The Future of Clinical Trials: Towards Diversity and Inclusion

Patient Perspective

Cardiovascular Round Table of the European Society of Cardiology

Richard Mindham
Vienna, Wednesday 5th July 2023
Patient Perspective

- Research experience
- Why interested in research
- Patient attitude to data
- Research issues
  - General
  - Diversity
  - Resistance
- Research priorities
  - Doctors
  - Patients
## Research Experience

<table>
<thead>
<tr>
<th>Year Range</th>
<th>Description</th>
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<tbody>
<tr>
<td>2011 – present</td>
<td>Royal Brompton &amp; Harefield Trust Patient Advisory Group (PAG). Critiquing/advising on research, consent, materials</td>
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<tr>
<td>2016 – 2022</td>
<td>IRONMAN trial: safety, efficacy, QoL of IV iron, &gt;1700 HF patients. Involved in preliminary trial design. Patient representative on steering committee</td>
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<tr>
<td>2019</td>
<td>James Lind Alliance - HF Research. Group member, ~30 patients &amp; clinicians setting HF research priorities</td>
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<td>2019 – 2020</td>
<td>TRED-HF Outcome Analysis - Patient Interpretation &amp; Review; co-author</td>
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<td>2021 – present</td>
<td>Reducing Bureaucracy in Clinical Trials: Working Group Member (Informed Consent) &amp; Co-author of Patient Version</td>
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<td>2021 – present</td>
<td>Queens University Belfast (QUB) Cardiac Research Group (CRG). Patient member of group critiquing/advising on research.</td>
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<td>2022</td>
<td>Co-applicant to UK funding agency (NIHR): Paediatric Cardiac Fitness; physical fitness + QoL in children with CHD</td>
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<td>2022 – present</td>
<td>MitoDCM Trial; efficacy of MitoQ supplement in patients with DCM. Patient member of steering committee</td>
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<tr>
<td>2023 + 5 years</td>
<td>More-EUROPA, five-year Horizon-funded programme. Patient member of advisory board</td>
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<tr>
<td>2023 + 5 years</td>
<td>RAPHAEL; funding application to Horizon. Five-year programme, named in application, patient member of advisory board</td>
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<tr>
<td>2023</td>
<td>James Lind Alliance (Edinburgh University) - Priority Setting Partnership - Digital Health for Heart Health. Patient member of steering group</td>
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Why Involved?

• Beneficiary of earlier research (BB, ARB, ACEI, statins, etc)

• Altruism

• Avoid Repetition of (Bad) Experience
Patient Heterogeneity

Some Patients

• It is MINE!

• Health service/university

• Big Pharma

Richard Mindham

• Any legitimate purpose*

*but do not tell my insurer
Issues I – Information & Data

• Complexity
  • Patient Information
  • Informed Consent - pragmatism vs protect sponsor/drug company

• Feedback

• GDPR
  ○

• Cross-Border Data

• AE/SAE Reporting

• Recruitment – many patients, but where are the patients?
Issues II - Diversity

• Representation of women
  • Participation
  • Drug efficacy
  • RA, Fatal MI, MS, etc

• Representation of non-Caucasians
  • Africans* – HF, angio-oedema, MCS/HTX
  • South Asians° – T2D, HF, PPCM
  • Socio-economic status (Europe/NAm)
  • History of suspicion (esp USA)
  • Cadaveric donation

• ?Culture/religion

England 2011: *2.4m (~4%), °4.1m (~7%)
Resistance

• Family attitudes
  • lung biopsy, bleeding, extremely unwell
  • alter patient attitude to long term health/treatment, e.g. Alzheimer’s or MS research

• ?Accidents
  • Northwick Park, UK, 2006
  • cytokine storm
  • multiple organ failure

• ?Rogue researchers
  • China, 2019
  • Crispr-Cas9 rewrite of DNA in twin girls
  • Unethical inducements
Comment I

- Animals
  - Veganism
  - Animal activism
  - Male models
  - Mice $\rightarrow$ rats $\rightarrow$ higher animals
  - Bovine, porcine, egg

- New Drugs vs Quality of Life*
  - ESC PF: QoL vs Mortality/Hospitalisation

*Open Heart 2020, doi:10.1136/openhrt-2020-001258
**Comment II – Advanced HF**

- **Researcher vs Patient Priorities**
  - Patients & carers: QoL + managing uncertainty
  - HCPs: “difficult conversations” + drug treatment

- **Researcher & Patient Alignment**
  - importance of patient empowerment
  - end-of-life care
  - psychological support
  - vital role of carers

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<tr>
<th>Research priority</th>
<th>Group (patients, carers or healthcare professionals) whose survey responses were incorporated into this research question</th>
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<tbody>
<tr>
<td>1.</td>
<td>Which treatments have the biggest impact on the quality of life of people with advanced HF?</td>
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<td>2.</td>
<td>What amount and type of exercise is safe and effective for people with advanced HF?</td>
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<td>3.</td>
<td>What is the most empowering and effective education and self-management advice for people with advanced HF and their carers? (eg. dealing with fatigue)</td>
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<td>4.</td>
<td>How should HF charities be better integrated with NHS services to optimise the care of people with advanced HF?</td>
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<td>5.</td>
<td>Which approaches, in addition to standard therapies, are effective in supporting breathlessness in people with advanced HF?</td>
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<td>6.</td>
<td>How do we break down barriers for patients with advanced HF, carers and healthcare professionals to enable talking about end of life care?</td>
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<td>7.</td>
<td>What are the benefits of asking a person with advanced HF “what is important to you”?</td>
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<td>8.</td>
<td>What is the most effective way to use diuretics in advanced HF with respect to fluid overload, kidney function, survival and quality of life?</td>
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<td>9.</td>
<td>How can patients with advanced HF and professionals be helped to communicate about symptoms that are difficult to express such as anxiety and low mood?</td>
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<td>10.</td>
<td>What support would be most effective for carers of people with advanced HF? (eg. support groups)</td>
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When we tested this drug on mice, nobody noticed any side effects.