Patient and Public Involvement in Research

What is it and why is it important to us?

Dr Margaret O’Hara, Trustee, @Know_HG
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What Is PPI?
3 levels of activity

ENGAGEMENT

Science festivals, open days

Public lectures

Media stories

Dissemination to charities and patient groups

Social media
3 levels of activity

**PARTICIPATION**
- Being recruited to a study
- Completing a questionnaire
- Doing a survey

**ENGAGEMENT**
- Science festivals, open days
- Public lectures
- Media stories
- Dissemination to charities and patient groups
- Social media
3 levels of activity

**IN Volvement**
- As co-applicant on research project
- Identify research priorities
- As members of advisory or steering groups
- Commenting on PI leaflets
- Carrying out research

**Participation**
- Being recruited to a study
- Completing a questionnaire
- Doing a survey

**Engagement**
- Science festivals, open days
- Public lectures
- Media stories
- Dissemination to charities and patient groups
- Social media
Why do PPI?
Why do PPI?

It makes research better

“People-focused research in the NHS simply cannot be delivered without the involvement of patients and the public. No matter how complicated the research or how brilliant the researchers, patients and the public always offer unique, invaluable insight.”

Prof Dame Sally C Davies, Chief Medical Officer and Chief Scientific Adviser, Dept of Health
When to do PPI?
Patients can be involved at any stage in the research cycle

Identifying and Prioritising
Commissioning
Designing and Managing
Undertaking
Disseminating
Implementing
Evaluating Impact
How can PPI improve research?

Ensure methods are acceptable to patients
- Is test uncomfortable? Too long?
- Will test exacerbate symptoms?
- Helps recruitment

Improve information
- Ensures fully informed consent
- Improves recruitment

Spot confounding factors
- Previous medication
- Social support

Help interpret findings
- Explain unexpected findings
- See alternative explanations for observed associations

Ensure outcomes are meaningful
- Not just vomiting
- Surrogate markers?
- Quality of life
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Recurrence risk in hyperemesis gravidarum

Lill I.S. Trogstad, a Camilla Stoltenberg, b Per Magnus, b Rolv Skjærvø, c Lorentz M. Irgens c

Method
- Search registry entries for hospital admissions for HG 1967 - 1998

Conclusions
- Recurrence rate 15%
- Change of partner recurrence rate 10%
Example – Ignorance of confounders leads to flawed conclusions

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- Recurrence rate 15%
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Patient interpretation?
1. Hospital admission for HG not same thing as having HG
2. Admission in later pg less likely due to earlier treatment, more support
3. New partner more supportive so avoid admission
### How can PPI improve research?

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<thead>
<tr>
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Explain unexpected findings

See alternative explanations for observed associations

Not just vomiting

Surrogate markers?

Quality of life

Dr M O’Hara   @Know_HG
Diet before pregnancy and the risk of hyperemesis gravidarum

Margaretha Haugen¹*, Åse Vikanes², Anne Lise Brantsæter¹, Helle Margrete Meltzer¹, Øvrej M. Grjibovski³,⁴,⁵ and Per Magnus²

Method
-Self Reported questionnaire
-13-17 wk pg
- Asked to describe diet before pg

Conclusions
Women with HG less likely to eat vegetables and seafood before pg
Example - Inbuilt bias skews results

Diet before pregnancy and the risk of hyperemesis gravidarum

Margaretha Haugen1, Åse Vikanes2, Anne Lise Brantsæter1, Helle Margrete Meltzer1, 
Mirej M. Grjibovski3,4,5 and Per Magnus2

Method
-Self Reported questionnaire
-13-17 wk pg
-Asked to describe diet before pg

Conclusions
Women with HG less likely to eat vegetables and seafood before pg

Patient interpretation?
Women with HG less reliably able to think about food!

Lesson – don’t ask people who feel sick to tell you about their previous eating habits
Example – Ignorance of condition leads to flawed conclusions

**Method**
- Interview at 15 and again at 20 wk pg
- Anxiety, stress and depression scoring scales

**Conclusions**
- HG+ more emotionally disturbed
- Even after cessation of vomiting, HG+ more likely to be anxious so maybe anxiety causes HG?
Example – Ignorance of condition leads to flawed conclusions

Method
- Interview at 15 and again at 20 wk pg
- Anxiety, stress and depression scoring scales

Conclusions
- HG+ more emotionally disturbed
- Even after cessation of vomiting, HG+ more likely to be anxious so maybe anxiety causes HG?

Patient interpretation?
1. Cessation of vomiting not same as cessation of HG
2. Many reasons for continued anxiety – still nauseous, unable to work, relationship issues, fears for baby, financial problems
How can PPI improve research?

**Ensure methods are acceptable to patients**
- Is test uncomfortable? Too long?
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- Helps recruitment

**Improve information**
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**Help interpret findings**
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**Ensure outcomes are meaningful**
- Not just vomiting
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Current issues re outcome measures

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<th>No validated quality of life tool</th>
<th>Length of follow up</th>
<th>No easy biomarker</th>
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<tr>
<td>• No validated nausea scale for HG</td>
<td>• HG severity varies with gestational week</td>
<td>• Ketonuria unrelated to symptoms</td>
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<tr>
<td>• PUQE score validated for NVP</td>
<td>• Meds may work for a short time then relapse</td>
<td>• When does severe NVP become HG?</td>
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<tr>
<td>• Food intake usually ignored</td>
<td></td>
<td>• When to use IV fluids?</td>
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<td></td>
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<td>• When to escalate to eg steroids?</td>
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JLA is a non-profit making initiative which brings patients, carers and researchers together.
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**TOP 10 RESEARCH PRIORITIES**

**Preterm birth Top 3**
1. Preventative interventions
2. Infection prevention
3. Prevention of necrotising enterocolitis

**Stillbirth Top 3**
1. Assessment of placenta
2. U/S in 3rd tri – does it help?
3. Lifestyle factors and risk
Dangers of Poor Research

Opens blind alleys
- Stimulates others to investigate flawed hypotheses

Wastes Time and Money
- Effort does not lead to improvements in care
- Effort spent refuting poor research

Causes direct harm
- Underestimate recurrence risk
- Underestimate impact on women
- Think change of partner may prevent
- Overestimate risk of antiemetics
- Psychogenic etiology
The PSS PPI Panel

Setting Research Priorities

- Take part in JLA Priority Setting Partnership

Consult on research studies

- Contribute to study design
- Comment on PI leaflets
- Comment on lay summary

Comment on published studies

- Read and comment on published papers
- Write letters to journals
NIHR INVOLVE
- NIHR funded national advisory group
- Aims to support public involvement in health & social care research

NIHR Information leaflets
- Info for patients/public

Testing Treatments
- Free E-book and website
- Written by patients
- Guide to research issues in lay language
“We see two types of PPI in our applications – **genuine PPI** where it is clear how researchers have worked with patients to plan better research for the NHS, and **token PPI** where a patient has been drafted in to agree with the team’s preconceived ideas. Try to be the former.”

*Prof Hywel C Williams, Chair, HTA Commissioning Board*
Is it engagement?
Is it engagement?

Is it Participation?
Is it engagement?

Is it Participation?

No, it’s genuine Patient Involvement!