Pregnancy in IBD
“Now we know what to tell the mother....or do we?”

Professor Ailsa Hart
St Mark’s Hospital, London
Introduction

- **Overview** of approach to consultation
- Highlight **importance of research** in this field
- **Limitations in data**
- **Outcomes** measured
- **Key principles**
- **Questions** asked by patients
Overview

- Emotional period for prospective parents
- Patients perceptions of risk/benefit may be different
- Reflect on your approach to managing your patients & how this impacts decision-making
  - sense the levels of emotion/anxiety
  - concerns about lack of data
  - feel need to give clear advice
  - own experience
  - fear of litigation
Decisions regarding fertility & pregnancy affect a lot of our patients

- Increasing incidence of IBD; prevalence surpasses 0.3%\(^1\)
- Highest prevalence values
  - UC: 505 per 100 000 (Norway)
  - CD: 319 per 100 000 (Canada)
- Accelerating incidence in newly industrialised countries
- Peak age of onset of IBD in child-bearing years
- About 25% of females conceive after diagnosis

Ng et al Lancet October 2017
Evidence

Mainly case-control, cohort studies

**NO** randomised controlled studies

Meta-analyses – heterogeneity

Guidelines based on consensus

- Faculty of Sexual and Reproductive Healthcare (CEU 2009); British Society of Gastroenterology Gut 2011
- World Congress of Gastroenterology Am J Gastro 2011;106:214-223
- Canada; Toronto Consensus statements for management of IBD in pregnancy Gastroenterology 2016; 150:734-57
Outcomes

- Inconsistent reporting of outcomes
- What are the relevant outcomes?
- Relevance of different outcomes to patients & clinicians?
  - Patient and offspring
  - Gastroenterologist
  - Obstetrician
- How can we improve reporting of outcomes?
Outcomes

**Patient/ mother**
- Fertility
- Miscarriage and still birth
- Ectopic pregnancy
- Termination of pregnancy
- Pregnancy complications e.g. placental abruption,, pre-eclampsia, placenta praevia, premature rupture of membranes
- Delivery mode e.g. vaginal, caesarean section
- Complications of delivery
- Breast feeding
- Disease control during pregnancy
- Post-natal depression
- Continence short and long-term

**Offspring**
- Low birth weight (with consequences)
- Pre-term deliver (with consequences)
- Congenital abnormalities (major & minor)
- APGAR score
- Admission to neonatal ITU
- Developmental delay
- Infections in childhood
Development of a core outcome set for epilepsy in pregnancy (E-CORE): a national multi-stakeholder modified Delphi consensus study

General Information

Abstract:
Objectives:
To develop a set of core outcomes for studies on pregnant women with epilepsy.

Design:
Delphi consensus study.

Population:
Healthcare professionals, and patient representatives with lived experience of epilepsy in the UK.

Methods:
We used a modified Delphi method and a consultation meeting to achieve consensus. Potential outcomes were identified by systematic review, and were scored using a Likert scale anchored between 1 (least important) and 5 (most important). We included outcomes that scored ≥4 by >70% of participants, and outcomes that scored ≥2 by <15% of participants.

Main outcome measures:
Outcomes in studies on epilepsy in pregnancy.

Results:
Seventy-five healthcare professionals completed the first round, 48 (64%) completed the second round, and 37 (49%) completed the third round of the survey. Twenty-four patient representatives participated. The final core outcome set included 31 outcomes in three domains: neurological, offspring, and obstetric. Outcomes in the neurological domain were seizure control in pregnancy and postpartum, status epilepticus, maternal mortality, drowning, sudden unexpected death in epilepsy, postnatal depression, and quality of life. Offspring domain included congenital abnormalities (major and minor), fetal anticonvulsant syndrome, neurodevelopmental disorder, neonatal clinical complications, admission to a neonatal intensive care unit, and anthropometric measurements. The obstetric domain included live birth, stillbirth, miscarriage, ectopic, termination of pregnancy, admission to a high dependency or intensive care unit, breastfeeding, mode of delivery, preterm birth, pre-eclampsia, and eclampsia. Outcomes specific for studies on anti-epileptic drugs (AEDs) included maternal AED toxicity, AED compliance, neonatal withdrawal symptoms, and neonatal haemorrhagic disease.

Conclusion:
Embedding this core set in future clinical trials will promote the standardisation of reporting to inform clinical practice.

Aim:
To develop a set of core outcomes for studies on pregnant women with epilepsy.

Authors:
<table>
<thead>
<tr>
<th>Neurological</th>
<th>Offspring</th>
<th>Obstetric</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seizure control</td>
<td>Congenital abnormalities (major &amp; minor)</td>
<td>Live birth</td>
</tr>
<tr>
<td>Status epilepticus</td>
<td>Neurodevelopment</td>
<td>Stillbirth</td>
</tr>
<tr>
<td>Maternal death</td>
<td>Autism</td>
<td>Miscarriage</td>
</tr>
<tr>
<td>Post natal depression</td>
<td>Admission to neonatal ITU</td>
<td>Ectopic</td>
</tr>
<tr>
<td>QoL</td>
<td></td>
<td>Termination of pregnancy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mode of delivery</td>
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<tr>
<td></td>
<td></td>
<td>Breast-feeding</td>
</tr>
</tbody>
</table>

Development of a core outcome set for epilepsy in pregnancy (E-CORE): a national multi-stakeholder modified Delphi consensus study
Key principles

Healthy mother → healthy baby

Education:
patient; primary care; secondary care; midwives; obstetricians

Multi-disciplinary Approach
(gastroenterologist, surgeon and obstetrician)

Careful documentation
Consultations

- Establish counselling clinic for prospective parents
- Web-tools
- Don’t forget to discuss / encompass in overall strategy of all patients of child-bearing age
- Multi-disciplinary follow up - identify higher risk patients
  - Face to face
  - Telephone
  - Role of IBD specialist nurse
Questions asked by patients

• Will my disease affect my fertility?
• Will my disease affect the baby?
• Will my child get the disease?
• Will the medications affect the baby?
• Can I have a vaginal delivery?
• Can I breast-feed?
• What about vaccinations for my child?
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# Fertility

Fertility normal in quiescent IBD  
Reduced fertility in active CD (mechanisms unclear)  
Voluntary childlessness (up to 18% cf 6%)

<table>
<thead>
<tr>
<th>Inflammatory Bowel Disease/Treatment Type</th>
<th>Effect on Fertility</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Male</td>
</tr>
<tr>
<td></td>
<td>Female</td>
</tr>
<tr>
<td>Active disease</td>
<td>No effect</td>
</tr>
<tr>
<td>Sulphasalazine</td>
<td>Significantly reduces</td>
</tr>
<tr>
<td>5-Aminosaliclyc acid</td>
<td>No effect</td>
</tr>
<tr>
<td>Corticosteroids</td>
<td>Reduces</td>
</tr>
<tr>
<td>Mercaptopurine/azathioprine</td>
<td>No effect</td>
</tr>
<tr>
<td>Biological agents</td>
<td>Unlikely</td>
</tr>
<tr>
<td>Small/large bowel resection</td>
<td>Unlikely</td>
</tr>
<tr>
<td>Ileal pouch anal anastomosis</td>
<td>Reduces</td>
</tr>
</tbody>
</table>

Questions asked by patients

- Will my disease affect my fertility?
- Will my disease affect the baby?
- Will the medications affect the baby?
- Can I have a vaginal delivery?
- Can I breast-feed?
- Will my child get the disease?
- What about vaccinations for my child?
Disease Activity

- Active disease is a risk for
  - foetal loss & stillbirth; preterm delivery (< 37 weeks) around 4x increased risk; low birth weight (<2500g); small gestational age; thromboembolic events, caesarean section
  - Increased neonatal ITU admission, low APGAR score
  - developmental defects/congenital anomalies (limb deficiencies and urinary malformations) – debatable

Disease Activity

How active is active?
Severity of flare?
Timing of flare?

Difficult to unpick impact of disease activity versus medications versus other factors on outcomes

Disease Activity

Advice:

Gain disease control pre-conception
Goal is to keep mother in remission & well nourished

Influence of pregnancy on disease course

- Conception occurring during remission
  - 1/3 patients relapse during pregnancy
- Conception occurs during active disease
  - 2/3 patients ongoing active disease; of these 2/3 deteriorate
- Risk of flare post-partum = baseline risk CD; increased UC
- May be positive benefits of pregnancy on disease course

Advice: conceive during remission
Will my child get the disease?

- Family history strongest predictor for developing IBD
- If one parent is affected, risk for the child is **2-13 x general population** but absolute risk is low
  - If one parent has UC, risk of child developing IBD ~ **2%**
  - If one parent has UCD, risk of child developing IBD ~ **5%**
- If two parents are affected, lifetime risk for the child is **up to 30%**
- Transmission more common from mother to child in CD; female offspring at higher risk; earlier age at diagnosis; concordance in disease type and location but not severity
- Maternal smoking during pregnancy associated with ↑ risk of developing IBD
Questions asked by patients

- Will my disease affect my fertility?
- Will my disease affect the baby?
- Will my child get the disease?
- Will the medications affect the baby?
- Can I have a vaginal delivery?
- Can I breast-feed?
- What about vaccinations for my child?
Medications during pregnancy

Proactive management of disease

Benefit:risk ratio to be considered in counselling patients

No published long term data on infant outcomes

Risk to mother & foetus is active disease,

*not* the medications used to treat it
Aminosalicylates

**Sulphasalazine**

Safe in pregnancy & breast-feeding

Sulphasalazine interferes with folate absorption

⇒ importance of folate supplementation (2mg)

**5ASA**

Safe in pregnancy (doses up to 3g per day)

Note: exception of formulations with dibutylphthalate coating

Aim: switch to 5ASA drug without DBP if contemplating pregnancy
Corticosteroids

Cross the placenta, but converted to less active metabolites

Small ↑ risk of cleft lip/palate (first trimester); inconsistent data
Case reports of neonatal adrenal suppression

1 study on budesonide (8 patients) – no issues

Topical therapies are safe

Overall no increase in anomalies in humans

Benefit of treating active disease likely outweighs the risks
Azathioprine & MP

- 2 meta-analyses no increase in congenital anomalies\textsuperscript{2,3}

- Observational/ cohort studies since \(\rightarrow\) increase preterm delivery

- Long term studies (>3 years) \(\rightarrow\) normal physical & mental development

- One study, 28 pregnancies \(\rightarrow\) 60% of infants had anaemia

- Issue if TPMT homozygosity in infant

- Increased 6MMP in mothers during pregnancy \(\rightarrow\) careful monitoring
Azathioprine & 6MP

Fathers

<table>
<thead>
<tr>
<th>Variable</th>
<th>Exposed group</th>
<th>Control non-exposed group</th>
<th>P value (GEE)</th>
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<tbody>
<tr>
<td>N</td>
<td>46</td>
<td>84</td>
<td></td>
</tr>
<tr>
<td>Fertility impairment</td>
<td>7 (15.2%)</td>
<td>7 (8.3%)</td>
<td>0.596</td>
</tr>
<tr>
<td>Time to achieve pregnancy (median months, range)</td>
<td>1 (0–60)</td>
<td>0 (0–48)</td>
<td>0.73</td>
</tr>
<tr>
<td>Unsuccessful pregnancies</td>
<td>5 (10.9%)</td>
<td>11 (13.1%)</td>
<td>0.718</td>
</tr>
<tr>
<td>Premature births</td>
<td>2 (4.3%)</td>
<td>2 (2.4%)</td>
<td>0.769</td>
</tr>
<tr>
<td>Pregnancy length (mean weeks, s.d.)</td>
<td>38.9 (2.2)</td>
<td>39.4 (1.4)</td>
<td>0.111</td>
</tr>
<tr>
<td>Low weight at birth</td>
<td>3 (6.5%)</td>
<td>5 (6%)</td>
<td>0.939</td>
</tr>
<tr>
<td>Weight at birth (mean grams, s.d.)</td>
<td>3,063 (533)</td>
<td>3,248 (493)</td>
<td>0.004</td>
</tr>
<tr>
<td>Congenital malformations</td>
<td>1 (2.2%)</td>
<td>2 (2.4%)</td>
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GEE, Generalized Estimating Equations model.

Azathioprine & 6MP
Fathers

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Meta-analysis – no association between congenital abnormalities & thiopurine use by father at conception
(Akbari et al. Inflamm Bowel Dis 2013; 19:15-22)

\( P \) value (GEE), Generalized Estimating Equations model.

Ciclosporin

Most data from transplant & rheumatology literature
- Higher rate of prematurity and low birth weight

In IBD
- Small case series in UC – no influence on foetal outcome
- No published use in Crohn’s
Methotrexate

Contraindicated in pregnancy

Teratogenic and embryotoxic
Methotrexate

Counsel women on use of contraception

If conception accidentally occurs, obstetric assessment

Prospective mother told to stop methotrexate; importance of folic acid

Metabolites of methotrexate take ~ 6 weeks to wash-out need to be off methotrexate for 3-6 months

Same advice for prospective fathers
Thalidomide

Contraindicated in pregnancy

Teratogenic and embryotoxic
As with all IgGs, infliximab and adalimumab cross placenta beginning in the 2\textsuperscript{nd} trimester
Placental transfer of infliximab

<table>
<thead>
<tr>
<th>Pt #</th>
<th>1</th>
<th>2</th>
<th>3*</th>
<th>4*</th>
<th>5*</th>
<th>6</th>
<th>7*</th>
<th>8*</th>
</tr>
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<tbody>
<tr>
<td>* Breastfed</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother IFX (mcg/ml)</td>
<td>15.1</td>
<td>1.4</td>
<td>19.2</td>
<td>3.8</td>
<td>4.8</td>
<td>14.5</td>
<td>16.5</td>
<td>2.2</td>
</tr>
<tr>
<td>Cord Blood IFX</td>
<td>--</td>
<td>2.0</td>
<td>26.5</td>
<td>3.3</td>
<td>8.8</td>
<td>20.5</td>
<td>26.5</td>
<td>8.4</td>
</tr>
<tr>
<td>Newborn IFX at Birth</td>
<td>25.3</td>
<td>2.9 W:2</td>
<td>23.6</td>
<td>4.2</td>
<td>8.7</td>
<td>28.2</td>
<td>27.5</td>
<td>10.6</td>
</tr>
<tr>
<td>Month IFX Undetectable</td>
<td>5</td>
<td>2</td>
<td>7</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>3</td>
</tr>
</tbody>
</table>

Serum levels of infliximab in newborn have been detected up to 7 months later. Can persist up to 9 months (around 10% still have detectable IFX at 9 months)
Anti-TNFs

Pregnancy in Inflammatory Bowel Disease and Neonatal Outcomes (PIANO study) >1000 pregnancies

- Prospective enrollment
- Every trimester, birth, 4, 9 and 12 months
- Patients divided into 4 groups:
  - Group 1 unexposed
  - Group 2 azathioprine/6-mercaptourine
  - Group 3 Infliximab/Adalimumab
  - Group 4 Combo thiopurine + anti-TNF

No differences in the adverse pregnancy outcomes rates

Increased infection rate during first year of life in combination group

Mahadevan et al. Gastroenterology 2012;142:abstract s149
Infliximab

Father

No associated congenital anomalies\textsuperscript{1}

Decrease in sperm motility & morphology\textsuperscript{2}

Unknown whether these effects translate into altered fertility

Anti-TNFs

**WCOG Statement 3.3**
Effect of infliximab during pregnancy and breast feeding

Infliximab in pregnancy is considered to be low risk and compatible with use during conception in men and women and during pregnancy in at least the first two trimesters. It is also compatible with breastfeeding [EL 3b]

**ECCO Statement 5D**

Infliximab and adalimumab cross the placenta and their use beyond the second trimester results in neonatal levels exceeding maternal levels [EL3]. This exposure can be limited by stopping the treatment around gestational week 24–26 when considered appropriate by the clinician and the patient [EL3]
Since June 2015 (to August 2017):
8 further studies, which all support statement 10A
*No increased risk of LBW or preterm birth if anti-TNT used in 3rd trimester

No long-term outcome studies

Since June 2015 (to August 2017):
4 further studies, which all support statement 10B
However, for **adalimumab**, suggestion of stop date at ~30 weeks

Define remission as: symptomatic remission 12 pre-conception; no active disease endoscopy/ imaging; no secondary LOR; therapeutic levels; no prior resections; no hospitalisation 3 years

131 women on anti-TNF therapy which was stopped at 22-24 weeks if patient in remission from 6 months pre-conception

Linear regression model indicated optimal stop date to achieve anti-TNF level below 3μg/ml (considered low risk) was:

- **24.6 weeks** for infliximab
- **36.8 weeks** for adalimumab

Stopping Anti-TNFs

- 80 women on anti-TNF therapy
- Maternal and cord blood levels of infliximab and adalimumab
- **Infliximab**
  - Median cord IFX 2.2μg/ml if stopped before 30 weeks
  - Median cord IFX 10μg/ml if stopped after 30 weeks
- **Adalimumab**
  - Median cord adalimumab 0.2μg/ml if stopped before 30 weeks
  - Median cord adalimumab 2.5μg/ml if stopped after 30 weeks
  - 8 of 36 ADA exposed infants whose mother stopped ADA median 32 weeks had **undetectable** ADA levels
  - Adalimumab cleared more quickly by infant

*Julsgaard et al 2016*
Discontinuation of anti-TNF during second trimester of pregnancy in IBD patients with quiescent disease does not

- Increase the risk of flare during pregnancy
- Increase the risk of allergic reactions when anti-TNF restarted
Thiopurines + anti-TNFs

Statement 16. In pregnant women with IBD who are thiopurine naïve and starting anti-TNF therapy, we suggest anti-TNF monotherapy over combination therapy with anti-TNF and thiopurine therapy. GRADE: Conditional recommendation, very low-quality evidence. Vote: strongly agree, 0%; agree, 83%; uncertain, 17%.

Since June 2015 (to August 2017):
1 further study, which supports statement 16

Relative risk of infection in infants exposed to combination therapy was 2.7 (compared with anti-TNF alone)

Vedolizumab

Limited data

In primates no adverse outcomes; doses 20x those given to humans

Data from clinical trials and post-marketing data from global safety database – no indication of safety concerns

“... should be used during pregnancy only if the benefits to the mother outweigh the risks to the mother and unborn child”

Note half-life of vedolizumab is longer than IFX and ADA

Theoretical risk of impact on gut-specific infections

Mahadevan et al. Aliment Pharmacol Ther 2017; 45(7):941-950
Ustekinumab

Limited data

In primates no adverse outcomes; doses 100x those given to humans

2 case reports of successful pregnancy in CD
1 case report ustekinumab 4-6 weekly in pregnancy; cord levels 2x higher than mothers
1 case report of miscarriage in CD

Case series of 7 successful pregnancies in psoriasis
Case report of miscarriage in patient with psoriasis

Venturin et al. BMC Gastroenterology 2017;17(1):8; Lund et al. Dermatol Ther 2017;30(3); Fotiadou et al. J Dermatol Case Rep 2012;6(4):105-7; Rowan et al JCC 2017
Questions asked by patients

- Will my disease affect my fertility?
- Will my disease affect the baby?
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- Will the medications affect the baby?
- Can I have a vaginal delivery?
- Can I breast-feed?
- What about vaccinations for my child?
Mode of delivery

- Multi-disciplinary approach to mode of delivery
- Dictated primarily by obstetric necessity
- Vaginal delivery for quiescent / mild disease
- Vaginal delivery if colostomy / ileostomy
- Caesarean section if active rectal/perianal disease
- Consider caesarean section if IRA/pouch
- Avoid episiotomy in CD (but preferable to uncontrolled laceration)
Questions asked by patients

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- What about vaccinations for my child?
Breast-feeding

May decrease risk of developing IBD later in life
# Breast-feeding

## Table 1. ECCO overview on drug risk during pregnancy and lactation.

<table>
<thead>
<tr>
<th>Drug</th>
<th>During pregnancy</th>
<th>During lactation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mesalazine</td>
<td>Low risk</td>
<td>Low risk</td>
</tr>
<tr>
<td>Sulfasalazine</td>
<td>Low risk</td>
<td>Low risk</td>
</tr>
<tr>
<td>Corticosteroids</td>
<td>Low risk</td>
<td>Low risk, 4h delay before breastfeeding is advised</td>
</tr>
<tr>
<td>Thiopurines</td>
<td>Low risk, limited data on 6-TG</td>
<td>Low risk</td>
</tr>
<tr>
<td>Anti-TNF agents</td>
<td>Low risk, consider stopping around week 24 in patients with sustained remission. See text</td>
<td>Probably low risk, limited data</td>
</tr>
<tr>
<td>Methotrexate</td>
<td>Contraindicated</td>
<td>Contraindicated</td>
</tr>
<tr>
<td>Thalidomide</td>
<td>Contraindicated</td>
<td>Contraindicated</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>Avoid first trimester</td>
<td>Avoid</td>
</tr>
<tr>
<td>Ciprofloxacin</td>
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</tr>
</tbody>
</table>
Breast-feeding

<table>
<thead>
<tr>
<th>Table 1. ECCO overview on drug risk during pregnancy and lactation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentration of thiopurines in breast milk is miniscule</td>
</tr>
<tr>
<td>Major part is excreted in breast milk with 4 hours of dose</td>
</tr>
<tr>
<td>No increased risk of infection or achieving developmental milestones in thiopurine exposed children (PIANO)</td>
</tr>
<tr>
<td>Concentration of anti-TNF in breast milk is 1/100th to 1/200th maternal level</td>
</tr>
<tr>
<td>How much is absorbed by infant?</td>
</tr>
<tr>
<td>No increased risk of infection or achieving developmental milestones in thiopurine exposed children (PIANO)</td>
</tr>
<tr>
<td>Julsgaard <em>et al</em> studied 65 breast-fed infants, 3 monthly bloods concluded breast-feeding did not affect anti-TNF clearance from infant</td>
</tr>
</tbody>
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Questions asked by patients

- Will my disease affect my fertility?
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- Will my child get the disease?
- Will the medications affect the baby?
- Can I have a vaginal delivery?
- Can I breast-feed?
- What about vaccinations for my child?
Vaccinations for child

Case Report:
Fatal case of disseminated BCG infection in an infant born to a mother taking infliximab for Crohn's Disease

- Vaccination strategy with non-live vaccines in children exposed to anti-TNFs same as non-exposed children
- Live vaccines (oral polio, rotavirus, BCG) should be avoided until no detectable anti-TNF levels OR for IFX wait 6-9 months and for adalimumab wait 6 months
Questions asked by patients

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- Will the medications affect the baby?
- Can I have a vaginal delivery?
- Can I breast-feed?
- Will my child get the disease?
- What about vaccinations for my child?