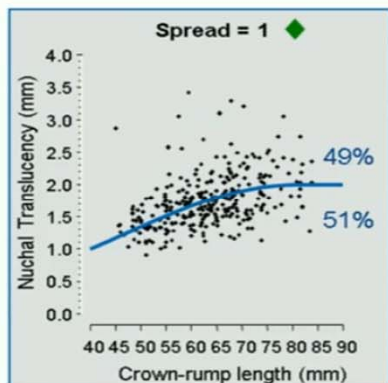
Nisbet et al. ANZJOG 2010

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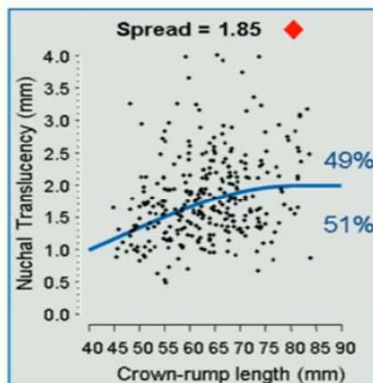


# Assessing NT distributions

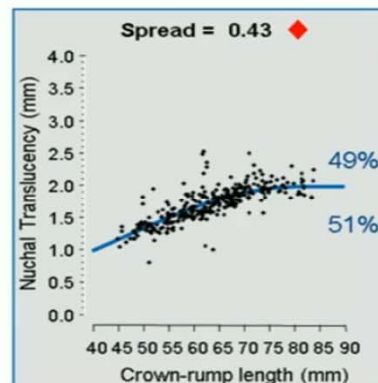
- current FMF technique



Pass: Spread >0.7 & <1.3



Fail: more than 1.3



Fail: less than 0.7

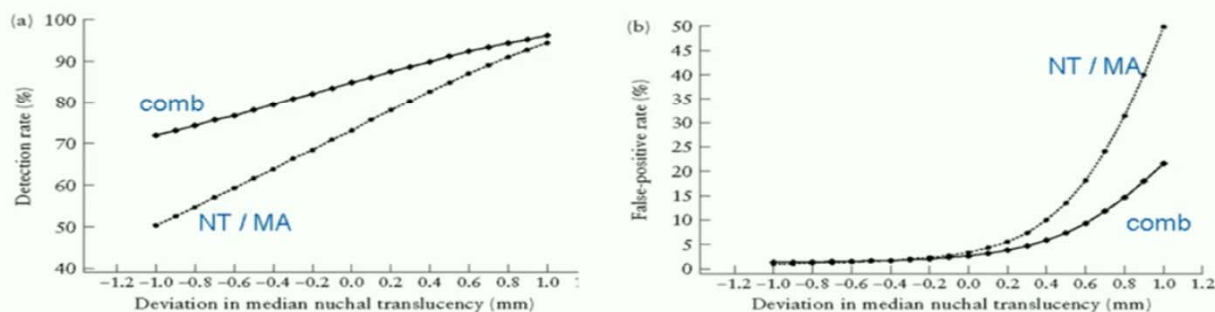
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Wright et al. DQASS 2010

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## Effect of under measuring or over measuring NT



Kagan et al. UOG 2009

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## 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%
<b>0</b>	<b>2.6%</b>	<b>85%</b>
0.1	3.1%	86%
0.2	3.7%	87%
0.3	4.6%	88%
0.4	5.7%	90%

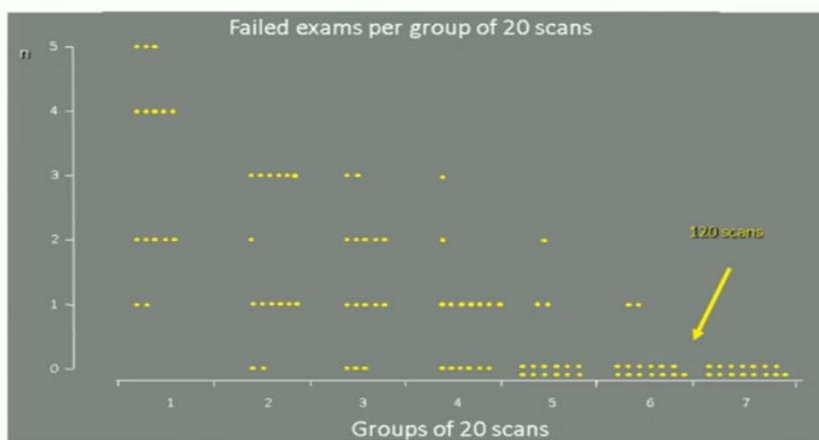
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## Nasal bone: importance of operator experience



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## Quality assurance of subjective measures



	Absent NB		LR
	Trisomy 21	Normal	
<b>Total</b>	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 <95 <sup>th</sup>	61%	1.8%	34
95 <sup>th</sup> – 4.4mm	65%	3.7%	18
>4.5 mm	52%	11.8%	4

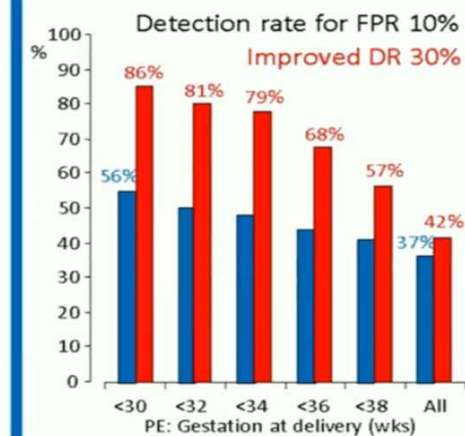
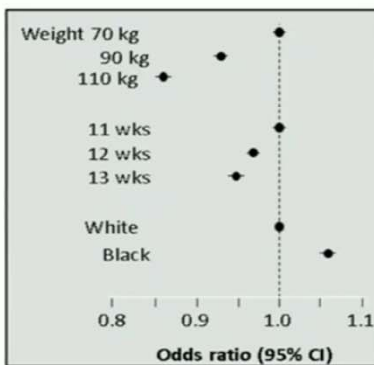
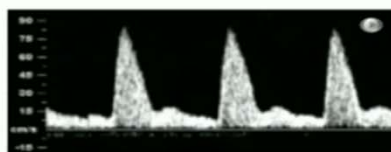
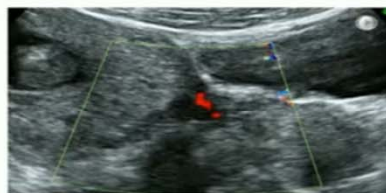
Cicero et al. 2003

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## Screening for ePET: Uterine Artery Pulsatility Index

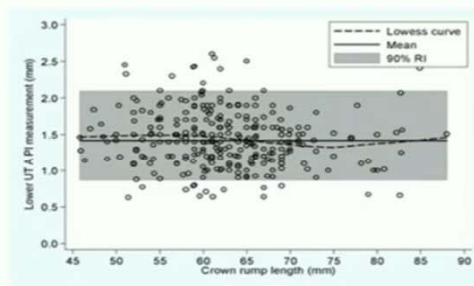
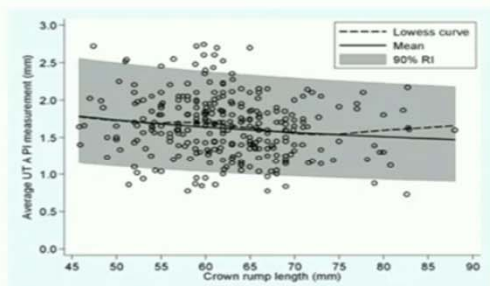
FMF UK: Prospective screening study at 11-13 wks  
Total: 64,647; PE: 1,482 (2.3%)



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## Screening for ePET: Uterine Artery Pulsatility Index



Ridding *et al.* FDT 2014

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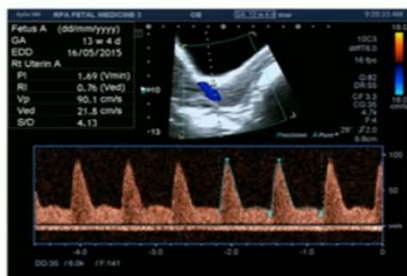
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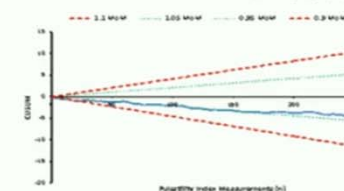
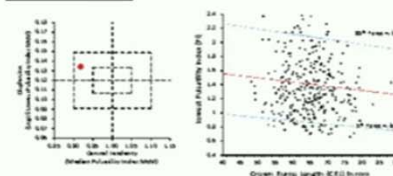
## Screening for ePET: Uterine Artery Pulsatility Index



### Pulsatility Index Quality Assurance Assessment

Sonographer: SPA P T      Period Start: 2015-08-21  
 Date of Assessment: 25-Apr-15      Period End: 25-Nov-15

Lowest Pulsatility Index Mean	1.50
Overall Mean	1.50
Upper 95% CI	1.50



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Software c/o Sahota / CUHK | Ridding *et al.* 2014



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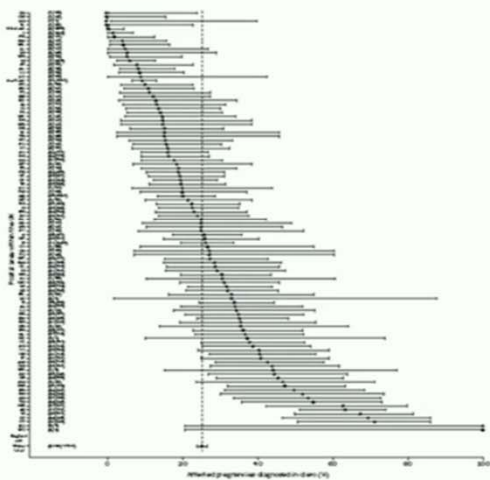




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## National audit of screening performance



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

Bull; Lancet 1999

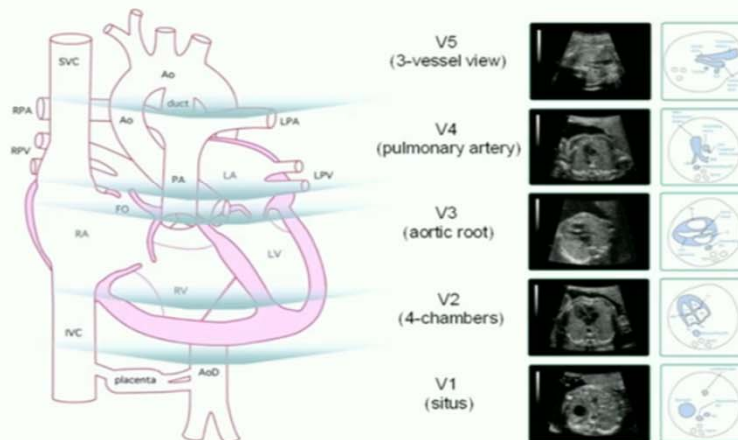


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## Assessing the fetal heart: sequential exam / fixed views



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

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## 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

J Ultrasound Med 2016; 35:679–681

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## Methods of assessing quality

- Qualitative
- Quantitative
  
- Single Operator
- Local group
- National comparisons
  
- Training implications
- Frequency | Automation of process

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

**Confucius 551 – 479 BC**

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## Post talk Quiz: Question 1

- **NT measurement:**
  - A. Has a direct impact on personalised risks for aneuploidy
  - B. Is best monitored through image assessment
  - C. Can only be performed by operators doing >200 tests / year
  - D. Should be completed to nearest 1mm measurement
  - E. Requires visualisation of the complete fetus

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## Post talk Quiz: Question 2

- **The fetal heart:**
  - A. Is complex and not amenable to quality assurance
  - B. Units should achieve detection rates >75% anomalies
  - C. Lends it self to CUSUM analysis
  - D. Should be imaged in five pre-defined views
  - E. Should be imaged using automated software

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## Post talk Quiz: Question 3

- **The nasal bone (at 12 weeks):**
  - A. length is measured to define hypoplasia
  - B. The nasal skin should be not be imaged
  - C. The nasal skin should be more echogenic than the bone
  - D. Is a qualitative tool requiring image review for QA
  - E. Has equal prevalence of absence in different ethnic groups

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