Patient involvement in drug licensing: implications of a case study

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Why do it?

- Rights based argument: patients are the end users
- Better decision making: patients have potentially valuable expertise and knowledge
Who am I to do this?

• Long standing interest in medicines use: over 100 peer reviewed publications as well as book *Medicines and Society* (Palgrave 2008)
• NIHR Collaboration for Leadership in Applied Health Research and Care for the south west peninsula (PenCLAHRC)
  • [http://clahrc-peninsula.nihr.ac.uk](http://clahrc-peninsula.nihr.ac.uk)
• PenCLAHRC lead for Patient and Public Involvement
Liraglutide case study

- Peninsula Patient Involvement Group (PenPIG)
- Long standing group of 15 people
- Involved in various research-related tasks
- Training in EBM
- Not a lobbying group
- Lay ‘licensing panel’ of 5 people
Choice of drug

• US Public Citizen Health Group

• 2nd line treatment for chronic illness
Research questions

• How does a lay group evaluate existing mechanisms for licensing drugs?
• How do they balance scientific and lay knowledge?
• How did they make their decisions?
• How did they view the experience of the patient panel?
Findings

• FDA processes

• Lay versus scientific knowledge

• Decision making

• Experience of being on the panel
FDA processes

- Decisions on incomplete knowledge
- Experts are not expert
- Inappropriate questions
- Non representative populations
Lay vs scientific knowledge

- Data compared with own experience
- ‘Minor’ side effects not minor
- Greater focus on harms than benefits
Decision making

- Voted 3:2 against
- Did not change mind during discussion
- 3 patterns:
  - Trust the professional
  - Benefits outweigh harms
  - Harms outweigh benefits
Experience of being on the panel

- Agreement that patients should be involved in drug licensing
- Disagreement about how much information to read
- Disagreement about status of own views
Implications of case study

• Feasibility

• Nature of the patient group

• Preparation of material

• Training and support of patients
Next steps

• Move beyond proof of concept

• Stronger evidence base: what questions do you want the answer to?

• Can we agree what evidence is needed?

• Evaluation
Discussion

• What are the potential benefits of patient involvement in drug licensing?

• What are the challenges to patient involvement?

• Strengths, weaknesses, opportunities, threats?

• What evidence do you need?
Reference

N Britten, S Denford, F Harris-Golesworthy, S Jibson, N Pyart, K Stein (2015)
Patient involvement in drug licensing: a case study.
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