Patient and public involvement in guidelines and research

Prof Gavin Perkins
Conflict of interest

Academic:
Research funding: National Institute for Health Research, Resuscitation Council (UK), British Heart Foundation
Volunteer roles: RC(UK), ERC, ILCOR

Commercial:
Nil
Outline

• Changing landscape
• Defining patient and public involvement
• Added value
• Case examples

“I think we’re all agreed that it is invaluable to have input from local people with real experience of health issues.”
From research subject to research partner
.........lots of terms used, some having the same meaning, some are very different......
What do we mean by PPI?

Research being carried out ‘with’ or ‘by’ members of the public rather than ‘to’, ‘about’ or ‘for’ them

INVOLVE: http://www.invo.org.uk/
Levels of patient and public involvement

Participation

Engagement

Involvement
Types of involvement

Participation
- Research subject
- Complete questionnaire

Engagement
- Science festival
- Debate
- TV / media
- Dissemination

Involvement
- Co-applicants
- Research cycle
What does PPI add?

- Democratic
- Improve quality
- Improve relevancy
- Improve acceptability
- Accountability
PPI throughout the research cycle

Prioritising research → Prioritising research

Consultation, Collaboration, Co-production → Data collection and analysis

Research design → Advisory / Management

Dissemination and implementation
How to involve

• Planning and preparation – involve early
• Be clear about what you want
• Be accessible
• Provide appropriate resources
• Offer training and support
UNTRAP
Universities/User Teaching and Research Action Partnership
The Professional Development Award: User-Involvement in Teaching and Research

Course content includes:

- An introduction to user-involvement and what it means to different stakeholders
- Teaching and learning techniques and styles
- Presentation skills, Assessment and feedback
- Research design and ethics
- Committee work and Governance.

6 full teaching days over 1 academic year

Builds on participants’ experiences of involvement

Highly supportive learning environment

Interactive teaching techniques

Option of resubmitting assignments using feedback from course facilitators

Personal tutors for all participants
Impact on research activities reported by course participants

“I just want to reiterate... I know exactly what I’m looking for, gave me more confidence to read a research report and to make valid comments.”

“It’s given me the confidence to speak to researchers directly.”

“Having done the course and got the accreditation and being a member of UN-TRAP gives you a certain credibility when you say something that might seem a bit common-sense in the world of high academia.”
Define a core set of outcomes that should be reported, as a minimum, in all cardiac arrest effectiveness trials

Laura Whitehead
A systematic review of the outcomes reported in cardiac arrest clinical trials: The need for a core outcome set

L. Whitehead, G.D. Perkins, A. Clarey, K.L. Haywood

160 different outcomes
39 different definitions of survival
He's very inpatient now, he gets more impatient with people, situations, definitely got a shorted fuse that he did have."

"It is it scary, I'm scared incase it happens again ain't it. I cant get to sleep because I'm thinking I'm not going to wake up."

"I just, my brain just goes. It's like as if it goes to sleep and body goes eowww. I just need I just need to lie down. It's just comes all of a sudden you know, it isn't something that builds up"
Systematic review

Patient interviews

Delphi

Consensus conference

Pre-arrest

Cardiac arrest

Post-arrest

Future

**Searching for a cause**
- Why me?
- Not a "typical patient"
- Diet, smoking, lack of exercise or age
- Genetics
- Self blame

**Relationships with healthcare**
- Praise and gratitude
- Reclucatance to complain
- Complaints
- Blame not spotted by doctors

**Disruption to normality**
- Survival
- Physical symptoms
- Emotional wellbeing
- Social wellbeing and participation
- Impact on others

**Coping with what has happened**
- Denial and playing down
- Humour
- Positivity
- Talking to others
- Understanding health

**Moving towards normal**
- Active change
- Gain in confidence
- Constant adaptation

**Uncertainty**
- Concerns
- Hopefulness
- Uncertainty
Delphi survey

- 2 rounds
- 113 healthcare professionals
- 87 patients / public
- 27/44 outcomes shortlisted
Consensus conference

Systematic review

Patient interviews

Delphi

Consensus conference
Writing group

Core Outcome Set for Cardiac Arrest (COSCA): An Advisory Statement From the International Liaison Committee on Resuscitation

Kirstie Haywood*  
Laura Whitehead*  
Vinay Nadkarni†  
Felix Achana  
Stefanie Beesems  
Bernd Boettiger  
Anne Brooks  
Maaret Castrén  
Marcus Eng Hock Ong  
Mary Hazinski  
Rudolph Koster  
Gisela Lilja  
Koenraad Monsieurs  
Peter Morley  
Laurie Morrison  
Graham Nichol  
Valentino Oriolo  
Ken Spearpoint  
Michael Smyth  
Gustavo Saposnik  
John Long  
Barry Williams
PPI involvement: Adrenaline trial

• Consultation
  – Concept
  – Important outcomes
  – Acceptability
  – Priority

• Involvement
  – Conduct of research
  – Communication
  – On-going management
Concept, acceptability, outcomes, priority
CONSENT

When is it OK to do research in cardiac arrest?

- No research without consent – i.e. Never
- Community consultation / opt out
- Only if relative consents at time
- Get consent afterwards

How do we know the treatment has worked?

- Short term – heart
- Long term – heart
- Long term – heart and brain

- Short = until arrives in hospital
- Long term = goes home from hospital

Adrenaline – things to consider

- What do you think about the evidence for adrenaline?
- If you or a loved one sustained a cardiac arrest
  - Would you be willing to go in a randomised trial?
  - Would you be willing to go into a trial comparing adrenaline with placebo?
Important outcomes

- Short term Heart
- Long term survival
- Long term survival without brain damage
There is a need for a trial

- Agree: [High percentage]
- Neutral: [Low percentage]
- Disagree: [Low percentage]
Willing to participate

- Agree: 80%
- Neutral: 20%
- Disagree: 0%
Conduct of research

- How best to approach consent to continue
- How to explain the trial
- When to approach patients in hospital
- Use of routine available data
- Opt out considerations
- Patient information and consent forms
- Communication
- Website
Non-survivors: passive / active information

• I've tried to think back to my own experience. With everything that was going on in the moments surrounding and immediately following his death, I don't think there's any way I could have dealt with any extra issues on the spot. The days after are full of frantic activity, there's so much to be done with arranging funerals etc., and receiving something through the post during that period would have felt much more like an intrusion than anything else.

• Making it possible for people to seek information means that if they choose to do so, they can also choose when to do so. The shock of what has happened may mean they don't register for some time that the opportunity is there, but when and if they do and they make an approach, it probably means they're now in a frame of mind to hear the information and take it in. It also gives them the chance to go through the "shall I, shan't I?" - sometimes what seems like a good idea the first time it pops into your head can change in nature as you think it over.
Trial management group
Liaison with community
Review and advise on trial materials
Information about trial

Should adrenaline be used when someone’s heart stops?

The PARAMEDIC2 trial is looking at whether adrenaline is helpful or harmful in the treatment of a cardiac arrest that occurs outside a hospital.

Answering this question will help to improve the treatment of people who have a cardiac arrest.
Taking Part in PARAMEDIC2

The PARAMEDIC2 trial is testing if adrenaline is investigated whether adrenaline is helpful or harmful in the treatment of out-of-hospital cardiac arrest. Answering this question will help to improve the treatment of people who have a cardiac arrest.

If you were to have a cardiac arrest you may receive adrenaline as part of your treatment or you may not. You will receive all treatments that are proven to work and it is only the adrenaline which will not be given to everyone.

If you do not want to take part in the trial, you can contact the study team (see below) who will send a 'No Study' branded to wear.

Ambulance Services taking part:

Should adrenaline be used when someone’s heart stops?

Information about the Paramedic2 Trial

Go Ahead for PARAMEDIC2

To protect patients, trials like this have to go through a lot of in-depth review and evaluations before they can start.

PARAMEDIC2 has been assessed and approved by an independent Research Ethics Committee and Medicines and Healthcare Products Regulatory Agency (MHRA).

The trial is further monitored by an independent committee that includes patient and public representation. Here is a quote from one of the representatives:

"After taking to the research team I am fully conversant of the need for the trial... I can't believe it hasn't been done already."

This trial is funded (and reviewed) by the National Institute for Health Research (NIHR) and is being managed by The University of Warwick.

Cymryd Rhan yn Nhreial PARAFEDDYG2

Mae treali PARAFEDDYG2 yn rhoi adrenalin ar bwys i wneud ymhen deledu nhreial, i mewn i bobl a oedd yn cael eu gwylltu yng Nghymru. Bydd y brwm wynebu'r hyn y mae'n golygu iawn sy'n cael eu caiff ar yr ail datblygiad.

Pe beth yw'r cysylltiad ar yr ochr a gheidio'n fawr iawn mewn beth arall? Yn bennaf, mae adeiladu'r cysylltiad â'r ochr yno. Pe beth sy'n wybodaeth mewn beth arall? Yn bennaf, mae adeiladu'r cysylltiad â'r ochr yno.

Os nad ychydig chi'n eiainu gyda'r adrenalin, gallach chi agos at ddiwydiant 'Owl Amdani' i chi ei gwmpas.

S4i Benidh i Drelai PARAFEDDYG2

I warchod cefnogaeth ym M'Llan i drefnu fel hyn nodir mewn sawl adwy o gwerthu'r bywyd yma, y prin na'n iawn. Mae Parafedyg2 a mabwysed i anghyfforddi ac Atbanciliaeth Rheidl ac Meddygialeth a Chynhyrchon Cofdi Hefyd (MHRA) wedi eu dullio i chymysgu'r PARAFEDDYG2.

Mae'r treali yn cael ei haddwl ym M'Llan gan bawb i bawb sydd wedi eu ymddangos gan arhosoldeb y cyfyngeddiat. Bydden ni wedi ganu'r ddiwydiant 'Owl Amdani' i chi ei gwmpas.

Gwasanaethau Ambiwns sy'n cymryd rhan:

A ddyliad deffnyddio adrenalin pan mae galon rhywun wedi stopio?

Gwybodaeth am Drelai Parafedyg2
## Communication strategy

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<tr>
<th>Audience Group</th>
<th>Description</th>
<th>Communication Methods/Channels</th>
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| Members of the public                 | This includes people in trial and non-trial areas, and also relatives of people who may be at risk of cardiac arrest (potential trial participants)                                                              | • Via Media (print, radio, television)  
• Website (although they would need to find out about it from another source initially)  
• Posters and leaflets in key places                                                   |
| Potential trial participants          | Anyone over the age of 16 (unless they have anaphylaxis or are pregnant/assumed pregnant). See more detailed profile of potential participants.                                                                   | • Posters and leaflets in key places  
• Website (although they would need to find out about it from another source initially)  
• Media (print, radio, television)                                                    |
| Media                                 | The media aren’t an audience as such, but provide us with the ability to reach other key audiences through dissemination of information via print, radio and television.                                      | • Press releases issued to regional press  
• One-to-one telephone conversations and press briefings instigated by press team     |
| Surviving patients enrolled in the trial | Surviving patients (and/or relatives) of people who have been enrolled in the trial. Research paramedics will monitor and track all patients admitted to hospital.                                        | • Patients/relatives are given a leaflet about the trial and spoken to by a health professional.  
• They will not routinely be told which condition they were in (i.e. adrenaline or placebo) but a mechanism is in place should this question be raised. |
| Relatives of patients who do not survive | Deaths must be registered at the local Registrar of Births and Deaths                                                                                                                                 | • Via Media (print, radio, television)  
• Website (although they would need to find out                                          |
Consensus on Science and Guidelines
Systematic review

- Formulate question
- Select outcomes
- Rate importance
- Outcomes across studies
- Create evidence profile with GRADEpro
- Rate quality of evidence for each outcome

Summary of findings & estimate of effect for each outcome

**Grade down**
1. Risk of bias
2. Inconsistency
3. Indirectness
4. Imprecision
5. Publication bias

**Grade up**
1. Large effect
2. Dose response
3. Confounders

**Overall quality of evidence**

Rate across outcomes based on lowest quality of **critical** outcomes

- “We recommend using...”
- “We suggest using...”
- “We recommend against using...”
- “We suggest against using...”

Guideline development

- Formulate recommendations:
  - For or against (direction)
  - Strong or weak (strength)

By considering:
- Quality of evidence
- Balance benefits/harms
- Values and preferences

Revise if necessary by considering:
- Resource use (cost)
Consensus on Science and Guidelines

1. PICO prioritisation
2. Systematic review
3. Consensus on Science
   • Treatment recommendations
Levels of patient and public involvement

- Participation: ✔
- Engagement: ✔
- Involvement: ❌
Libraries

Search our libraries of publications, evidence, examples, research projects and resources to help plan or develop public involvement in research.

Libraries

INVOLVE at 21
Conference registration now open

INVOLVE Publications library
Search our library of publications
Patient and public involvement

Democratic
Improve quality
Improve relevancy
Improve acceptability
Accountability