

# The Future of Clinical Trials: Towards Diversity and Inclusion

## Patient Perspective

Cardiovascular Round Table of the European Society of Cardiology

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Vienna, Wednesday 5<sup>th</sup> 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

2011 – present	Royal Brompton & Harefield Trust Patient Advisory Group (PAG). Critiquing/advising on research, consent, materials
2014 - 2015	SERCA-LVAD trial: safety & feasibility of gene transfer. Patient representative on trial steering committee
2016 – 2022	IRONMAN trial: safety, efficacy, QoL of IV iron, >1700 HF patients. Involved in preliminary trial design. Patient representative on steering committee
2019	James Lind Alliance - HF Research. Group member, ~30 patients & clinicians setting HF research priorities
2019 – 2020	TRED-HF Outcome Analysis - Patient Interpretation & Review; co-author
2021 – present	Reducing Bureaucracy in Clinical Trials: Working Group Member (Informed Consent) & Co-author of Patient Version
2021 – present	Queens University Belfast (QUB) Cardiac Research Group (CRG). Patient member of group critiquing/advising on research.
2022	Co-applicant to UK funding agency (NIHR): Paediatric Cardiac Fitness; physical fitness + QoL in children with CHD
2022 – present	MitoDCM Trial; efficacy of MitoQ supplement in patients with DCM. Patient member of steering committee
2023 + 5 years	More-EUROPA, five-year Horizon-funded programme. Patient member of advisory board
2023 + 5 years	RAPHAEL; funding application to Horizon. Five-year programme, named in application, patient member of advisory board
2023	James Lind Alliance (Edinburgh University) - Priority Setting Partnership - Digital Health for Heart Health. Patient member of steering group

# 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

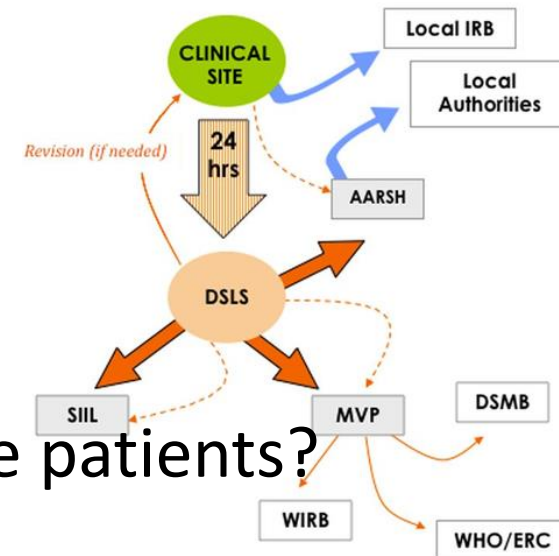


- GDPR

Added by you  
Yes 261 votes

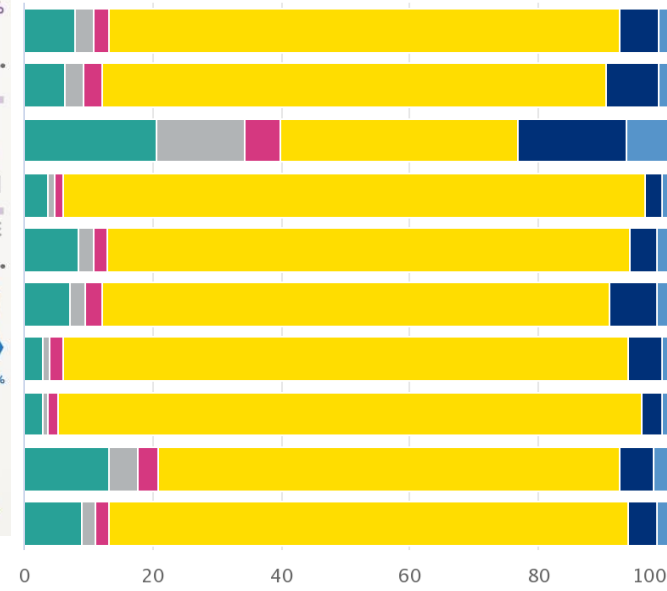
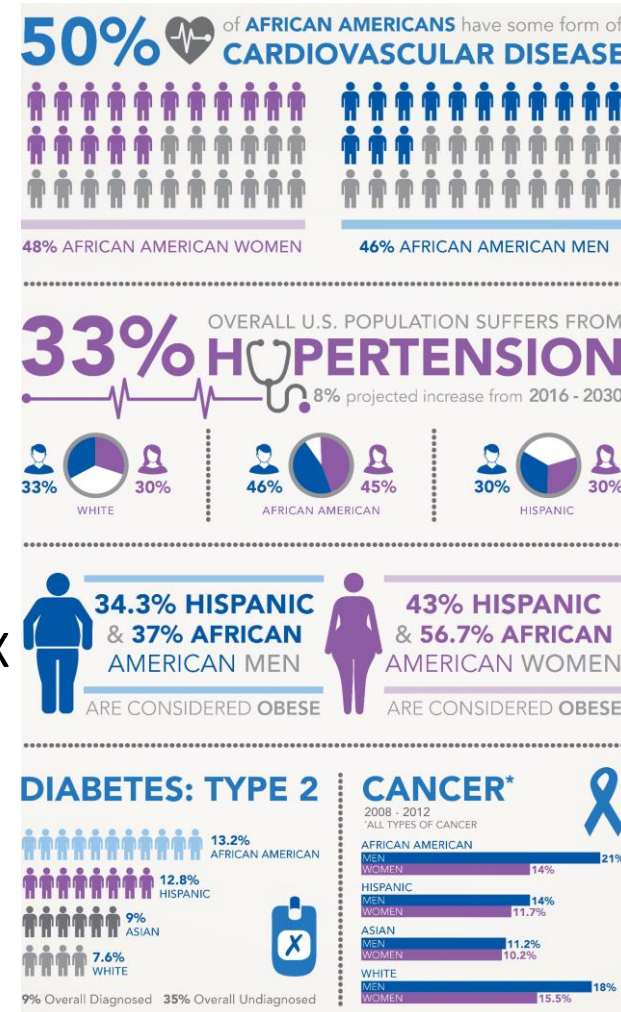
Added by you  
No 1 vote

- 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<sup>o</sup> – T2D, HF, PPCM
  - Socio-economic status (Europe/NAm)
  - History of suspicion (esp USA)
  - Cadaveric donation
- ?Culture/religion



Legend: Asian (green), Black (grey), Mixed (pink), White British (yellow), White other (dark blue), Other (light blue)

England 2011: \*2.4m (~4%), <sup>o</sup>4.1m (~7%)

# Resistance

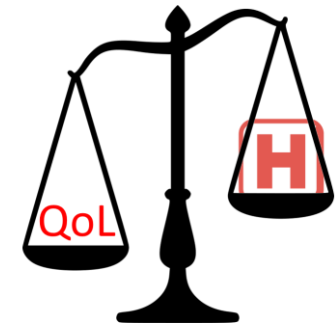
- Family attitudes
  - lung biopsy, bleeding, extremely unwell
  - alter patient attitude to long term health/treatment, e.g. Alzheimer's or MS research
- ?Accidents
  - Northwick Park, UK, 2006
  - cytokine storm
  - multiple organ failure
- ?Rogue researchers
  - China, 2019
  - Crispr-Cas9 rewrite of DNA in twin girls
  - Unethical inducements



# Comment I

- Animals
  - Veganism
  - Animal activism
  - Male models
  - Mice → rats → 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

Research priority	Group (patients, carers or healthcare professionals) whose survey responses were incorporated into this research question
1. Which treatments have the biggest impact on the quality of life of people with advanced HF?	Patients
2. What amount and type of exercise is safe and effective for people with advanced HF?	Patients and healthcare professionals
3. What is the most empowering and effective education and self-management advice for people with advanced HF and their carers? (eg, dealing with fatigue)	Patients, carers and healthcare professionals
4. How can the work of HF charities be better integrated with NHS services to optimise the care of people with advanced HF?	Patients
5. Which approaches, in addition to standard therapies, are effective in supporting breathlessness in people with advanced HF?	Healthcare professionals
6. How do we break down barriers for patients with advanced HF, carers and health professionals to enable talking about end of life care?	Patients, carers and healthcare professionals
7. What are the benefits of asking a person with advanced HF ‘what is important to you’?	Healthcare professionals
8. What is the most effective way to use diuretics in advanced HF, with respect to fluid overload, kidney function, survival and quality of life?	Healthcare professionals
9. 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?	Patients and healthcare professionals
10. What support would be most effective for carers of people with advanced HF? (eg, support groups)	Patients and healthcare professionals

WHEN WE TESTED THIS  
DRUG ON MICE, NOBODY  
NOTICED ANY SIDE  
EFFECTS.

SCHWAPP

