Early Pregnancy Standards

Roy Farquharson MD FRCOG
Miscarriage Clinic
Liverpool Women's Hospital, UK
rgfarquharson@yahoo.com

- Setting the scene
- Early pregnancy figures in UK
- Trends and shifts
- Care provision
- New horizons

When is Early Pregnancy?

- It's a universal journey occurring between fertilisation and 12 weeks (3 months) of pregnancy
- Why are humans so poor at reproduction compared to other animal species and primates?
- Is this high loss rate an evolutionary advantage over other species?

UK Figures (2008)

- 700,000 births per annum in UK
- 200,000 terminations
- 250,000 miscarriages
- 15,000 ectopic pregnancies

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Trends and Shifts

- Increasing average maternal age
- Increasing demand for all EP events
- Increasing knowledge about early pregnancy events (17,500,000 entries on Google)
- Patient Choice with care provider
- Establishing national standards for EP diagnosis and care

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Ethos of Care

- Patient Centred – changing the 'culture' & allowing prompt access; nurse specialist delivery; high quality 7/7 TVU ultrasound
- At all times women will be supported in making informed choices about their care and management allied to efficient management, patient counselling service and access to appropriate information.
- Standard Setting (2008 RCOG and NICE) – improves and harmonises national care delivery
- Protocol and Guideline development (website: earlypregnancy.org.uk/guidelines)

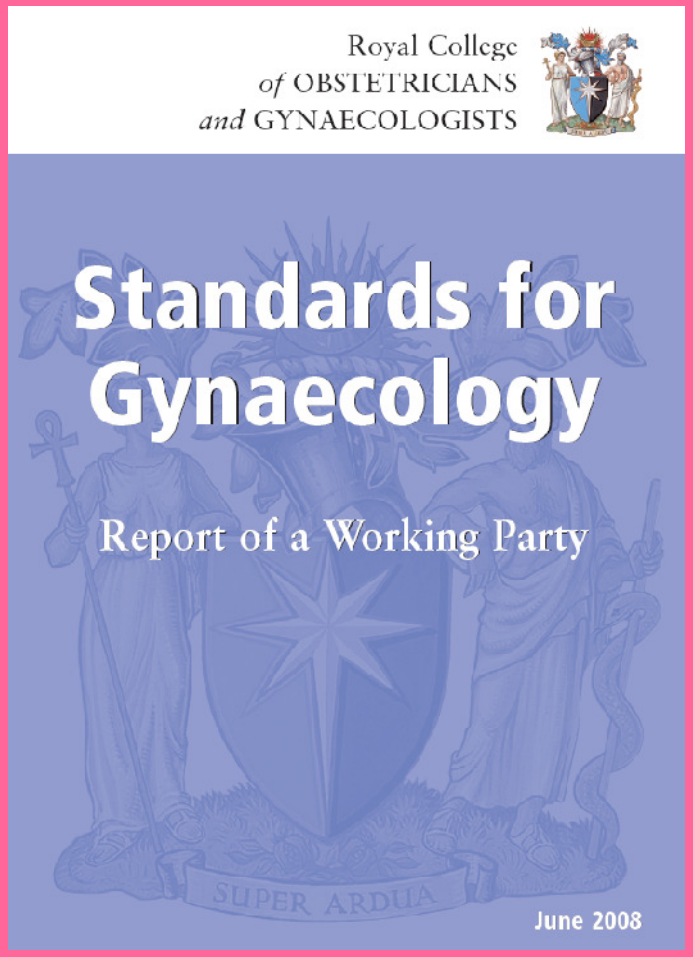
Standards in Early Pregnancy/Ectopic Pregnancy/Recurring Miscarriage

AEPU/RCOG Joint Document (2007)
RCOG Standards in Gynaecology (2008)

RCOG Tahir Mahmood, Chair, Working Party on Clinical Standards

AEPU Roy Farquharson, Chairman, Association of Early Pregnancy Units
Lesley Regan, Hon President, AEPU
earlypregnancy.org.uk/guidelines: rcog.org.uk/standards

June 2008



2. Early pregnancy loss

3. Ectopic pregnancy

4. Recurring Miscarriage

Standards in Early Pregnancy

Standard	CORE	Aspirational
Patient Information	Designated Reception Area Universal use of clear, understandable terminology by all staff	Dedicated staff constantly at reception desk to provide greeting, obtain patient details and explain structure and triage function of EPU
Patient Choice In Management	Education of patient relevant to diagnosis and management Open explanation of expectant, medical and surgical options	Dedicated phone line for patient queries and electronic access to protocols from outside unit
Dedicated Quiet Room	Room for breaking bad news away from work area	Single-use room only with soft furnishing and absence of medical equipment
Availability of Service	5 day opening during office hours	7/24 opening and service provision with full staffing and daily scan support
Competence of Scanning	Recognised ultrasound training and preceptor assessment and validation (RCOG/BMUS) Register of staff competent at scanning	Lead Clinician Presence of RCOG/BMUS trainer in EPU Annual assessment of audited activity

Opportunityisnowhere

Standards in Early Pregnancy (2)

Blood HCG level measurement	Laboratory access to blood HCG measurement and result within 48 hours of sampling	Same day sampling and result with electronic result link to laboratory
Written Information Leaflets	Visible open access to written information leaflets in EPU	Online external access to PIL
Acknowledgment of Privacy and Dignity	To provide individualised patient support and acknowledge confidentiality	Place one to one care as best practice at all times
Bereavement Counselling	All staff trained in emotional aspects of early pregnancy loss To enable access to counselling and provide immediate support	To provide all emotional and psychological counselling requirements within EPU and supported by dedicated staff and related agencies
Site of EPU	Geographically separate from all maternity areas	Own EPU entrance/exit

Opportunityisnowhere

Standards in Ectopic Pregnancy

Standard	Core	Aspirational
General		
Awareness of the condition	Healthcare professionals should be made aware of risk factors for ectopic pregnancy including the atypical way in which the condition may present.	A pregnancy test should be performed in any woman of reproductive age presenting to a health care professional with any type of abdominal pain, irregular vaginal bleeding or amenorrhoea.
Specialist referral	Women in the primary care or accident and emergency setting with suspected ectopic pregnancy should be referred directly to an Early Pregnancy Unit for immediate assessment or to the nearest Gynaecology Emergency Ward.	Early Pregnancy Units open 7 days a week accept self referrals from women with pain or bleeding in early pregnancy especially those with a previous history of ectopic pregnancy, as well as direct referrals from other health care professionals.
Patient information	Universal use of clear, understandable terminology. Clear explanations about diagnostic procedures, treatment options, follow-up procedures and future fertility.	Easy access to information, via websites and telephone lines staffed by appropriately trained health care professionals.
Written information leaflets	Open access to written information leaflets on all aspects of ectopic pregnancy diagnosis, management and future care.	Online external access to patient information leaflets. Leaflets available in other languages according to the local ethnic backgrounds

Diagnosis of Ectopic Pregnancy

Urinary hCG testing	Urinary pregnancy tests are now extremely sensitive and can detect a pregnancy when serum hCG levels are as low as 25 IU/L.	Urinary pregnancy tests should be readily available in the primary care setting to confirm or exclude pregnancy.
Ultrasound	All women with a suspected ectopic pregnancy should have a pelvic ultrasound examination. A transvaginal ultrasound examination is superior to a transabdominal scan.	All women with suspected ectopic pregnancy should undergo a transvaginal ultrasound examination. More than 80% of ectopic pregnancies should be visualised on scan prior to treatment.

Serum HCG biochemistry	Laboratory access to serum hCG measurement and result within same day.	Same day sampling and result with electronic result link to laboratory within 2 hours.
Follow-up of PUL ultrasound scan	Clinically stable women with no evidence of an intra-uterine pregnancy or ectopic pregnancy on scan should be classified as 'pregnancies of unknow n location' (PUL) and followed up with serial hCG measurements and repeat ultrasound examinations until the final location of the pregnancy is known.	Outpatient expectant management of asymptomatic women with pregnancies of unknown location. Clear diagnostic algorithms and protocols should be in place.

The Patient's Journey

- "It is always a good thing to walk a mile in another man's shoes"
- Nelson Mandela

Long Walk to Freedom The view from Robben Island Prison

Management of Ectopic Pregnancy

Choice of Management	Clear explanation of surgical, medical and expectant management options, depending on the clinical scenario and local availability.	Surgical, medical and expectant management available in all units.
Surgery	Laparoscopy should be the surgical approach of choice in haemodynamically stable women requiring surgery.	All gynaecologists should be proficient in the laparoscopic management of ectopic pregnancy.
Medical management	Medical treatment should be offered to suitable women, but only in units where women can access 24-hour telephone advice and emergency admission if necessary.	All units should offer medical treatment to appropriate women and have appropriate out-of-hours emergency back up.
Expectant management	Expectant management should be offered to suitable women, but only in units where women can access 24-hour telephone advice and emergency admission if necessary.	All units should offer expectant management to appropriate women and have appropriate out-of-hours emergency back up.
Serum HCG follow-up	A clear system should be in place to follow up women undergoing non-surgical management to monitor serum HCG levels and treatment success.	Computerised system for monitoring serum HCG levels and treatment success, allowing audit of practise.

Management of Ectopic Pregnancy

Handheld documentation	Women undergoing treatment for an ectopic pregnancy should have handheld notes documenting treatment details in case of need for emergency attendance out-of-hours or at another unit.	Hand-held individual up-to-date printed records detailing ultrasound findings, serum hCG levels, treatment given and follow-up serum hCG levels.
Anti- D immunoglobulin	All rhesus negative women treated for an ectopic pregnancy should receive anti-D immunoglobulin.	
Psychological support	All staff trained in emotional aspects of early pregnancy loss To enable access to counselling and provide immediate support	Direct access to counselling services, if required, for all women with an ectopic pregnancy.
Discharge documentation	Discharge letter detailing side of ectopic, treatment and whether or not anti-D was administered.	Information regarding normality or disease of other tube and pelvic organs
Subsequent follow-up	All women should ideally be offered a follow-up visit post treatment to discuss issues such as fertility and early management of subsequent pregnancies.	An early pregnancy unit follow-up clinic with an appropriately trained health care professional. Immediate presentation to EPU in future confirmed pregnancy test

Never make predictions, especially about the future.
Casey Stengel

Standards in Recurring Miscarriage

Standard	Core	Aspirational
General		
Awareness of the condition	Healthcare professionals should be made aware of risk factors for recurring miscarriage	Documentation of detailed analysis of pregnancy loss type and clinical event sequence assessment for each loss.
Specialist referral	Women in the primary care or hospital setting who present with known criteria for RM should be offered advice and referral to a specialised unit.	Patients with uncertain referral criteria should be able to access relevant information about referral
Patient information	Universal use of clear, understandable terminology. Clear explanations about diagnostic and follow-up procedures, treatment options and future pregnancy outcome.	Easy access to information, via websites and telephone lines staffed by appropriately trained health care professionals.
Written information leaflets	Open access to written information leaflets on all aspects of RM diagnosis, management and future care.	Online external access to patient information leaflets. Leaflets available in other languages according to the local ethnic backgrounds

Diagnostic Causes with RM

Genetic factors	Parental chromosome analysis will identify a balanced or reciprocal translocation in 3% of couples. Although this investigation is expensive, many couples choose to undergo genetic counselling (for themselves and other family members) and invasive prenatal diagnosis in subsequent ongoing pregnancies. Where financial constraints exist, selective testing should be focussed on younger women with more miscarriages and a strong family history.	Any future pregnancy failure should undergo placental cytogenetic analysis to exclude abnormal karyotype which would exclude the possibility of treatment failure. The live birth rate in RM couples with a balanced translocation is >80% There is no role for preimplantation genetic screening since the spontaneous live birth rate in n is > 50%.
Immune Factors	Antiphospholipid syndrome (APS) testing should be done and fit diagnostic criteria (Wilson et al, 1999).	Quality control assured laboratory testing and sampling procedures
Anatomical factors	Uterine anomaly screening by preconception transvaginal ultrasound (TVU) or hysteroscopy or HSG.	Cervical weakness assessment by preconception hysteroscopy combined with screening for Bacterial Vaginosis (BV).
Endocrine factors	Polycystic ovarian morphology itself does not predict an increased risk of future pregnancy loss among ovulatory women with RM.	Recognition of oligomenorrhoea (cycle >35 days) as a risk factor

I never think of the future - it comes soon enough.
Albert Einstein

Unexplained (idiopathic) Recurring Miscarriage	Early HCG measurement and serial scans after viability assessment. Success rates driven by maternal age and number of previous losses.	Continuity of care by same personnel and patient support tailored to individual needs. Pregnancy success prediction chart used for each patient
Oligomenorrohoea	Early ultrasound confirmation of viability and gestational age	HCG injection support from 6 to 12 weeks gestation if requested by patient
Thrombophilia with no maternal history of thrombosis	Initiate thromboprophylaxis with aspirin +/- heparin from diagnosis of positive urine pregnancy test	Continuation of heparin for 6 weeks postnatal Bone mineral density surveillance
Cervical Weakness	Transvaginal cerclage at 12 weeks Transabdominal cerclage prepregnancy or at 10 weeks gestation	Transvaginal ultrasound surveillance (TVU) of cervical length measurement (CLM) from 16 weeks Antibiotics from 12 weeks
Pregnancy Support Clinic	Weely early pregnancy clinic for viability until 12 weeks Dedicated antenatal clinic for women with RM history	Reassurance scans for viability Parallel clinic for TVU of CLM
Pregnancy failure	Effective and empathic management of loss with patient choice encouraged Follow-up appointment in 2 months and exclusion of molar pregnancy by repeat urine test	Cytogenetic analysis of placental material to exclude trisomy
Anti- D immunoglobulin	All rhesus negative women treated for fetal loss or repeated vaginal bleeding should receive anti-D immunoglobulin.	
Psychological support	All staff trained in emotional aspects of early pregnancy loss To enable access to counselling and provide immediate support	Direct access to counselling services, if required, for all women with an ectopic pregnancy.
Subsequent follow-up	All women should ideally be offered a follow-up visit post treatment to discuss issues such as fertility and early management of subsequent pregnancies.	An early pregnancy unit follow-up clinic with an appropriately trained health care professional. Immediate presentation to EPU in future confirmed pregnancy test

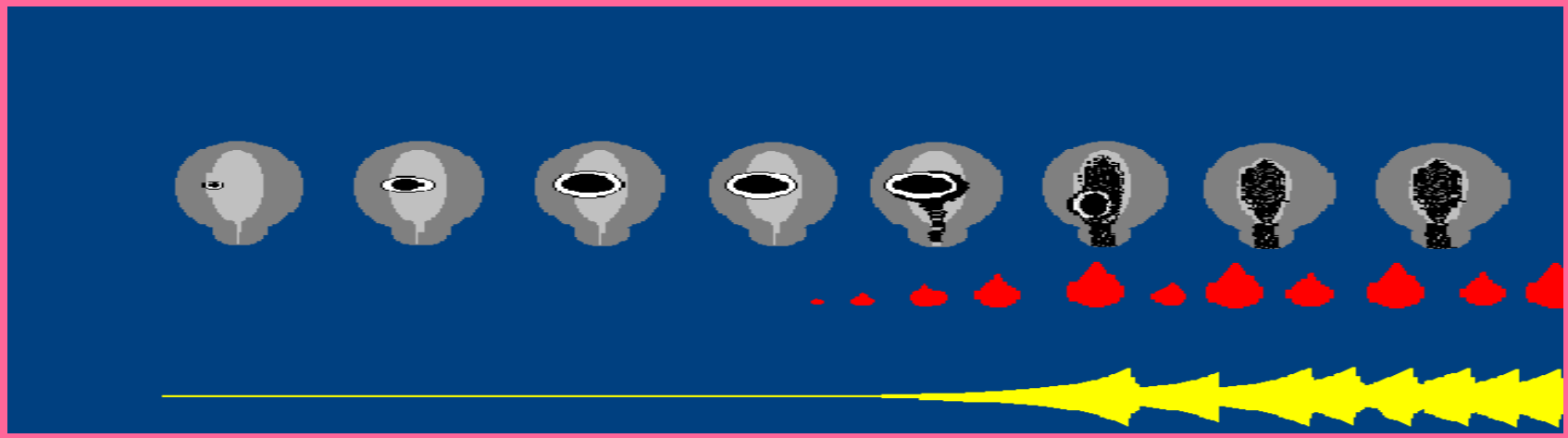
What does an Early Pregnancy Clinic/Unit do?

- All early pregnancy problems are seen by a multidisciplinary team in a dedicated area with easy patient access and privacy (for breaking bad news) plus good quality scan service and laboratory backup (HCG result computer link)
- Adapted (MEWS-based) Triage Assessment on presentation (~ 1-2% score>4)
- PUL/viability/ectopic/hyperemesis/molar
- Construction of Management Plan for Medical/Surgical/Conservative options
- Treatment & Surveillance of EP loss/failedPUL/ectopic/molar pregnancy

Early Pregnancy

- **Opportunity to exercise continuous vigilance for the commonest ‘killers’ in early pregnancy (CEMACH 2007):**
- **ECTOPIC PREGNANCY**
- **THROMBOEMBOLIC DISEASE**

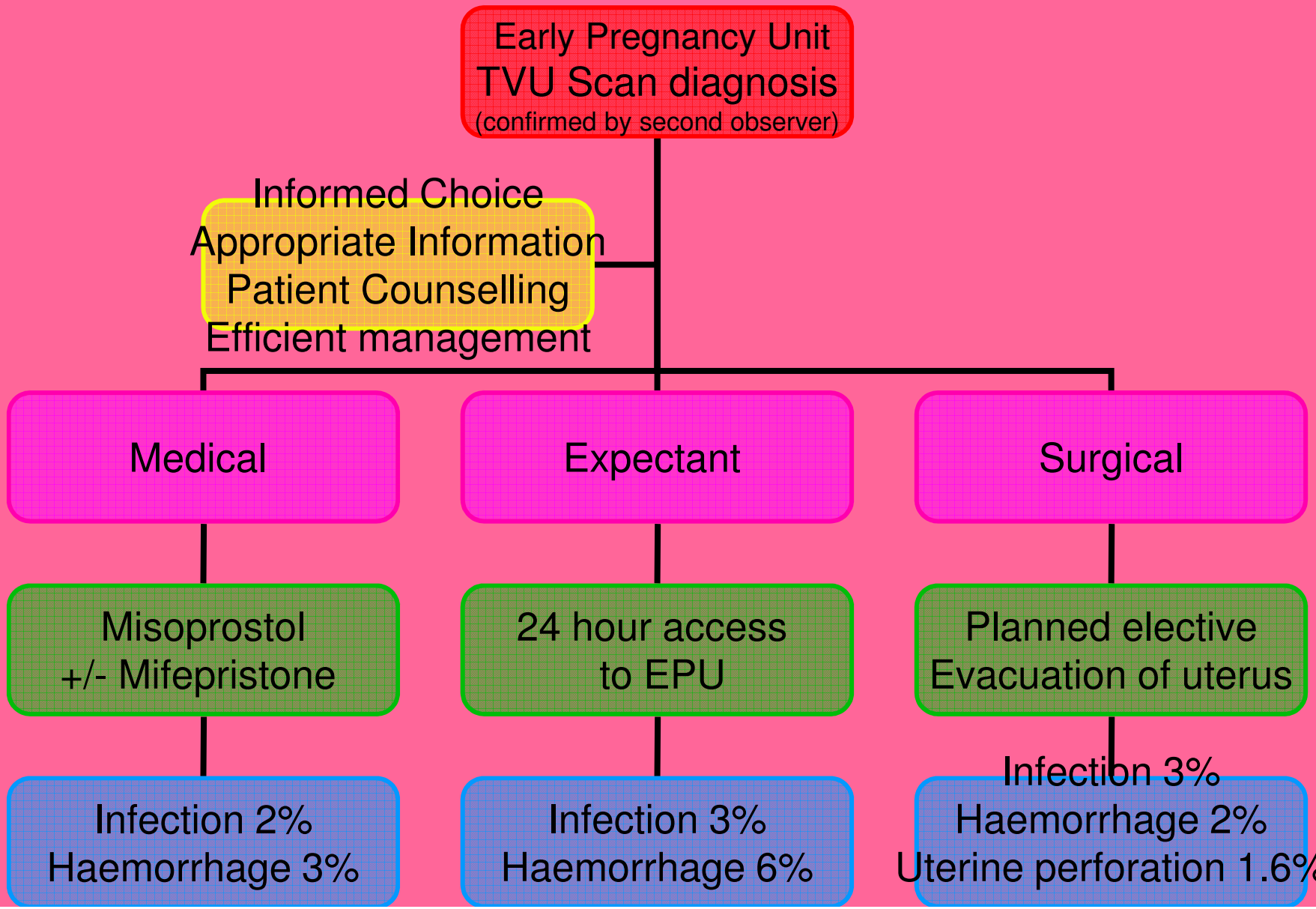
Commonest Complication - Miscarriage



Timeline Sequence of Early Pregnancy Events
Conservative or medical or surgical Rx
Patient choice and EBM

Management of Miscarriage

RCOG Guideline 25, 2006



Is Treatment Failure in RM a valid concept? - Cytogenetic Analysis of Pregnancy Loss in RM

	Philipp et al, Hum Rep,2003 (n=221) Culture 70%+CGH	Stephenson et al, Hum Rep, 2002 (n=420) Culture 82%+CGH	Rubio et al, Hum Rep, 2003 (n=71) PGD+FISHProbe	Sullivan et al O&G, 2004 (n=122) Culture 85%
Trisomy Frequency in Descending Order	15	15	16	16
	16	16	21	15
	21	22	13	NA
	22	21	22	NA
	14	14	18	NA

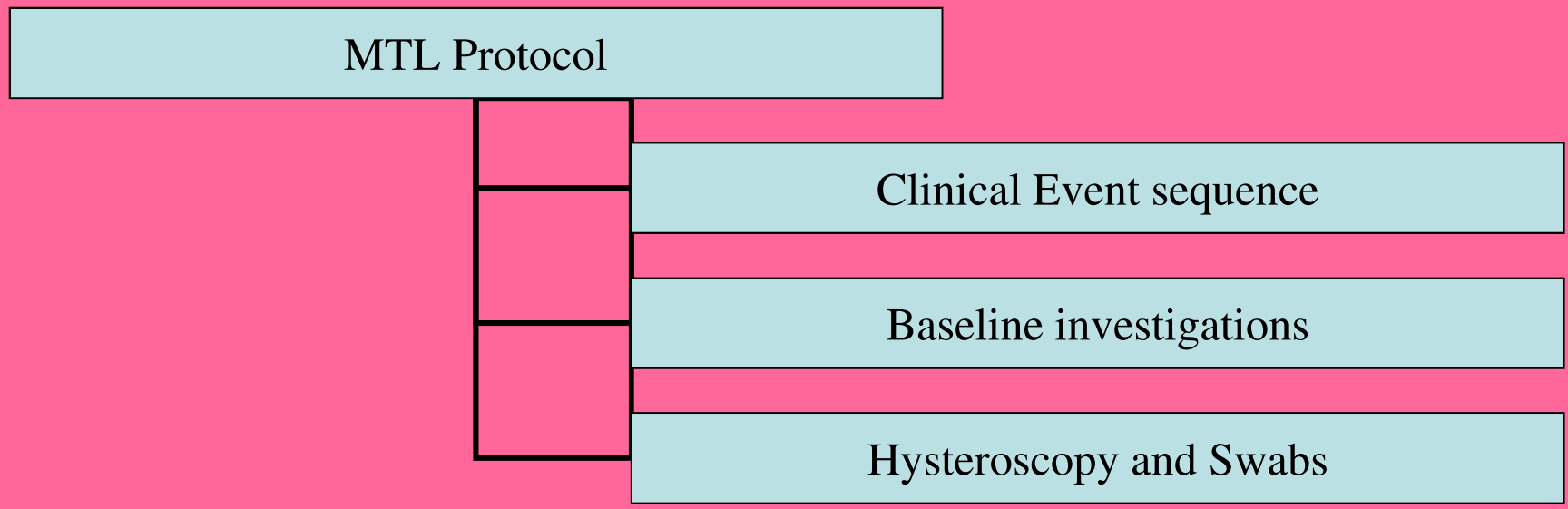
Pregnancy Success Prediction Matrix

Following idiopathic RM, the predicted probability (%) of successful pregnancy is determined by age and previous miscarriage history (95% confidence interval <20% in bold).

Age	Number of Previous Miscarriages			
(yrs)	2	3	4	5
20	**92**	**90**	**88**	85
25	**89**	**86**	**82**	79
30	**84**	**80**	**76**	71
35	**77**	**73**	**68**	62
40	69	64	58	52
45	60	54	48	42

Brigham et al, Hum Rep, 1999, 14, 2868-2871; PROMISE Trial 2008 MRC/HTA funded

First Presentation with Midtrimester Loss (MTL)
~2% risk between 12 to 24 weeks gestation



Event Sequence with Main Cause

EVENT versus CAUSE	CERVIX	LIQUOR PV	FETAL HEART ACTION
Cervical Weakness	OPEN	Absent until expulsion of sac	Present
Maternal Thrombophilia Eg APS	Closed	Absent	ABSENT (Intrauterine death)
Bacterial Vaginosis	Closed	PRESENT	Present ?until sac expulsion

Standards for Cerclage

- Prepregnancy investigation of Causal Factors as per MTL protocol inc. uterine cavity
- Surveillance in T1 (serial viability + rpt APS and BV testing)
- Surveillance in T2 (TVU of CLM >16/40)
- Treatment Interventions and compliance during pregnancy

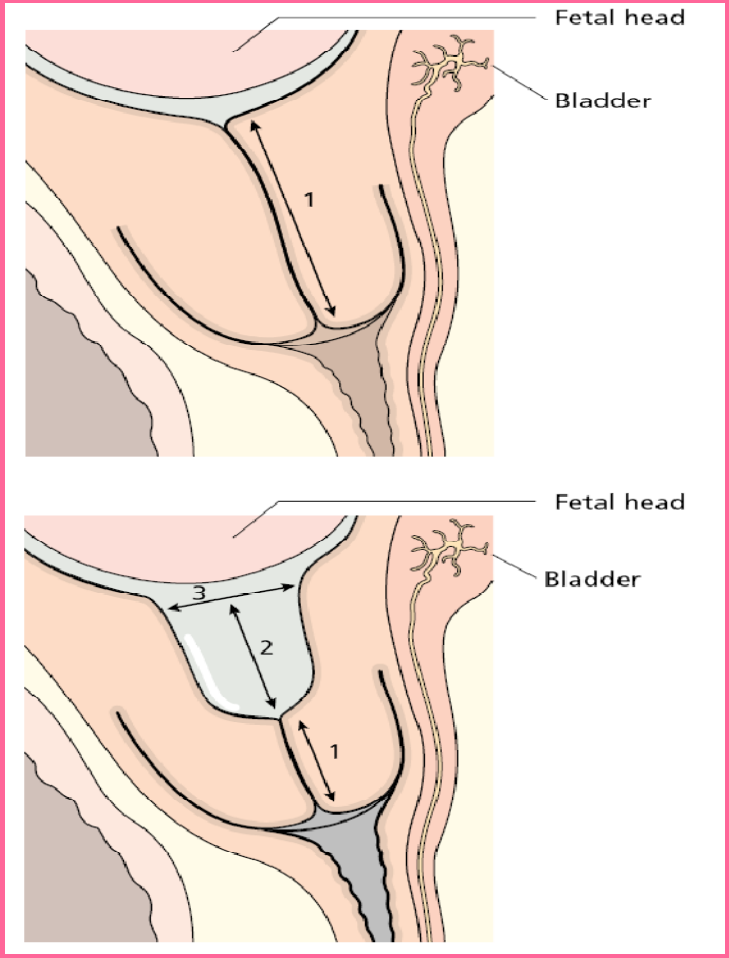
Update – the future website: earlypregnancy.org.uk

- AEPU 2009 Annual meeting in Glasgow and in Liverpool 11th and 12th Nov 2010
- Early Pregnancy Clinical Studies Group integral to National Reproductive Health Research Network
- RCOG EP meeting 24/25th March 2010
- Progress in ASRM & ESHRE

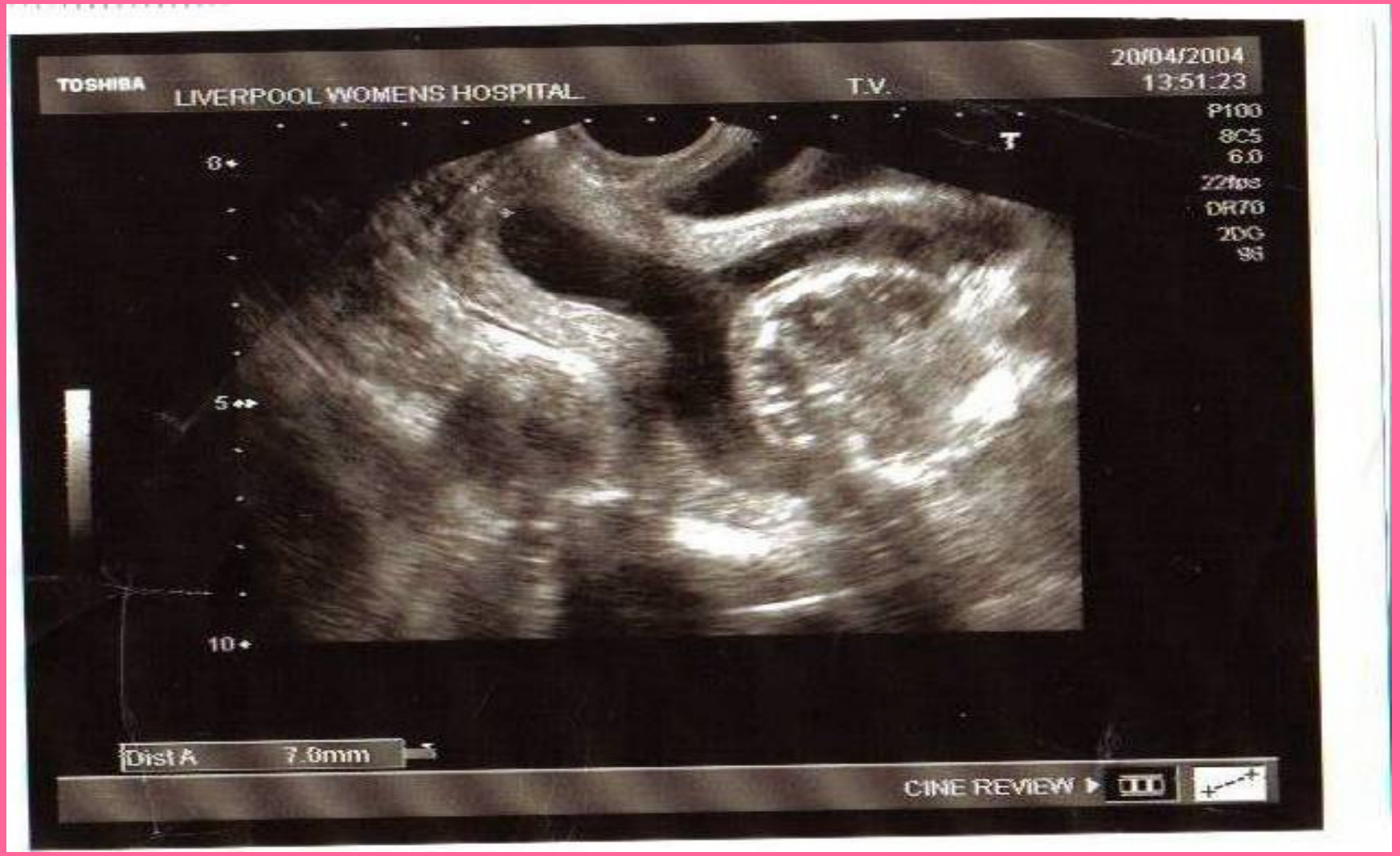
Cervical Length Measurement (CLM) and Funnelling

- Normal CLM circa 50mm

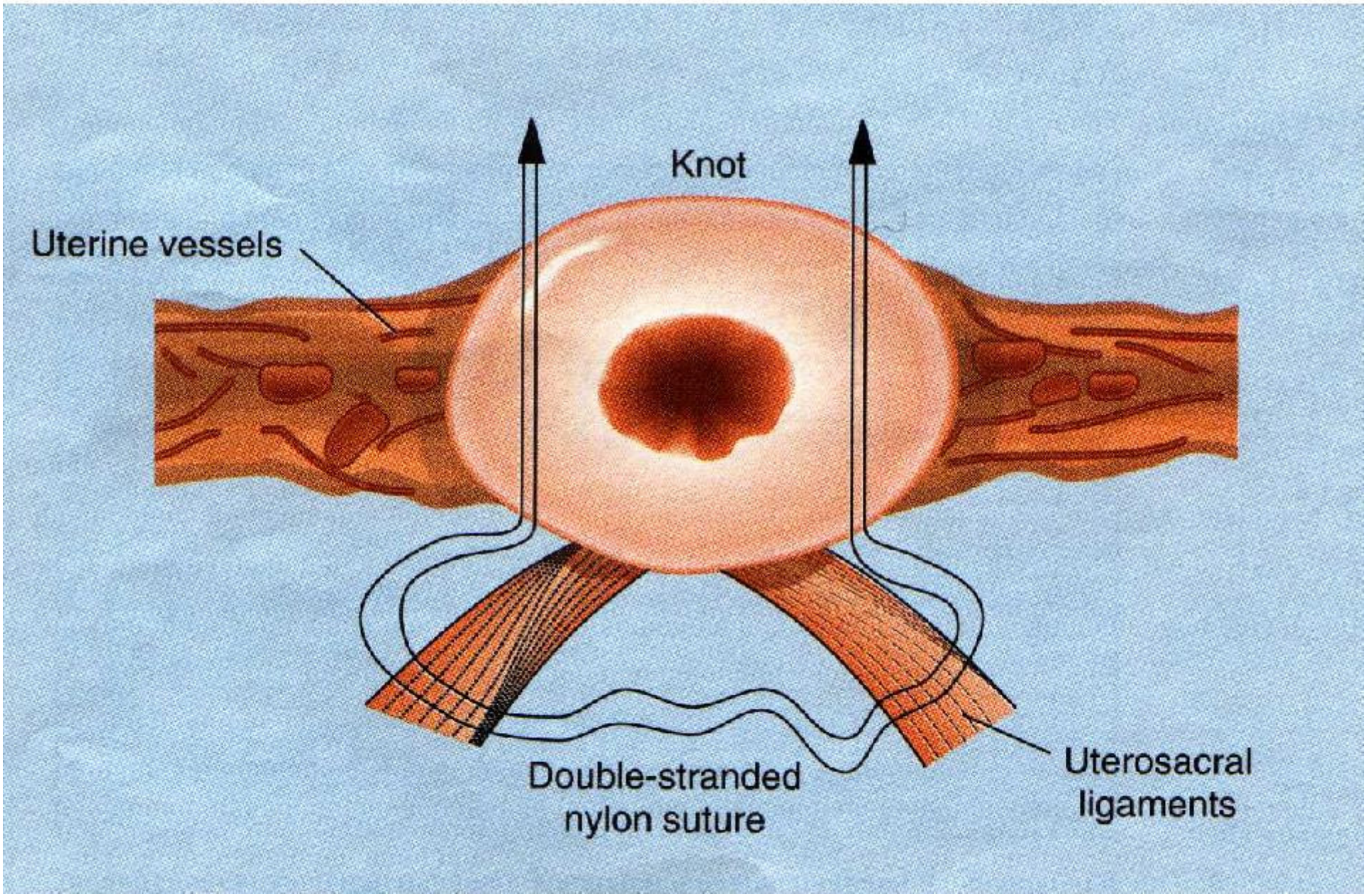
- Funnelling appears after 16 weeks if not before



TVU of Open Cervix at 16 weeks



Transabdominal Cerclage Technique



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Summary

- Lectures and/or meetings should create:
- Increased knowledge
- Clarify uncertainty
- Cause controversy & discussion
- At least some of the above
- Thank you for your attention


EPIDURAL
UPDATE

Update 2009

- RCOG Standards for EP, EctP and RM published
- AEPU recognised as Specialist Society for EP
- National EPU survey
- PROMISE Trial – funding secured £1.2M
- National Thrombophilia Survey completed
- AEPU guidelines adopted in Poland and Holland