

Towards national education resources in clinical trials consent communication.

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Why don't patients participate in RCT's?

- Preference for a particular treatment
 - ✓ Unwilling to be randomised
- Complications with logistics, travel, extra tests
- Concern that trials are only for desperate situations
- **They are not asked**

- No national systematic approach to training
 - No current accreditation system
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Challenges in consent communication

- Discussion of uncertainty changes the emotional tone
 - ✓ “Guinea pig” concerns in the community
 - Additional dialogue elements
 - ✓ Randomisation, placebos / blinding, tissue analysis
 - Takes more time
 - ✓ Complicates the patients’ thinking
 - ✓ “Supporting paperwork” not patient friendly
 - ✓ Complex teamwork required
 - Avoiding Coercion
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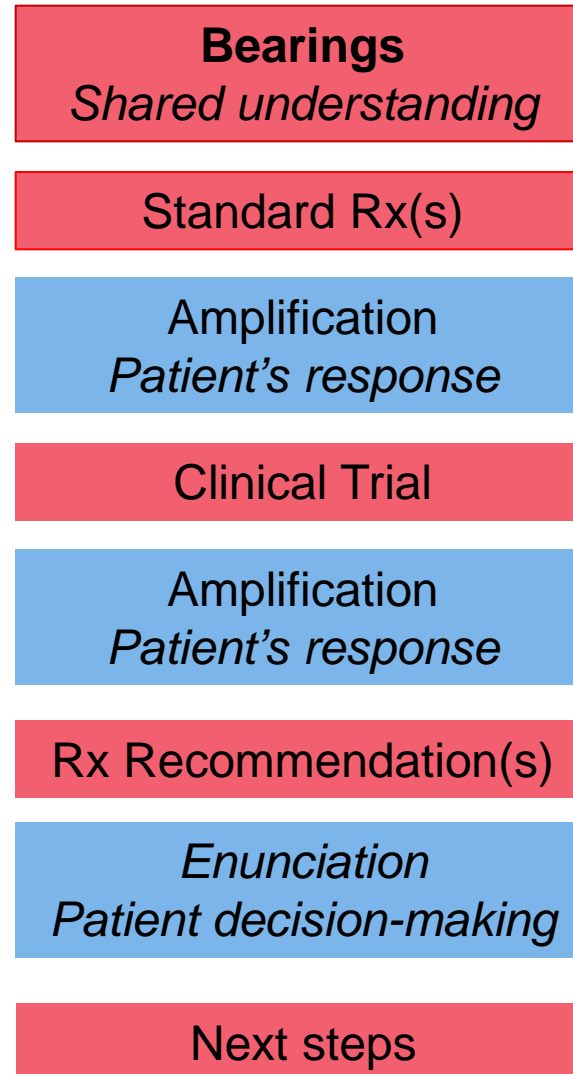
Coercion can be subtle

- Language
 - “You are eligible” vs “ The trial is suitable for your circumstances”
 - Trial design
 - Treatment not available or expensive off study
 - Time pressure from disease / anxiety to start Rx
 - Initial consent for “screening” sets the train in motion
 - testing of tissue for mutations, swabs for culture
 - Doctor-Patient relationship
 - Patient wants to help the Doctor with “their research”
 - CALD / low SES background,
 - inappropriate to question the Doctor
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What works best for patients?

- Collaborative communication style
 - ✓ Ask patient what they know
 - ✓ Tell them simply and clearly
 - Avoid or explain jargon
 - Back up with diagrams, lists, written information, discussion with research nurses
 - ✓ Ask them what they have understood, and clarify concerns
- Emotional support
- Time to process information

- Role of tissue analysis is not well understood
- Increasingly important in cancer clinical trials and may not be optional
- May include germline DNA analysis
 - ✓ Implications for family members
- Communication needs to be more emotion-focused



- RCT to evaluate training
 - ✓ workshop format – medical oncologists
 - ✓ demonstrated improved communication skills
 - Training conducted with:
 - ✓ Breast surgeons - SNAC trial
 - ✓ Utilised by ANZBCTG for complex multi-arm trials
 - ✓ eg ALTTO, as part of investigator meetings or ASMs
 - ✓ ANZMTG workshops for BRAF trials 2010-13
 - ✓ Perinatal trial workshops 2010-13 for trialists in premature labour studies
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- Potential to be accessible to all cooperative groups
- Content
 - ✓ Generic material on common dialogue elements, including video
 - ✓ Disease specific material and case studies
 - ✓ Specific consent issues eg surrogate consent in paediatric trials
 - ✓ Responding to difficult questions

- New investigators commencing academic trial participation
 - ✓ Clinicians and research nurses
- Potential for self assessment and accreditation as part of GCP training
- Current funding from Cancer Australia
 - ✓ Additional resources/collaboration welcome
 - ✓ ANZMTG /ANZBCTG are coordinating the development

➤ For further information:

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