Patient Involvement in Clinical Research

- how did I become involved?
- what did it entail?
- how was I able to contribute?
- what was the impact on me?

My Background

- Diagnosed HIV +ve (late) in 2000
- Hospitalised
- Visited by local support group (NYAA)
- Joined and chaired UK-CAB
- Worked with BHIVA on writing groups/committees

I became very interested in treatment
This involved getting to grips with data from RCTs

PIVOT (1)

- One of the largest recent UK-based trials
- Concepts developed around 2007
- Run by MRC, who consulted UK-CAB at design stage
- Keen to have patient involvement, not just participation as patients
  - in running trial
- Two main bodies involved in running trial
  - Data Monitoring Committee (DMC)
    - Assess progress, safety...can recommend modifications or halt trial
  - Trail Steering Committee (TSC)
    - Overall supervision of trial but doesn't see data
    - Responds to concerns of DMC (who do see data)
- Both have patient representatives (PRs) via UK-CAB

PIVOT (2)

- At that time, triple therapy successful, but many ARVs had severe side effects
- Some trials had shown that monotherapy could keep v/l suppressed
  - Suppress with triple for 6 months, then mono
  - Short-term data – 1 or 2 years only
- Could we use mono long-term?
  - Fewer pills to take
    - Better adherence
  - Fewer side effects
    - Better adherence, better QoL
  - Lower cost to NHS
  - ..but would it be safe long-term?

PIVOT (3)

- Long-term – 5 years
- Could you revert to triple without loss of options if mono failed?
  - Concern about developing resistance with mono
- Look at other factors to see if any problems long-term
  - Kidney, liver, CV, cognitive, sexual....

Patient representative (PR) on TSC

- lots of reading and reviewing!
Also meetings (at least annual)
My role – always voice the patient perspective!

Where might a PR contribute? (1)

- Recruitment
  - Clear info about trial for prospective participants
  - Easy to understand Patient Information Sheets
  - “advertise” in patient community
  - Advise on trial protocol and practicalities
    - Make sure it isn't more difficult than necessary for patients
- PIVOT recruitment went well
  - Not always the case
    - Examples of active community involvement in other trials to help get numbers

Where might a PR contribute? (2)

- Running the trial (TSC)
  - Some issues very technical
    - Change in way v\l measured
  - Voicing the patient perspective!
    - Cognitive function sub-study
      - Researchers keen to see how well ARVs cross blood-brain barrier
      - Wanted 100 lumbar punctures!
      - Agreed to 40; actually got 19

Other members of TSC very helpful

Where might a PR contribute? (3)

- Reviewing material before publication
  - Baseline cognitive function
    - Results compared with general population
    - More than half had cognitive impairment!
      - Challenge whether this comparison was accurate
        - Many PLWH come from disadvantaged communities
        - Many PLWH do not have English as first language
      - - when corrected for these factors, the effect was much smaller
      - Alarmist language avoided

Where might a PR contribute? (4)

- Communicating results of trial
  - Publications in academic literature not easy to read
    - Need a patient-friendly version
  - After the trial, researchers feedback meeting to discuss results
    - Also a meeting with trial participants

Impact on me

- Very interesting to see first-hand how trial is run
  - Incredible attention to detail
  - Impressive intellectual and practical skills in TSC
  - Amazing levels of knowledge, ability and passion
- Daunting at first, but other TSC members very helpful
  - Happy to explain
  - Not patronising
  - Welcoming environment

Being a PR might not be for everyone, but is rewarding