

# Qualitative Research Methods and Randomised Controlled Trials (RCTs)

Dr Suzanne Audrey

# Overview

- Introduction
  - ❖ Qualitative research
  - ❖ Mixing methods
  - ❖ Evaluating complex interventions
- Examples from Bristol research
  - ❖ What is the question? (ASPECTS)
  - ❖ Is a trial feasible? (Protect)
- Conclusions

# What is 'qualitative research'?

- Text, narrative-based (rather than numbers, statistics)
- Interpretative (meaning/explanation)
- Small-scale, depth (rather than large-scale, breadth)
- Theory/hypothesis generating (rather than hypothesis testing)
- Examining context and process (rather than outcome)
  - ❖ What works **for whom, under what circumstances?**
  - ❖ Exploring **how** and **why** outcomes are achieved

“Reaching the parts other methods cannot reach”

(Pope C, Mays N. *BMJ* 1995;311:42-45)

# Mixing methods

‘problems encountered in the health field tend to be **multi-dimensional and multi-disciplinary**’, requiring research that draws on ‘a wide spectrum of methodologies which can be integrated’

(Barbour, R. The case for combining qualitative and quantitative approaches in health services research, *Journal of Health Services Research and Policy*, 1999;4:39-43)

‘Evaluation of complex interventions **requires** use of qualitative and quantitative evidence’

(Campbell M *et al.* Framework for design and evaluation of complex interventions to improve health. *BMJ* 2000;321:694-696)



# Qualitative research in RCTs of complex interventions

Hypothesis generating/ modelling

What is the question/ possible intervention?

Phase I and II feasibility study

Acceptability of/ modifications to components of intervention & its evaluation.

Phase III Trial

Integral process evaluation  
Context, delivery, receipt of standardised intervention

Wider implementation

e.g. service evaluation

# Examples from Bristol research (briefly!)

- ASPECTS (**hypothesis generating**)
  - ❖ Qualitative study of patients experiences of palliative chemotherapy
  - ❖ Identified issue to be addressed
- ProtecT (**feasibility of recruitment to trial**)
  - ❖ Qualitative study to address problems with recruitment and randomisation to RCT
  - ❖ Significant improvement to recruitment, trial possible

**ASPEcTs**  
**A Study of Patients Experiences of  
Treatments\_**

**Dr Suzanne Audrey et al**

CANCER RESEARCH UK



# ASPEcTs: A Study of Patients' ExperiencEs of TreatmentS

## Study aims

- To use qualitative research methods to describe, comprehensively, patients' experiences of palliative chemotherapy
- To explore the process surrounding **treatment decision-making** and to consider ways in which this might be improved

# ASPEcTs: Study design

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## **Context:**

Large teaching hospital  
District general hospital

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## **Participants:**

37 patients with advanced cancer  
(colorectal, lung, pancreas)  
9 oncologists

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## **Methods:**

Consultations observed and audio recorded  
  
Recordings fully transcribed and coded  
using Atlas.ti; 'constant comparison' to  
identify similarities, differences, themes;  
'charting' from Framework data  
management method

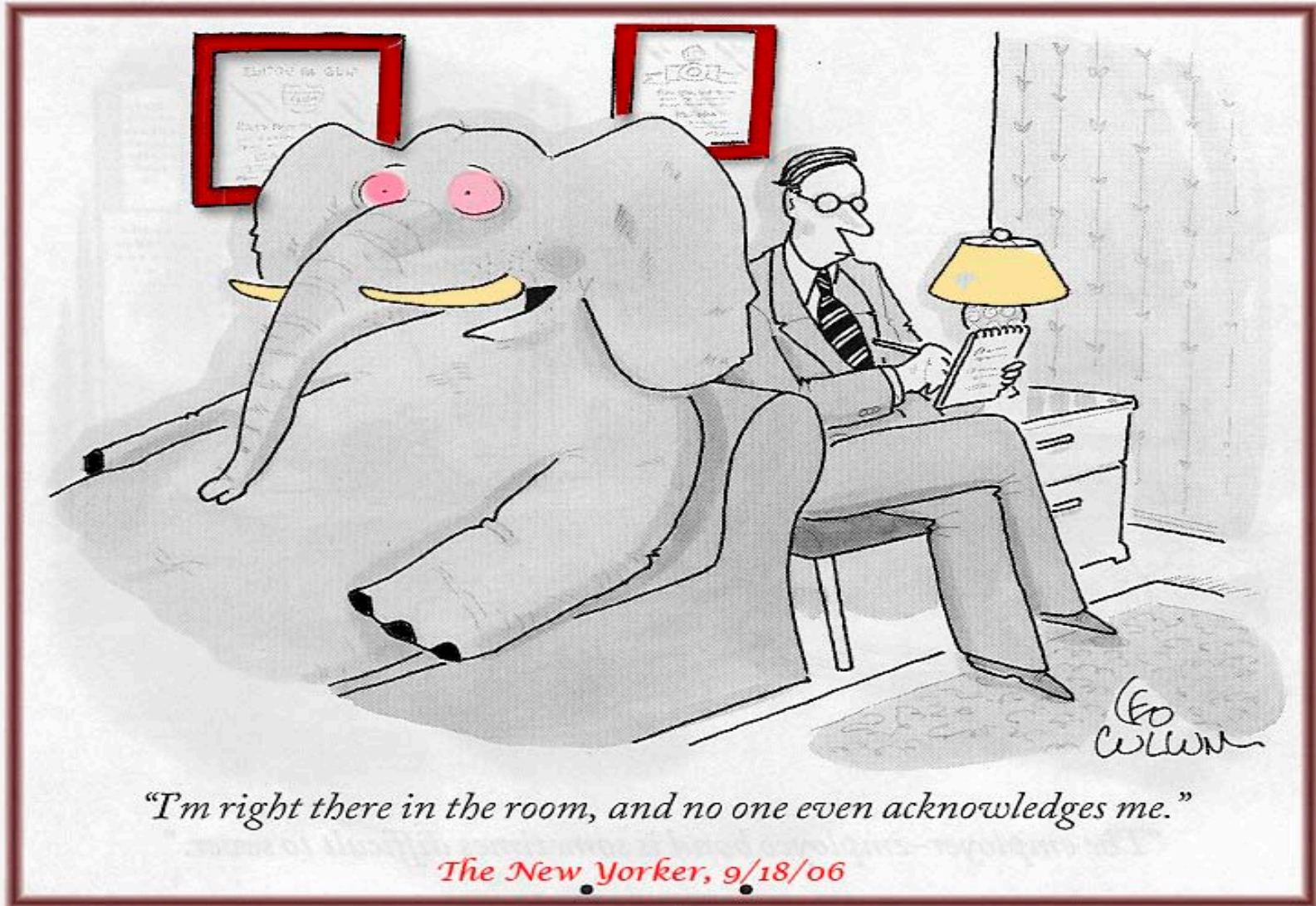
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# Decision-making & informed consent

- “enough information to make a decision”
- “the benefits they (*clinicians*) hope will result”
- “the chances of getting such benefits”

Consent—what you have a right to expect: a guide for adults. London: DH, 2001.

[Will the treatment prolong my life? How much longer?]



# ASPEcTs oncology consultations: survival benefit information

Numeric data	“About 4 weeks”	6
Idea of timescales	“A few months extra”	5
Vague	“Buy you some time”	<b>18</b>
Not mentioned at all		<b>8</b>
Total		<b>37</b>

Audrey S *et al.* What oncologists tell patients about survival benefits of palliative chemotherapy and implications for informed consent: qualitative study. *BMJ*; 2008;337:a752

# 'Protecting' the patient?

- Previous reluctance to give cancer diagnosis

*“ ... in November 1964 she became very unwell and an exploratory operation revealed that she had terminal cancer. In those days, patients weren't told and Mum came home believing she would convalesce and get better. Sadly, that was not to be.”* (Bristol Evening Post, June 7<sup>th</sup> 2010)
- Present reluctance to give information about the limited survival benefit of palliative chemotherapy?
- Informed consent focusing on description of side-effects
- NICE guidance for patients does not include information about survival gain (clinician guidance includes this information)

# **(Some) oncologists' response to findings**

**No-one is average**

**Median survival gain is difficult to explain**

**You can't discuss survival gain without discussing prognosis**

**The patient doesn't want to talk about prognosis**

# Implications for practice

- Oncologists' responsibility to inform patient of “the benefits they hope will result” and “the chances of getting such benefits”
- Training for oncologists should include guidance in how to inform patients about the survival benefit of palliative chemotherapy
- Range as well as average retains ‘hope’
- NICE patient information should include information about survival gain

Development and evaluation of intervention?

**Strategies for enhanced recruitment to  
randomised trials:  
integrating qualitative research**

**Professor Jenny Donovan *et al***

# ProtecT study

- No RCTs of treatment for PSA detected prostate cancer
- No proven survival advantage for any one treatment; very different side effects
- Previous trials had failed
- Trial “could not be done”
  - ❖ “Treatments too different”: radical surgery (prostatectomy), radical radiotherapy, monitoring
  - ❖ “Men would not accept randomisation”
  - ❖ BUT – everyone agreed it had to be done!

# ProtecT randomisation rates 2000-1

<u>Date</u>	<u>Eligible</u>	<u>Randomised</u>
May 2000	30	10 (33%)

- Low numbers agreeing to randomisation
- Most opted for surgery, some for radiotherapy
- Why? Qualitative research conducted in earnest!

Donovan J, et al. Improving design and conduct of randomised trials by embedding them in qualitative research: ProtecT study. *BMJ* 2002; 325:766-770

# ProtecT recruitment: qualitative research

- Data collection
  - ❖ Recruitment appointments observed and audio-recorded
  - ❖ Follow-up, in-depth interviews with recruiters and patients
- Issues explored
  - ❖ Delivery of information
  - ❖ Participants' interpretation of trial information
  - ❖ Reasons for different recruitment rates between centres and over time

# Qualitative findings

- Recruiters had difficulty discussing equipoise (best treatment in terms of survival was not known) and presenting treatments equally
- Participants did not interpret treatment options equally and had problems accepting equipoise
- Terminology was misinterpreted by participants:
  - ❖ ‘Trial’ was mistaken for non-radical monitoring arm (“try and see”)
  - ❖ ‘Watchful waiting’ interpreted as “no treatment” (“watch while I die”)

# Modifications to recruitment process

- Terminology
  - ❖ Avoid 'random', 'trial'
  - ❖ Avoid 'watchful waiting'
- Non-radical arm
  - ❖ 'Active monitoring' (regular check-ups and access to radical treatment if required)
- Order of presentation of treatments
  - ❖ 'Active monitoring' (rather than surgery) first
- Staff training
- Trial information revised

# Randomisation rates 2000-2002

Date	Eligible	Randomised
May 2000	30	10 (33%)
August 2000	45	23 (51%)
November 2000	67	39 (58%)
January 2001	83	51 (61%)
May 2001	155	108 (70%)
January 2002	200	137 (69%)

# Randomisation rates 2003-2008

Date	Eligible	Randomised
January 2003	381	263 (69%)
January 2004	622	430 (69%)
January 2005	914	621 (68%)
January 2006	1319	889 (67%)
January 2007	1762	1153 (65%)
January 2008	2232	1441 (65%)

# Qualitative methods within RCTs

- Hypothesis generating → intervention development
- Support the development, design and feasibility of trials (e.g. recruitment, development of outcome measure)
- Enhance participants' understanding and experience of RCTs
- Improve participants' understanding and acceptability of interventions
- Enhance interpretation of trial findings (e.g. qualitative data on 'why' and 'how' intervention worked or not)
- Ensure effective design and conduct of trial throughout ...

# MRC Trials Methodology Hub

- Bristol ConDuCT Hub: a regional focus for innovative research methodology in randomised trials
- **Qualitative theme**
  - ❖ Developing and integrating qualitative research methods to improve design and conduct of difficult/challenging RCTs
  - ❖ Offer training to encourage other trials to adopt qualitative methods
  - ❖ Support new and ongoing trials

ConDuCT: Collaboration and innovation for Difficult or Complex RCTs