

Recruitment in Primary Care Trials

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FACTS OF LIFE I

- Early estimates of patient availability are usually unrealistically high
- The likelihood of achieving the stated recruitment target within the time allocated is small and takes a major effort
- Patients presumed eligible for study during planning mysteriously disappear as soon as the study starts

FACTS OF LIFE II

- Recruitment will be more difficult, cost more and take longer than planned
- Patients recruited will be healthier than planned in the sample size calculations – event rates lower – ‘underpowered’

PREPARATORY STEPS

- Collect reliable data to estimate patient availability
- Decide on general recruitment strategy
- Outline steps in recruitment process
- Establish network for recruitment
- Pilot data essential to assure granting bodies of feasibility before funding

APPROACHES

- Direct Patient Contact
 - Via general practitioners/clinic nurses
 - Screening on ‘walk-in’ patients.
 - Direct mailings or telephoning (paper, computer, GP generated databases)
- Indirect Patient Contact
 - Indirect appeals via media/advertisements
 - Only for large multi-centred GP trials / where no direct GP contact
- Which you choose depends on what you are studying and how you are studying it
 - E.g. secondary prevention, smoking cessation

MISTAKES & PROBLEMS I

- No recruitment goal
- Redefining goal during the trial
- Inadequate monitoring of recruitment & failure to identify barriers and address them
- Unrealistic timetable
- Competing with private physicians or other trials with same target population
- Competitive recruitment in multi-centred trials

MISTAKES & PROBLEMS II

- Failing to maintain adequate contact with GP co-investigators
- Ethics delays
- Attempting recruitment without support of colleagues, institutions & other stakeholders
- Taking access to records for granted
- Unenthusiastic staff
- Inadequate publicity

SPECIAL GROUPS

- Children
- Elderly
- Pregnant or lactating women
- Mentally incompetent
- Culturally/economically deprived
- Drug addicted
- Prisoners
- Indigenous populations

OTHER CONSIDERATIONS

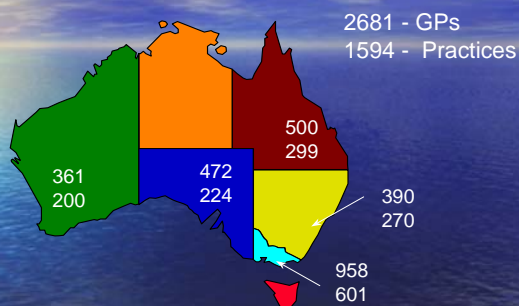
- Stability of study population
- Reliability of study participants
- Ethnic balance of study population
- Aids in recruitment such as incentive payments
- Policy on payments for usual care
- Need for confidentiality

RECRUITMENT STRATEGY FOR THE SECOND AUSTRALIAN NATIONAL BLOOD PRESSURE STUDY (ANBP2)

Second Australian
ANBP2
 National Blood Pressure Study



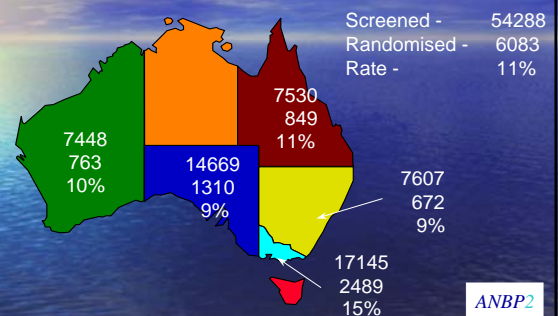
GP Involvement in ANBP2



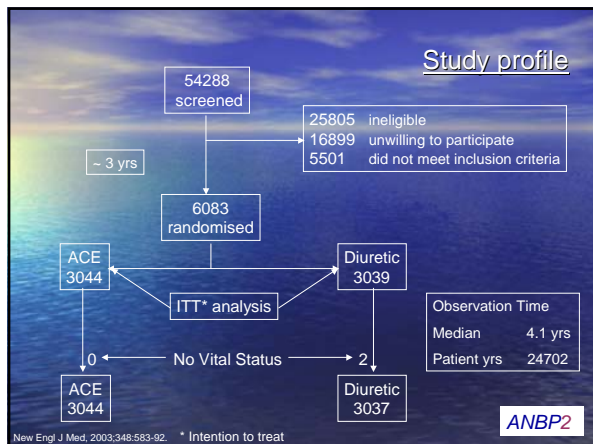
New Engl J Med. 2003;348:583-92.

ANBP2

ANBP2 Subject Recruitment



ANBP2



RECRUITMENT STRATEGY FOR ANBP2 – (1)

- Recruitment of GP co-investigators through DGP databases (+ others where unavailable) to get access to subjects with appropriate demographic profile. Letters or flyers, +/- dinner, with follow-up visits pamphlets and GP investigator kits.
- Search of medical records by age.
- Review of database by GP co-investigator for inclusion / exclusion criteria or whether 'suitable'.
- Letters of invitation to patients (direct approach inappropriate because needed to recruit GP).
- Screening by study nurse at practice.
- Review face-to-face by GP co-investigator for inclusion / exclusion criteria or whether 'suitable'.
- Randomisation by study nurse.

RECRUITMENT STRATEGY FOR ANBP2 – (2)

- Allocation of responsibility for recruitment to one person (regional medical co-ordinator) in each state.
 - Each state had own variation of recruitment
- Victoria [>1000 GPs, 2987 (41%) subjects]
- Charting size of 'raw' database from each practice, number first pass exclusions, response rates to letters, number who attended screening, second pass exclusions and enrolments on a regular basis
 - Comparison to and communication with other states to enhance recruitment
 - Reporting to the Steering Committee on rates
 - Monitoring effectiveness of recruitment methods
 - Continual feedback into recruitment strategy

MARKETING THEME

- To GPs
- "hypertension is a common condition managed in general practice"*
- "Importance of doing research where it is to be applied"*
- No direct marketing to patients – some study publicity

CONCLUSIONS ANBP2

- Target sample size was successfully recruited in 2½ years
- Resources were shifted to the most successful recruiters. Recruitment extended 6/12 in VRC (last 600 subjects)
- State differences evident Vic & NSW expected 30%, reality Vic 2489 (41%), NSW 672 (11%)
- Critical GP recruitment, screening:randomisation and GP:subject

REFERENCES

- Meinert CL. Design and conduct of clinical trials. 2nd edition, Baltimore, Johns Hopkins Center for Clinical Trials, 1990: pp119-122
- Thomas AP, Garrett SKM, McNeil JJ, Taylor HR. Community based recruitment strategies for a longitudinal interventional study. Presented to ARVO 1996