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Going to the PROM?

Are Patient Reported Outcome Measures
(PROMs) a useful tool to measure the
impact of nursing interventions?



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Patient Reported Outcome Measures (PROMs) in the NHS: an introduction

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Darzi report mentions outcomes
37 times (vs. 18 for cost
effectiveness vs. zero for
efficiency)

*'Assessing this [effectiveness]
will include clinical measures
such as mortality or survival
rates, complication rates and
measures of clinical
improvement. Just as important
is the effectiveness of care from
the patient's own perspective
which will be measured through
patient-reported outcomes
measures (PROMs)'*



Quality at the heart of
everything we do

High quality care throughout the NHS

A patient from Cheltenham and a
physiotherapist at the National Spinal
Injuries Centre at Stoke Mandeville
Hospital, Aylesbury

Outcomes

Structure ⇒ **Process** ⇒ **Outcome**

- **Structure:** the inputs into care – e.g. personnel, equipment and facilities
- **Process:** the activities of care - such as hospital episodes, outpatient visits, investigations and so forth
- **Outcome:** the impact of care on individuals and the environment



PROMs

Standardized instruments for assessing a patient's perception of their own health described in terms of symptoms, function and well-being using numerical scoring systems

'Patient reported Outcome Measure' is a term used by DH derived from one used by the US FDA of 'PRO' that describes a class of measures aka self-report measures of health, health status or health related quality of life (or even quality of life)

Typical content

- Symptoms of illness e.g. pain
- Functioning - personal e.g. mobility/dexterity
 - social e.g. leisure activities, role
- Psychological health
- General well being



Why not use more objective measures of outcome?

- **Mortality**
- **Process based outcomes**
 - re-admission rates, relapses, complications
- **Clinical/biomedical measures**
 - ECG, FEV, blood pressure (mmHg), blood sugar (mmol/l), bone mineral density

These measures are important, but do not capture a key benefit to patient – how the care impacts on their ‘quality of life’



Why use patient report?

- Because it is ultimately experienced by the patient: be it symptoms (e.g. pain or depression), physical functioning or well-being - and therefore they cannot be entirely assessed by “objective” measures
- There is evidence of significant differences between what professionals (e.g. doctors and nurses) and carers’ report on patients health compared to what patients say about themselves

Types of measures

- Condition specific - designed to assess health outcome is specific medical conditions
e.g. St.George's Respiratory Questionnaire
- Generic – designed to be appropriate for any medical condition
 - Profile measures (e.g. SF-36)
 - Preference-based index for calculating QALYs (e.g. EQ-5D)

Individualised measures – choose your own dimensions, score them and monitor change (e.g. MYMOP)



Example: SF-36

- A 36 item questionnaire designed for administration in a wide range of interfaces and languages
- Measures general health across 8 dimensions: physical functioning, role limitations, social functioning, pain, vitality, mental health and general health
- One of the most widely used measure of HRQOL in the world
- Validated across a wide range of medical conditions



SF-36 Physical Functioning items

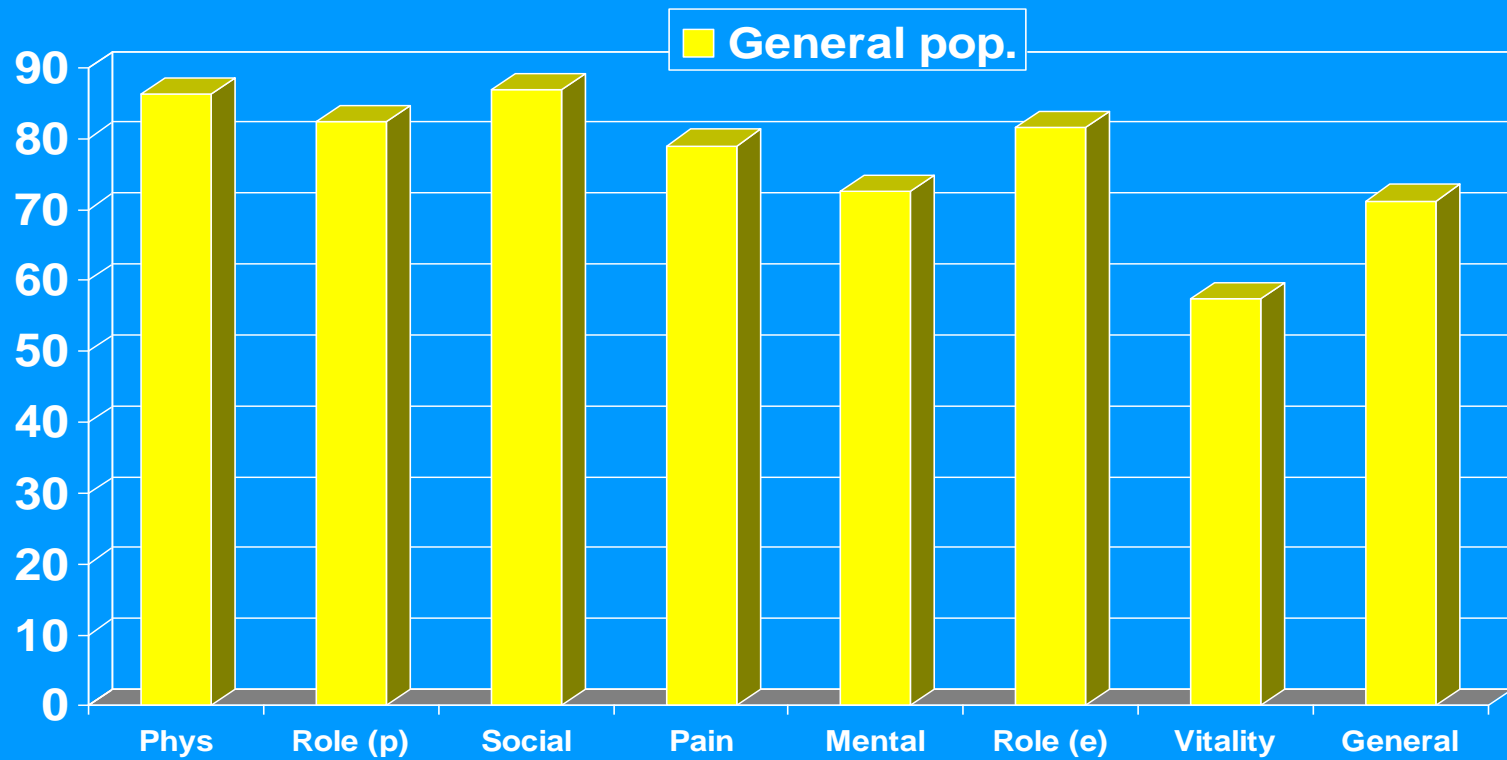
The following questions are about activities that you might do during a typical day. Does your health limit you in these activities? If so, how much?

(circle one number on each line)

ACTIVITIES	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b. Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
c. Lifting or carrying groceries	1	2	3
d. Climbing several flights of stairs	1	2	3
e. Climbing one flight of stairs	1	2	3
f. Bending, kneeling or stooping	1	2	3
g. Walking more than a mile	1	2	3
h. Walking half a mile	1	2	3
i. walking 100 yards	1	2	3
j. Bathing and dressing yourself	1	2	3

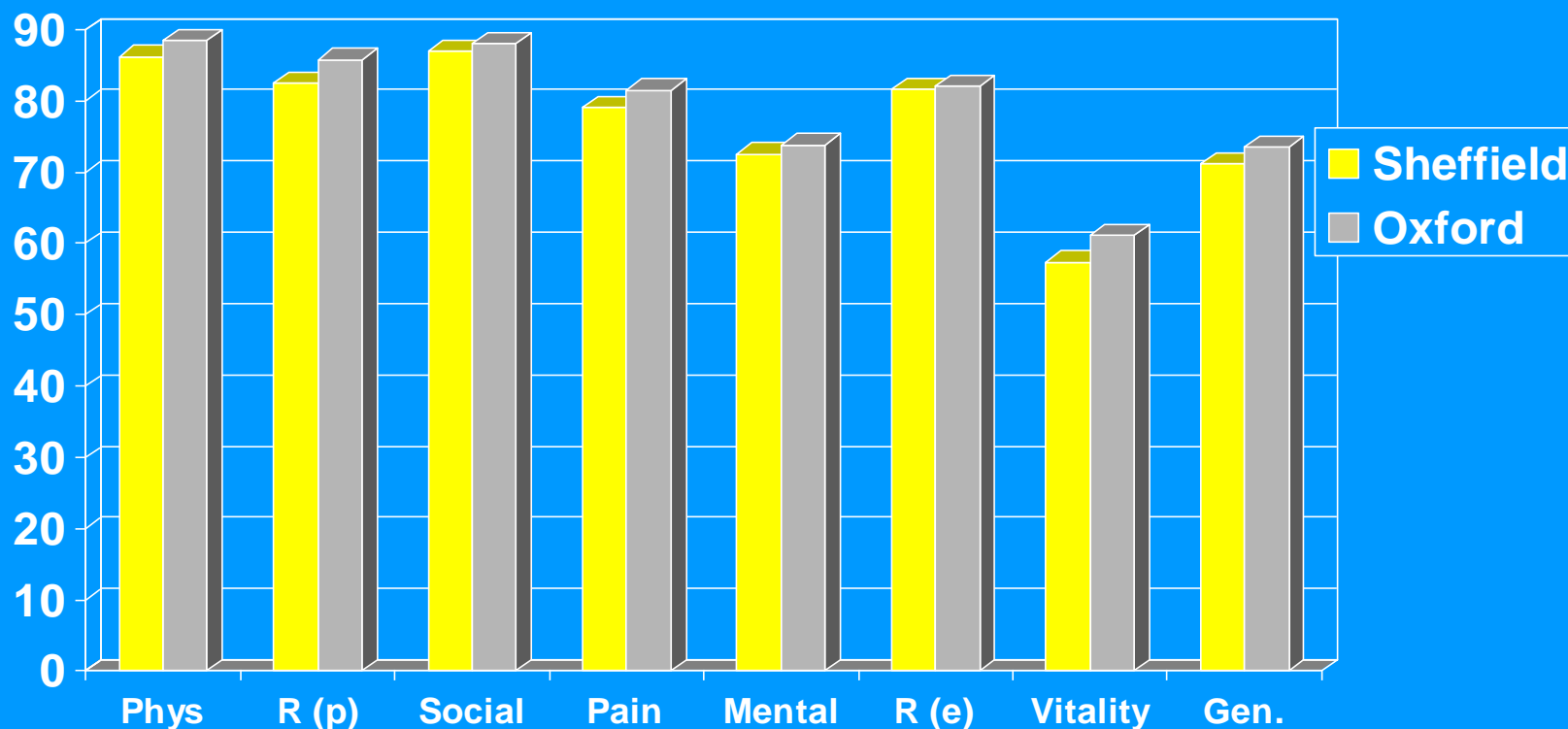


SF-36 data: general population of Sheffield, UK.



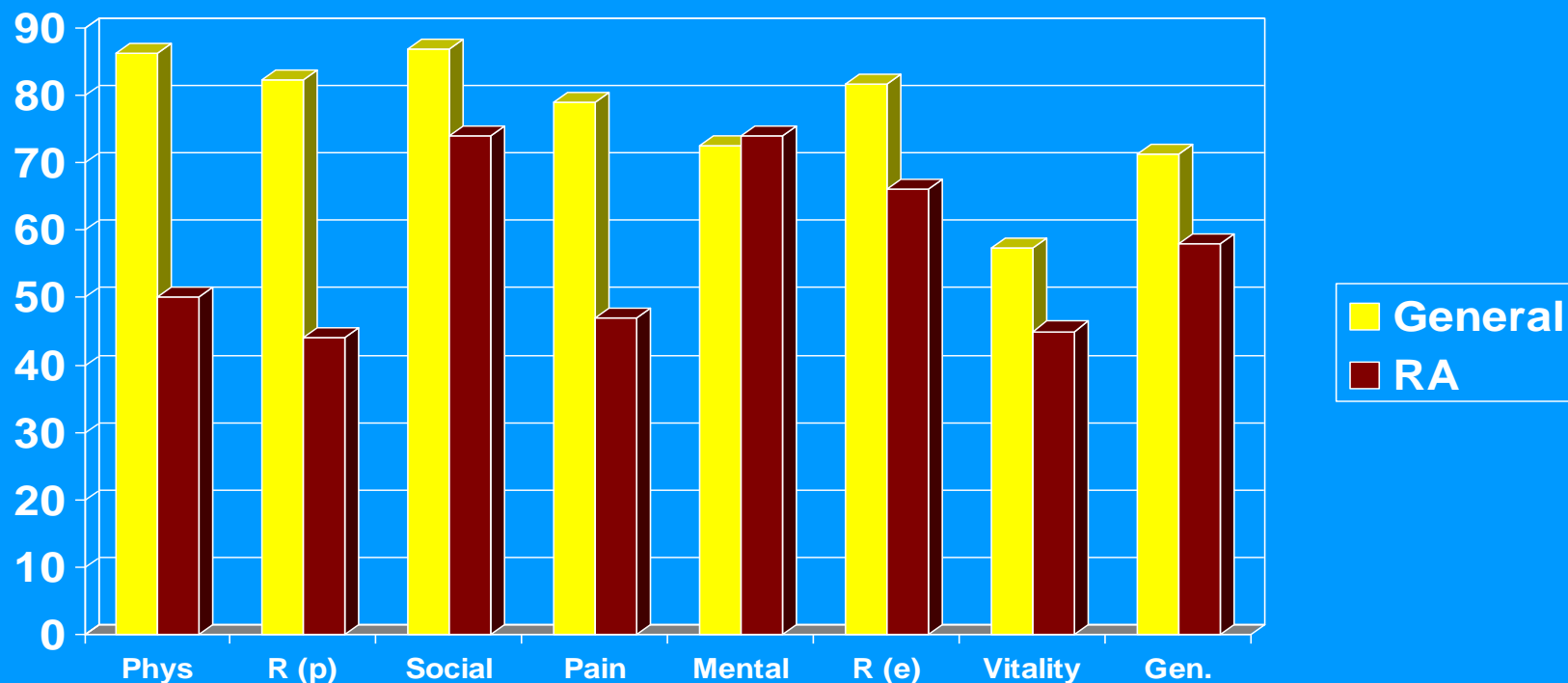


SF-36 data: comparison of two general populations



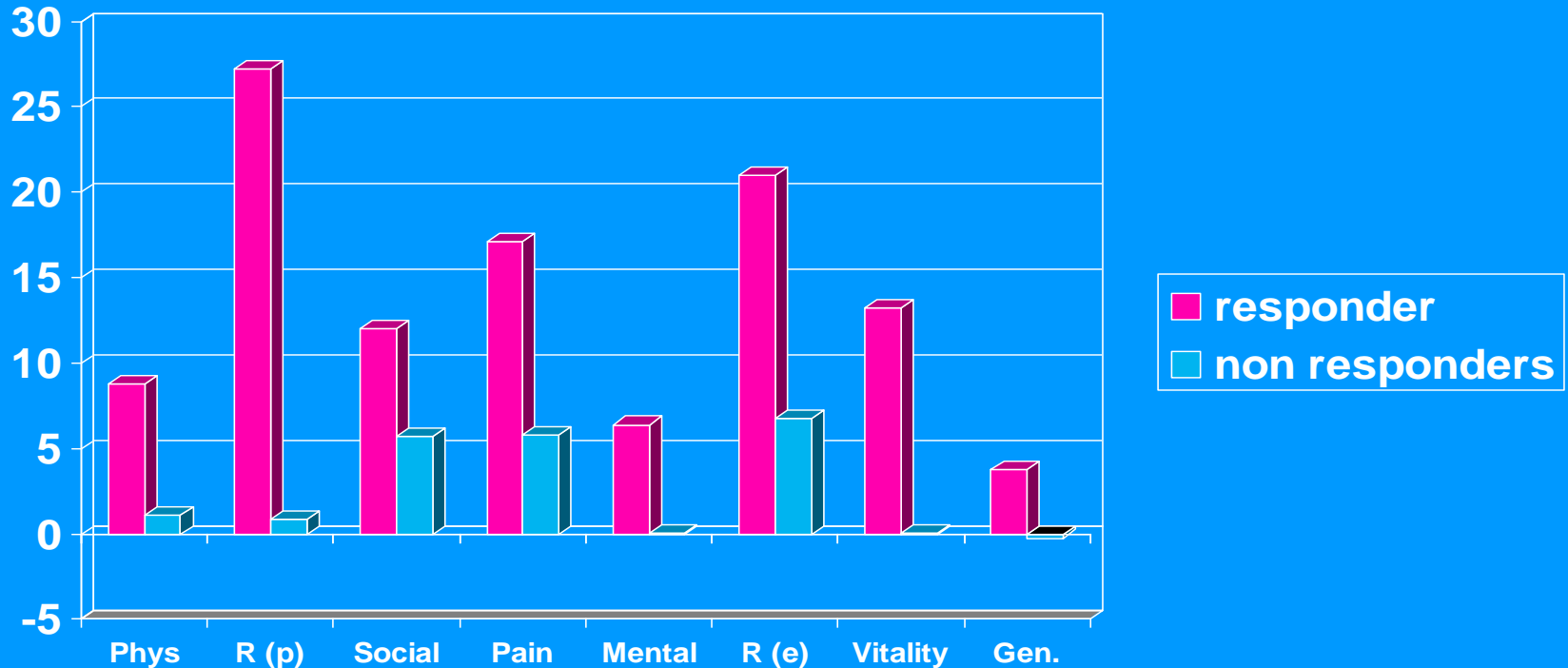


SF-36 data: comparison of general population and Rheumatoid Arthritis





SF-36 data: Changes over time by response to therapy in Rheumatoid Arthritis





What can PROMs be used for?

1. Patient care
2. Assessing performance (e.g. DH PROMS initiative with pre-op and post-op administrations)
3. Informing resource allocation (e.g. cost effectiveness assessment for NICE)



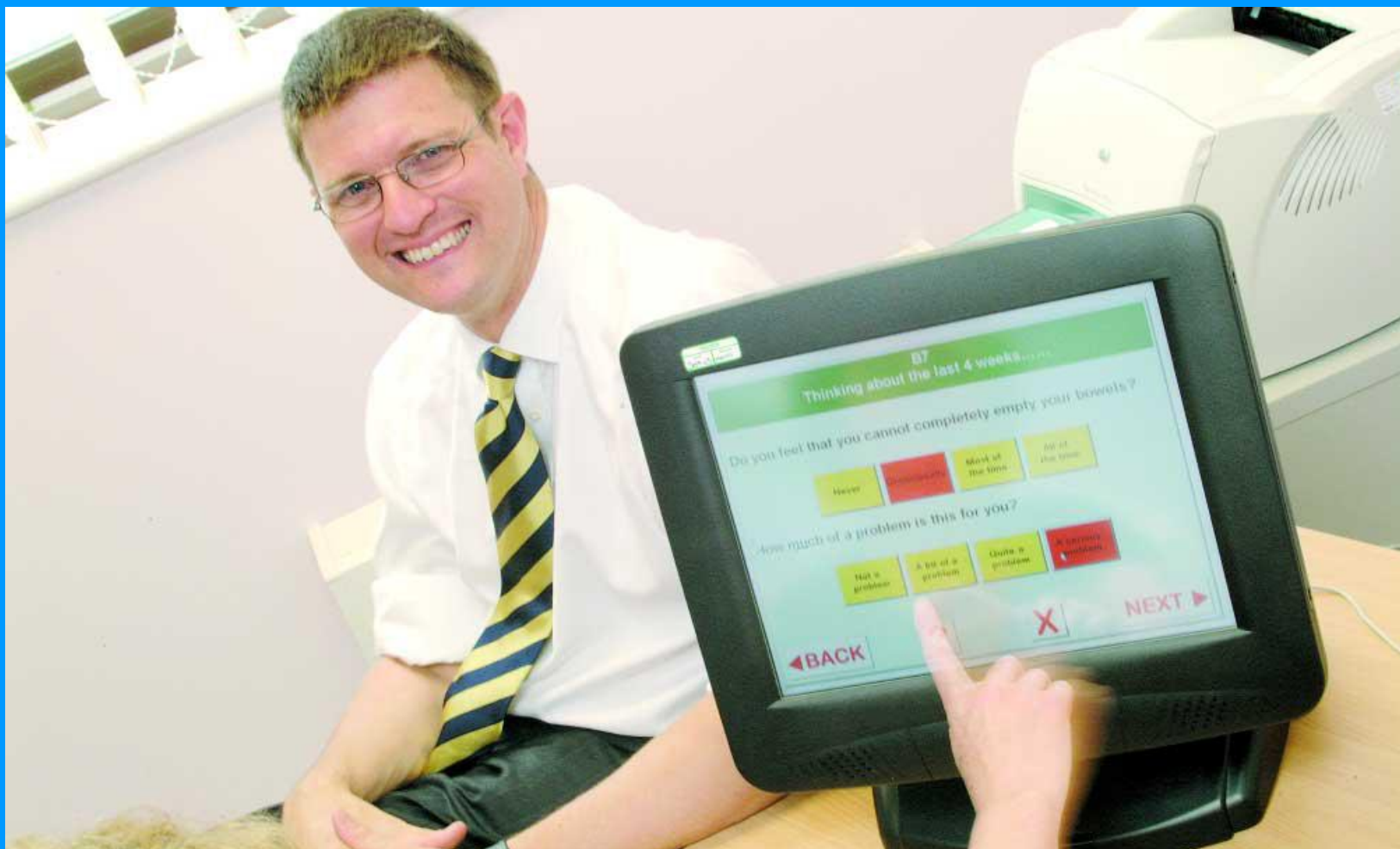
1. Use in patient care

- Audit clinical work within teams
- Inform patient choice – this is part of the longer term agenda
- Inform clinical/patient encounter – far more interesting (e.g. ePAC)



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Electronic personal assessment questionnaire





Using PROMs directly to inform and monitor care: e.g. ePAC

- Provides a real time assessment
- Results can be used to inform the diagnosis and management of the patient
- Allows the patient to express symptoms and concerns that may be missed by traditional history taking



2. Assessing performance in the NHS

- NHS requirement to use PROMS routinely used in 4 elective surgical procedures from April 2009 (Contract for Acute Hospital Services) before and after surgery
- Plans to extend to include chronic conditions and mental health in next 2 years

Recommended instruments for DH PROMs programme

Procedure	Generic	Condition specific
<i>Primary Unilateral Hip Replacement</i>	EQ-5D	Oxford Hip Score
<i>Primary Unilateral Knee Replacement</i>	EQ-5D	Oxford Knee Score
<i>Groin Hernia Repair</i>	EQ-5D	None
<i>Varicose Veins</i>	EQ-5D	Aberdeen varicose vein questionnaire



By ticking one answer in each group below, please indicate which statements best describe your own health state TODAY.

Please tick one

1. Mobility

I have no problems in walking about

I have some problems in walking about

I am confined to bed

2. Self-care

I have no problems with self-care

I have some problems washing or dressing myself

I am unable to wash or dress myself

3. Usual Activities

I have no problems with performing my usual activities
(e.g. work, study, housework, family or leisure activities)

I have some problems with performing my usual activities

I am unable to perform my usual activities

4. Pain/Discomfort

I have no pain or discomfort

I have moderate pain or discomfort

I have extreme pain or discomfort

5. Anxiety/Depression

I am not anxious or depressed

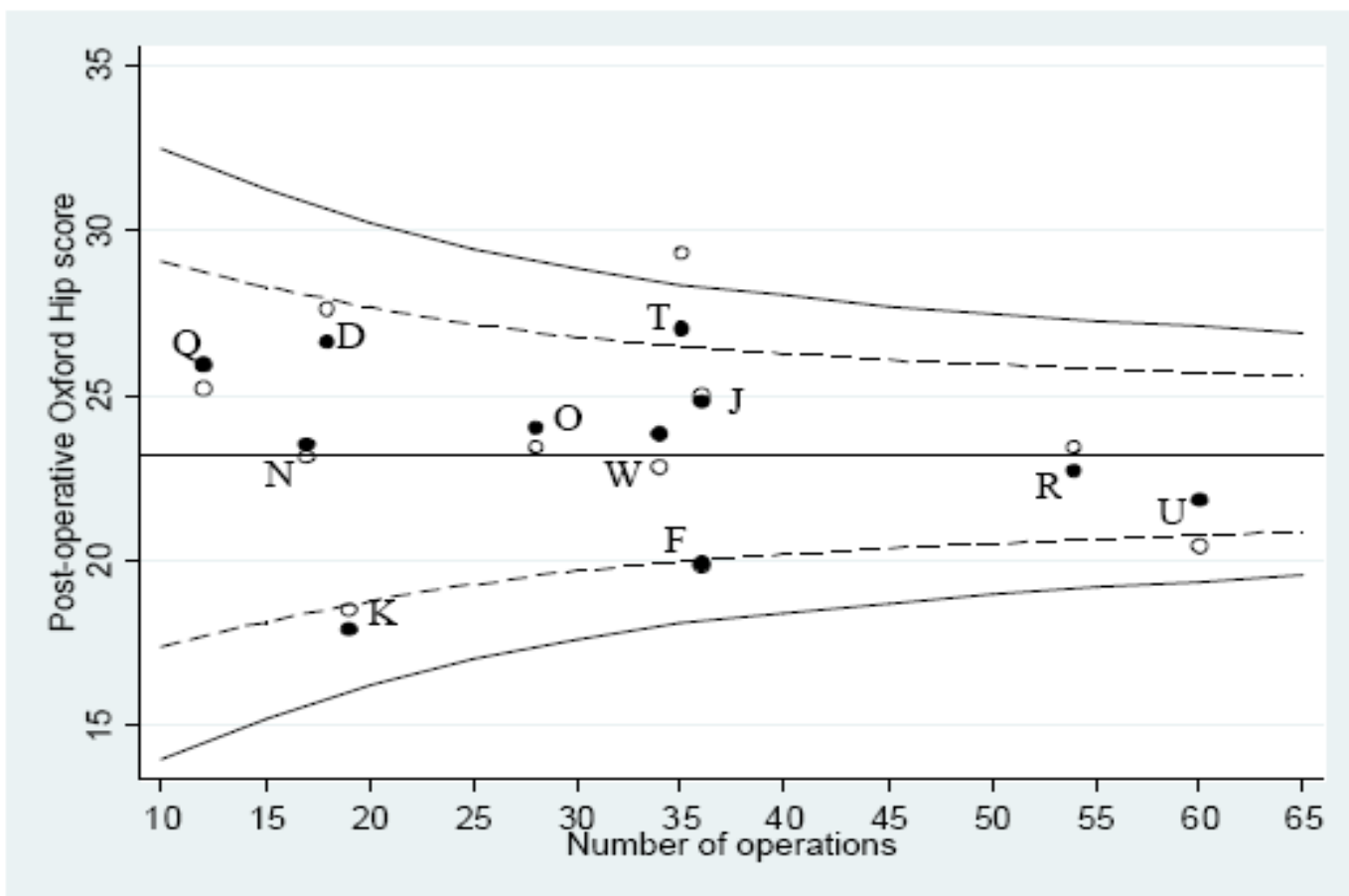
I am moderately anxious or depressed

I am extremely anxious or depressed



Funnel Plots

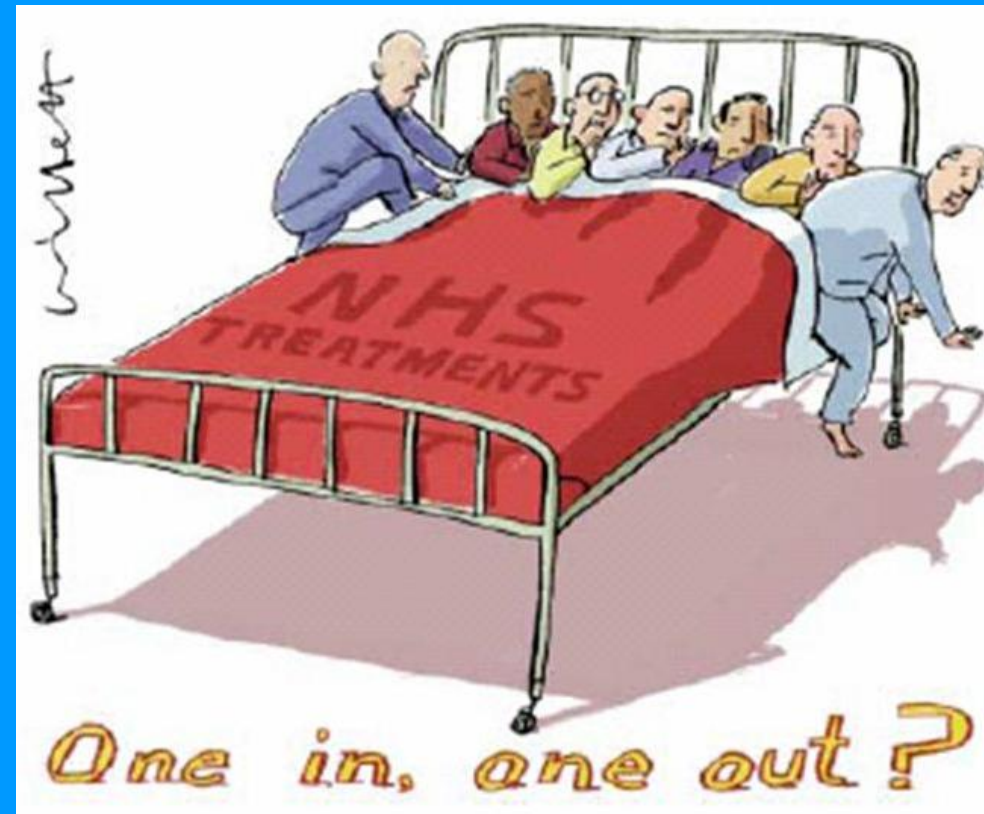
Figure 4.7: Funnel plot of post-operative Oxford Hip Score in hip replacement surgery.





3. Use in informing resource allocation

- If a fixed budget system like the NHS spends more on one thing, it has to do less of something else
- Choices have to be made between alternative ways of spending
- How should these choices be informed?

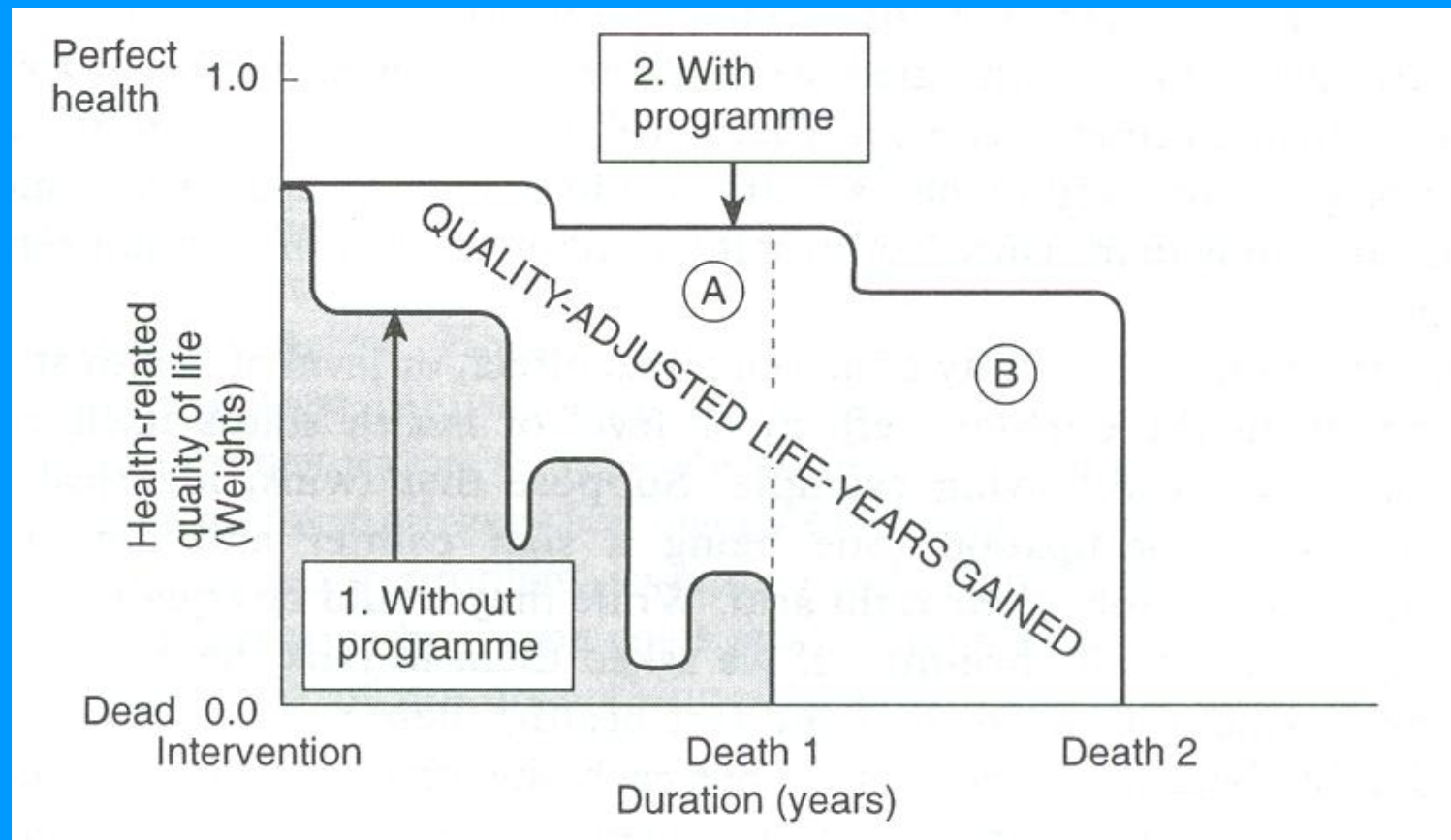




NICE Appraising new interventions

- Clinical effectiveness – can it work in practice (e.g. improving clinical outcomes, and this may include PROMs)?
- Cost-effectiveness – is it value for money?

Quality-adjusted life years



Source: Drummond et al, 1997



Cost-effectiveness

$$\text{cost}_{\text{new}} - \text{cost}_{\text{current}}$$

$$\text{health gain}_{\text{new}} - \text{health gain}_{\text{current}}$$

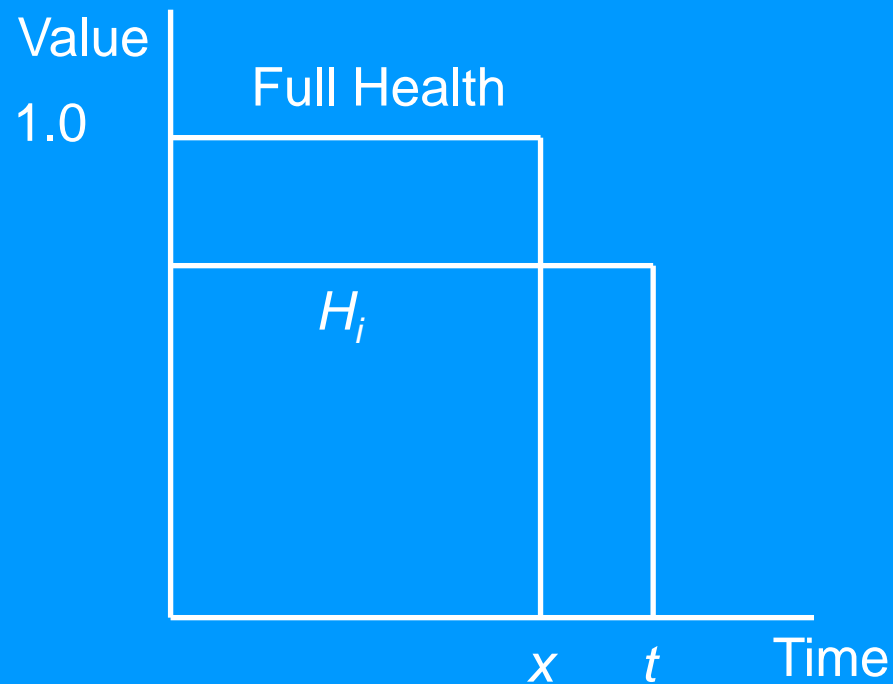
Cost of new intervention 50,000 and old intervention 20,000

QALYs of new intervention 4 and the old 2

→ ICER = 15,000 per QALY



Valuation of health: Time Trade-Off



Vary time period, x , until indifference between H_i for t years and full health for x years



EQ-5D UK Values

Dimension	Level	Coefficient
Constant		.081
Mobility	2	.069
	3	.314
Self-care	2	.104
	3	.214
Usual activity	2	.036
	3	.094
Pain/discomfort	2	.123
	3	.386
Anxiety/depression	2	.071
	3	.236
N3		.269



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Feeding the 'Beast'





PROMs issues addressed in this symposium

Design

- Purpose: patient care, audit, performance assessment or economic evaluation
- Content: what dimensions and items?
- Scoring

Methods

- How to develop measures?
- How can they be tested?

Application

- How to use them (in nursing)?



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PROMs, Nursing and Economic Evaluations

Simon Palfreyman MSc PhD
Research Nurse
Sheffield Vascular Institute



Definitions: PROMS

Patient Reported Outcome Measures PROMs

“**Questionnaires**, interview schedules and rating scales that measure states of health and illness from the **patient’s perspective**. They provide a measure of their experiences and concerns in relation to illness, health status and quality of life. These instruments can be used in a number of applications including clinical trials, economic evaluation and routine patient care.”

UK DoH website



Definitions: Nursing

“The use of clinical judgement in the provision of care to enable **people** to improve, maintain, or recover health, to cope with health problems, and to achieve the best possible **quality of life**, whatever their disease or disability, until death.” RCN 2003



Definitions: Economic Evaluation

“The **comparative** analysis of alternative courses of action in terms of both their **costs** and **consequences**” - Drummond et al 2005



Why does it matter to nursing?

Three key interconnected reasons

1. Need for efficiency and effectiveness

- Darzi report 2008
- Quality Accounts
- Quality, Innovation, Productivity and Prevention (QIPP)

2. Need to demonstrate nursing interventions affect patient outcomes

- Nursing outcomes and metrics.

3. Payment by results



High Quality Care for All: NHS Next Stage Review (Darzi 2008)

- NHS needs to focus on improving health as well as treating sickness.
- Systematically **measure** and **publish** information on the quality of care.
- Care should be based on what can actually be measured



PROMs and UK DoH Policy

- PROMs should have a greater role in the NHS.
 - Since 2009 routine administration of PROMs for specific surgical procedures
 - Condition specific
 - EQ5-D
- Since 2009 the NHS Contract for Acute Services includes a requirement to report on evidence from PROMs.
- In 2010 funding to be linked to results from PROMs and patient satisfaction.



Measuring Nursing Outcomes

- 19th Century – number of deaths
 - Defining death
 - No link to interventions

Florence Nightingale:

“If the function of a hospital were to kill the sick, statistical comparisons of this nature would be admissible. As, however, its [the hospitals] proper function is to restore the sick to health as speedily as possible, the elements which really give information as to whether this is done or not, are those which show the proportion of sick restored to health, and the average time which has been required” (Nightingale 1863)



Modern Nursing Outcomes

1. Focus around collecting data sets
 - International Council of Nurses
 - International Classification of Nursing Practice
 - International Nursing Minimum Data Set (i-NMDS)
 - American Nursing Association
 - Nursing Quality and Safety Initiative (1994)
 - National Quality Forum Indicators (2004)
2. Collecting data on outcomes/ tasks linked to nursing



UK Nursing Outcomes

1. 2009 National Nursing Research Unit

- Identified 21 potential indicators from 123 different sources.
- Highlighted difficulty in establishing link between nursing interventions and patient outcomes.
- Recommended three areas based on the strength of (relatively poor) evidence.



UK Nursing Metrics

1. Safety

- Failure to rescue
- Hospital acquired infections.
- Pressure ulcers
- Falls

2. Effectiveness

- Staffing levels
- Staff satisfaction
- Staff perception

3. Compassion

- Experience of care (patient reported)
- Communication



UK Nursing Outcomes

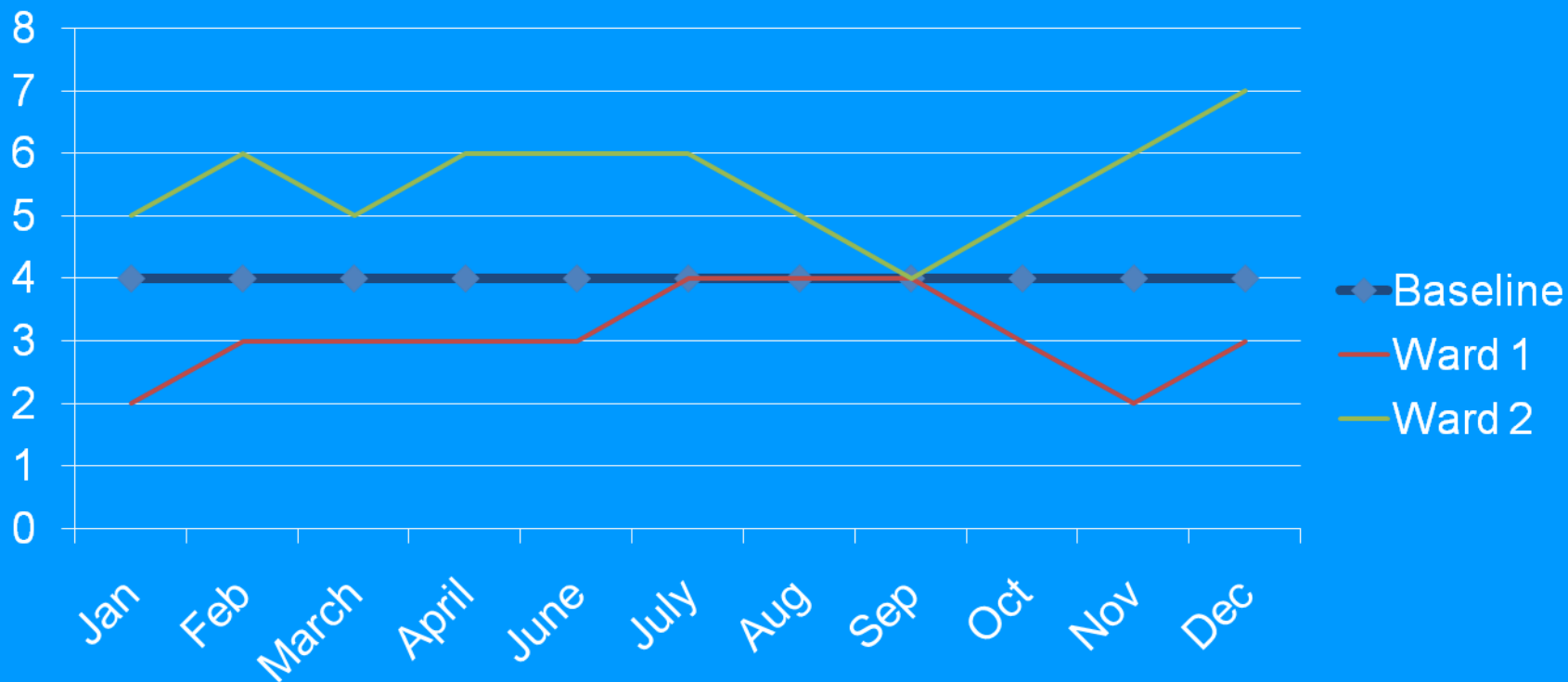
2010 First National Nursing Outcome Measures

- Number of falls resulting in physical injury (per 1,000 bed days)
- Pressure ulcers developed during previous month (per 1000 bed days or 10,000 population)
- Number of patients with indwelling urinary catheters (per 1000 bed days or 10,000 population)



Measuring nursing outcomes in practice

1. Comparison with Baseline/ Mean





2. Traffic Light System

Metric/ Outcome				
Falls	Criteria	Ward 1	Ward 2	Ward 3
	Risk assessment on admission	Red	Yellow	Green
	Care plan for at risk patients	Green	Red	Yellow
	Bed rail assessment	Yellow	Green	Yellow
Pressure Sores				
	Risk assessment on admission	Red	Yellow	Red
	Pressure sore incidence	Yellow	Green	Green



Potential Problems with Metrics

- No current mechanism for collecting these data
- Task orientated
- Focus on nurses not patients
- Poor level of evidence
 - Correlation does not necessarily imply causation
- Gaming
- Regression to the mean
- May only capture a small percentage of the workload of nurses

“Not everything that counts can be counted; not everything that can be counted counts” (McKee 2004).



PROMs vs Metrics

- Patient focused
- Assess changes in health/ quality of life
- Enhance patient participation and communication
- Large number of validated instruments



Disadvantages PROMs

- Artificial
- Selecting appropriate instruments
 - 3215 separate PROMs (2007)
- Administrative burden
- Time constraints
- Difficult to isolate nursing contribution
- Medical focus of many instruments
- Few nursing PROMs
- Few nurses developing PROMs



PROMs and Economic Evaluations

- PROMs used as an outcome in economic evaluations
- Some PROMs (preference-based measures) can be used to calculate Quality Adjusted Life Years (QALYs)
- Health care commissioners (NICE, FDA) stipulate that PROMs should be used



Challenges for Nursing

- Need to link nursing care to patient outcomes.
- Nursing contribution to quality of care is under recognised.
- Other agencies/ professions deciding on nursing outcomes
- Need to justify the added value of registered nurses/ nurse specialists
- Potential for reduced funding of nursing posts
- DoH planning to link hospital payments to “nursing indicators”



Final thoughts

19 years Ago: “Nurses and their managers need to know whether, what amount and what kind of nursing care makes a difference to patient outcome” Bond and Thomas (1991)

15 years ago: “There is a long history of outcome research in nursing but little evidence of an emerging body of knowledge” Griffiths (1995)



15 years ago: “Demonstrating the value of nursing in terms of its effects on patients has never been so urgent” (Thomas and Bond 1995)

*2 years ago: “Nursing’s positive contributions do not easily translate into specific objective outcomes either because nursing makes a small contribution to the overall outcome (such as functional status) or because their contribution is to the subjective experience of the patient.”
Griffiths et al 2008*



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The experience so far in the creation of a PROM for amblyopia in the paediatric population

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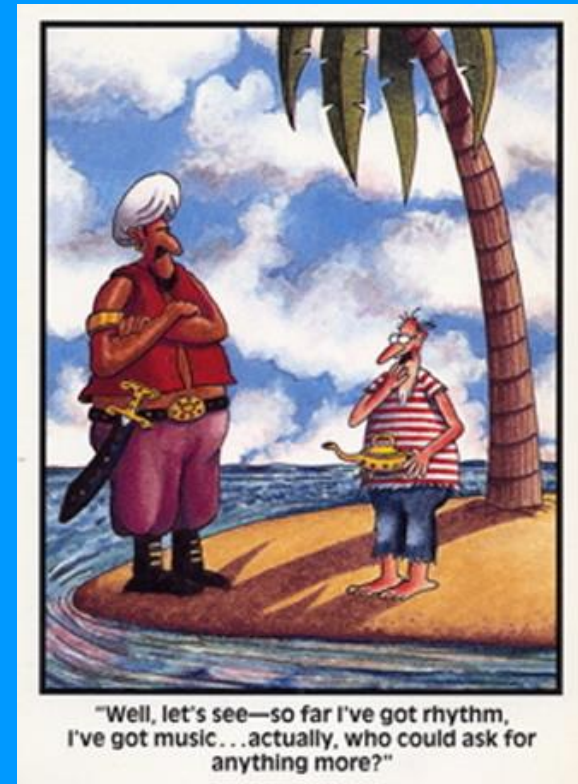
Contents

- What is Quality of Life?
- Amblyopia and quality of life
- Development of a paediatric disease-specific measure of health related quality of life (HRQoL) in amblyopia
- Problems and challenges



What is Quality of Life?

- “A state of complete physical, mental and social well-being, and not merely the absence of disease and infirmity”¹
- “Concept incorporating all the factors that might impact on an individual’s life”²





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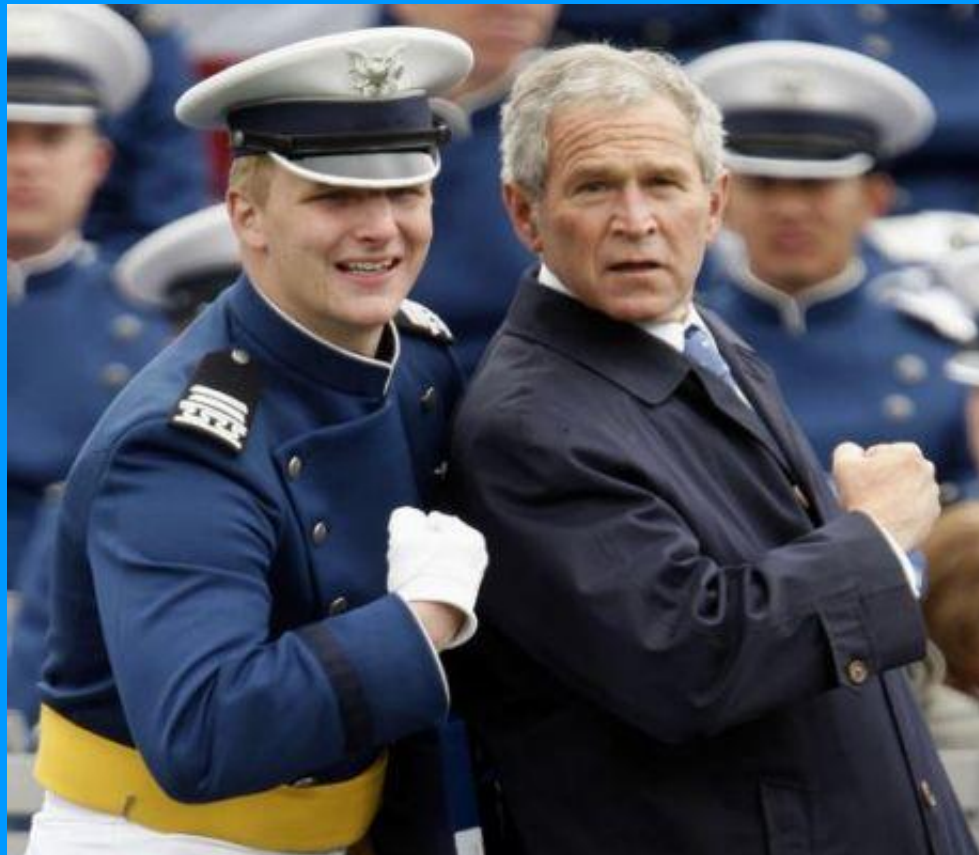
Symptoms and side effects of treatment





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Physical and functional status





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Emotional status





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Social functioning





What is amblyopia?

- Amblyopia is a visual condition which occurs in childhood
- Can be associated with strabismus (squint)
- Detected through screening programmes (HV, SN, orthoptists)





Why develop a PROM for amblyopia?

- Conventional treatment is patching
- Can occur during school time
- Some evidence to suggest impacts upon HRQoL





Impact of amblyopia treatment on the child's QoL from the parental perspective

- Treatment compliance – parental understanding and attitudes
- Changes in behaviour
- Changes to family dynamics





Impact of amblyopia treatment on the child's QoL from the child perspective

- Inappropriate measures used
- Suggestion of bullying and peer victimisation





Impact of amblyopia treatment on the child's QoL from the adult perspective having undertaken amblyopia treatment as a child

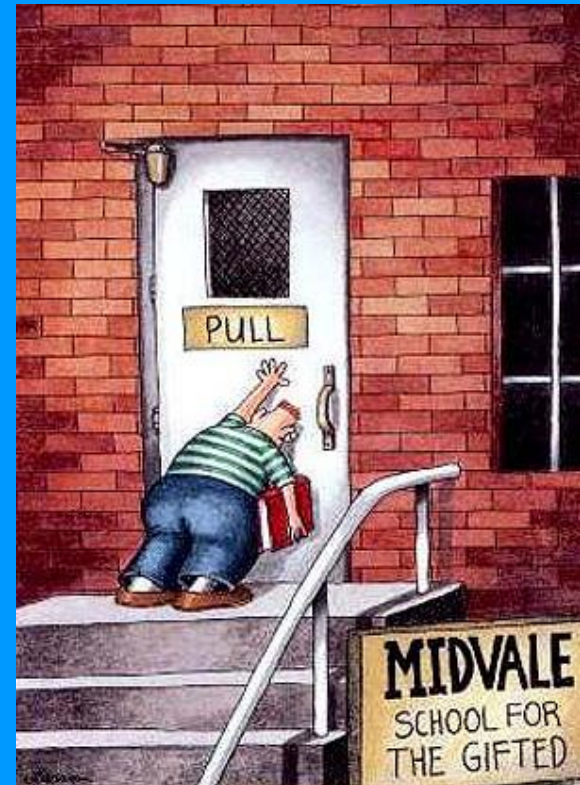
- Recall
- Adult perspectives on childhood experiences





Impact of amblyopia and/or its treatment on adults

- Educational attainment
- Career opportunities
- Depression/bullying





My current research

- Aim:
 - To develop a paediatric disease-specific measure of HRQoL in amblyopia
- Purpose:
 - To evaluate HRQoL from a child's perspective
 - To evaluate whether treatment methodology impacts upon a child's HRQoL





Development of a paediatric disease-specific measure of HRQoL in amblyopia

- Mixed method study
 - Qualitative techniques
 - (focus groups and interviews)
 - Quantitative techniques
 - Rasch analysis, factor analysis
 - Psychometric techniques



Progress so far...

- Systematic literature review
- Focus groups with clinicians
- Interviews with children



Problems and challenges

- Funding
- Ethics and research governance
- Interdisciplinary working
- Parents
- Children!
- Environment and recruitment



Funding

- Can be difficult to find!
- MRC, NIHR, Wellcome Trust, charities, studentships etc..
- Often involves an application process





Ethics and Research Governance

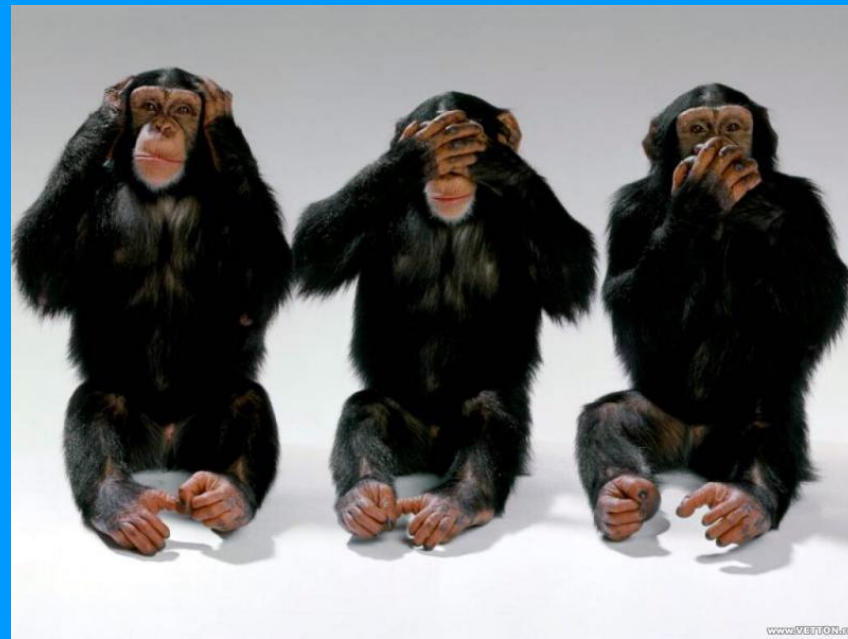
- A necessary evil!
- Can be a lengthy and demoralising process
- Identifies potential problems with the project before it starts





Interdisciplinary Working

- Communication is key
- May involve clinicians, admin, play specialists, volunteers
- Identify eligible participants
- Often first person to talk to parent/pt about study





Parents

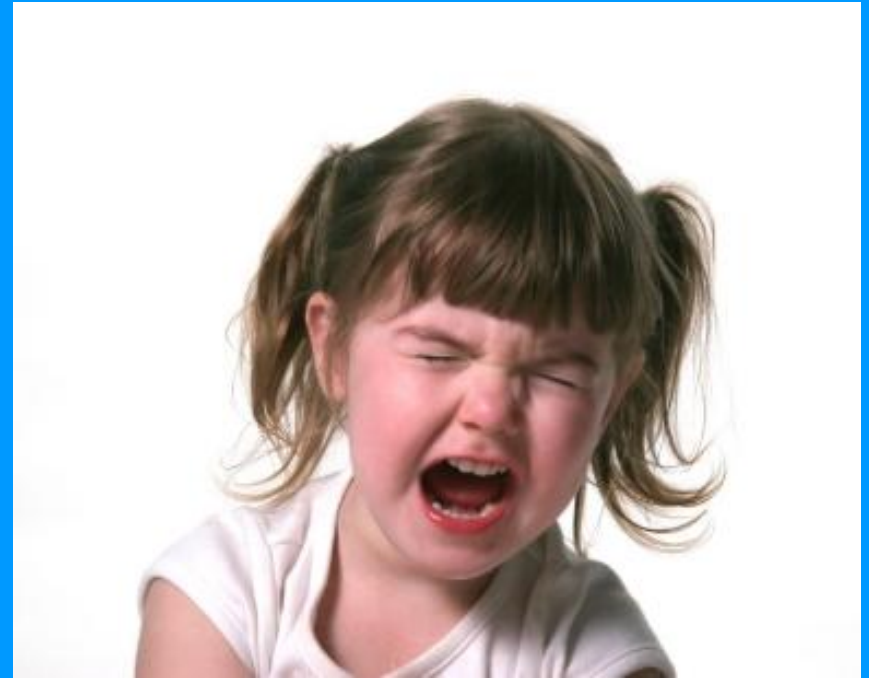
- Can help but often hinder!
- Necessary part of consent process
- May have different motivations to participating





Children

- Some want to please
- Some don't!
- Have a limited attention span
- Can have their own agenda!





Environment and recruitment

- Location is important
 - Noise
 - Distractions
 - Familiar
- Eligibility criteria
 - Cannot be too specific
 - If you think you see 5 a week, in reality you probably see 1!





References

1. World Health Organization. The constitution of the World Health Organization. *WHO Chron* 1947;**1**: 29
2. Billingham LJ, Abrams KR, Jones DR. Methods for the analysis of quality-of-life and survival data in health technology assessment. *Health Tech Assess* 1999; **3**: 10
3. Schumacher M, Olschewski M, Schulgen G. Assessment of quality of life in clinical trials. *Stat Med* 1991; **10**: 1915-30



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Development of a preference based PROM for use in a paediatric population

Katherine Stevens BSc MSc PhD
Health Economics and Decision Science



Overview

- Why develop a new paediatric PROM
- How the PROM was developed
- How it is being used in practice



Why develop a new PROM?

- Increasing use of economic evaluation to aid resource allocation decisions
- Lack of research in this area for children
- Problems with existing measures that are non preference based
 - Too long
 - Not child based



Developing a descriptive system

- Who?
 - Children, parents, adults, paediatricians, other experts
- How?
 - Focus groups, one to one interviews, literature



Developing a descriptive system

- 2 primary schools in Sheffield (7-11 years)
- 1 to 1 interviews with children at school
- Sampled purposively on basis of health and balanced for gender, age and ethnicity
- Topic guide
 - Tell me about your health/health problems.
 - How does this affect you (probing for school, home...)



List of Health Problems Covered in Interviews 7-9 years

Headache	Allergies - various
Feeling sick, being sick	Nose bleeds
Hearing, glue ear – grommets	Ear ache
Poor vision	Muscle not growing properly in stomach
Tummy ache	Fever
Eye infection	No feeling in legs
Dyslexia	Badly cut nose
Asthma	Nausea
Broken arm	Verruca
Tooth decay	Chicken pox
Leaky ear	Heat rashes
Flu	Sensitive to food colouring/hyperactivity
Pneumonia	Tonsillitis
Hay fever	Sticky/lumpy eyes
Cough	Twisted ankle
Spots/rash	Fits
Sore throat	Eczema
Broken toe	Itchy eyes



Developing a descriptive system

- Analysis
 - All interviews were recorded and transcribed verbatim
 - Thematic content analysis using Framework
 - Developed dimensions directly



Dimension	7-9 Years	9-11 Years
1	Worried Scared	Worried
2	Sad Upset	Sad Upset Unhappy Miserable
3	Annoyed Frustrated	Annoyed Frustrated Angry
4	Hurt Pain	Hurt Pain
5	School work	Learning
6	Daily Routine	Daily Routine
7	Tired Weak Drowsy	Tired Weak Energy Weary
8	Joining in activities that want to	Joining in activities that want to
9	Sleep	Sleep
10		Embarrassed
11	Jealous	



Developing a descriptive system

- Developing levels/scales
 - Use of qualitative data



Developing Scales

- Annoying
- It's just **really** frustrating
- I just feel **really** frustrated
- It was **really** annoying
- bored and annoyed and irritated
- I was **really** annoyed
- Really **really** annoyed
- it's **quite** annoying
- **really** annoys me
- they just kind of annoy me **a bit**.
- it **kinda** annoys me
- **a bit** annoyed.
- It's **a bit** annoying.
- it's annoying
- it just is annoying
- it still gets **a bit** annoying
- it was **really** annoying
- it's just annoying.



Developing scales

at all

a little bit

a bit

quite

quite a lot

much

a lot

very

very much

really



Ranking work to test the order of the scales

- I don't feel worried
- I feel a little bit worried
- I feel a bit worried
- I feel quite worried
- I feel very worried
- I feel really worried



Testing of the draft questionnaire

Methods

- **Study 1: 150 children in 2 schools**
 - 7-11 years
 - Balance of age, gender, ethnicity
 - 1 to 1 administration
- **Study 2: 97 children in hospital**
 - 7 – 11 years
 - Balance of age, gender, ethnicity
 - 1 to 1 administration
 - Mix of chronic and acute conditions. Surgical and medical patients, inpatient and day care.



Final PROM – The CHU9D

- The Child Health Utility 9D (CHU9D)
- 9 dimensions, (worried, sad, pain, tired, annoyed, schoolwork, sleep, daily routine, activities) each with 5 levels
- Application: generic
- Age range: 7-11 years
- Mode of completion: self completion
- Recall period: today/last night



Example health state

I feel very worried

I feel quite sad

I feel a little bit annoyed

I have a lot of pain

I feel a little bit tired

I have many problems sleeping

I have many problems with my daily routine

I have a few problems with my schoolwork

I can join in with some activities



Making it preference based

- Valuation work to obtain preference weights for the health states
- UK general population



How the CHU9D is being used

- Range of paediatric health care research studies in the UK, US and Australia, including economic evaluations alongside clinical trials, observational studies, methodological studies and routine data collection in clinics.
- Clinical areas include: obesity; diabetes; ADHD; intensive care; dentistry and clinical genetics.



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Further Information

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www.chu9d.org



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Development of a preference-based, disease-specific PROM for use with venous ulceration

Simon Palfreyman MSc PhD

Research Nurse

Sheffield Vascular Institute



Venous Ulcer

- Caused by venous hypertension.
- Non healing wound on the lower leg present for > 6weeks.
- More prevalent in the elderly and women.
- UK 1.3% of health budget (£600 million in 1995)
- High recurrence rate



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Typical Appearance



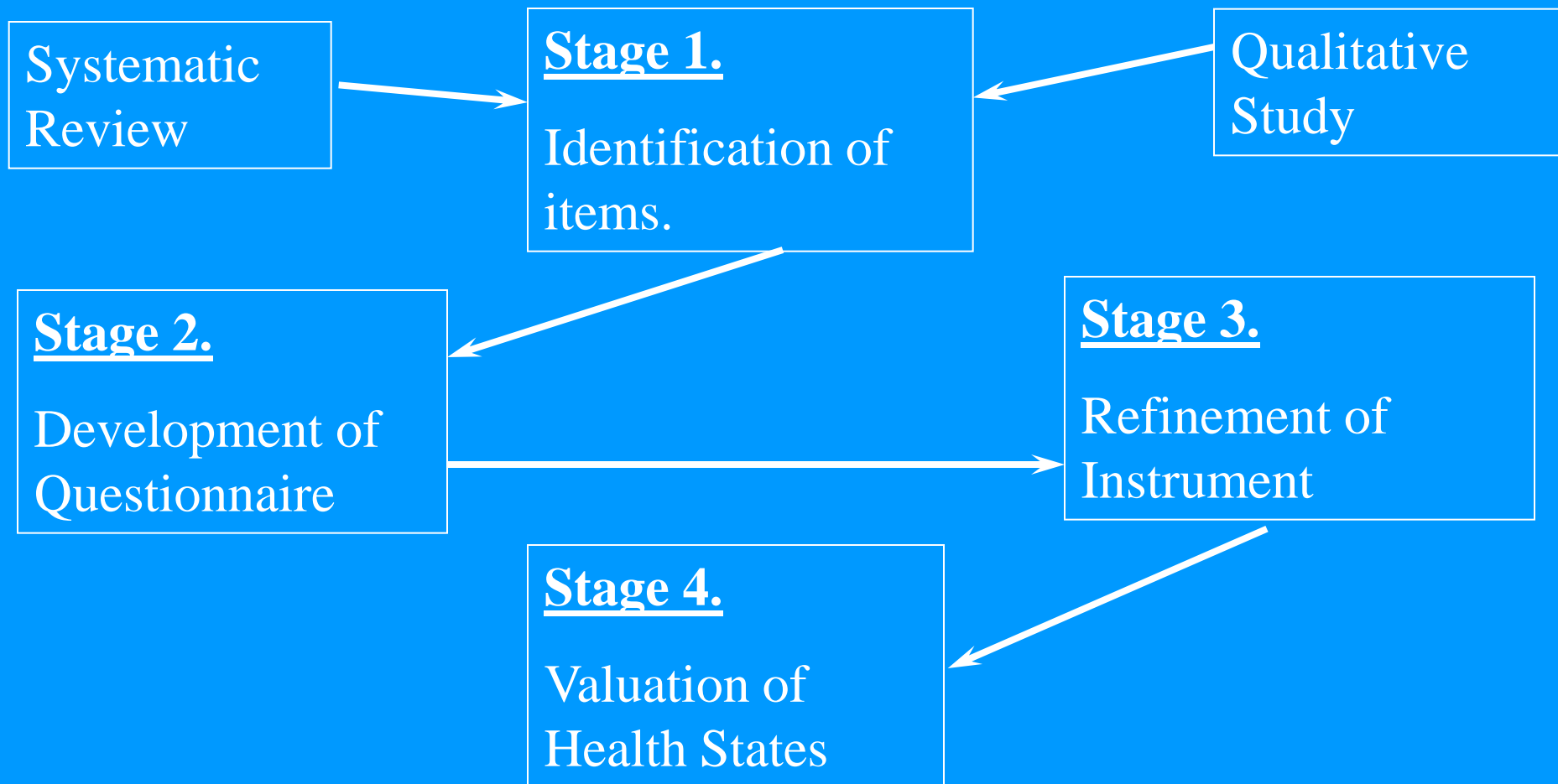


Project Aim

- To develop a tool that can be used to measure outcome for venous leg ulcers.
- To assess the instruments psychometric properties.
- To value the health states described by the instrument.



Project Plan





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Stage 1. Identification of Items to Include



1. Systematic Review

Methods

- Searches 2004 and updated Sept. 2008
- 14 databases, plus 11 Internet sites.
- Inclusion criteria:
 - All citations studies evaluated quality of life in venous ulceration.
- Exclusion criteria:
 - Case-series
 - Studies used single domain questionnaires
 - Non-systematic reviews



Studies using disease-specific instruments

	Number of Studies	Country of Origin	Target population
1. Cardiff wound impact schedule (28 items, 5 levels)	N = 3	UK	All wounds
2. Charing Cross (20 items, 5 levels)	N = 2	UK	Venous leg ulcers
3. FLQA (83 items, 5 levels)	N = 4	Germany	Chronic venous insufficiency
4. Hyland (33 items, 4 to 7 levels)	N = 3	UK	All leg ulcers
5. Venous leg ulcer questionnaire (34 items, 2 levels)	N = 1	UK	Venous ulcers
6. Loftus (6 items, unclear re no levels)	N = 1	UK	Venous ulcers
7. Pieper (9 items, 7 levels)	N = 1	USA	Venous ulcers



2. Qualitative Study Methods

- Semi-structured interviews
- Focus group
- Re-interviewing
- Interviews taped and transcribed.
- NVIVO.
- Framework analysis to identify themes and issues.



Participants

- 31 semi-structured interviews
 - 19 patients
 - Nine patients with a history of drug use
 - Five women and 14 men
 - Ages ranged 27 to 79
 - Duration of current ulcer ranged 6 months to 20 months
 - 68% (n=13) had a previous ulcer
 - 12 Staff
 - Consultants
 - Nurse specialist
 - Community nurses



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Stage 2. Development of Questionnaire



Stages in Developing PROM

Identification of items

1. Frequency or severity?
2. Item levels
 - Binary
 - Ordinal scale
3. Recall period
 - Now
 - Today, last week, month
4. Draft questionnaire



Potential Items for Inclusion

1. Pain
2. Mobility
3. Mood
4. Personal care
5. Sleep
6. Exudate
7. Smell
8. Leisure
9. Clothes
10. Social activities
11. Social isolation
12. Personal relations



Draft Questionnaire

	No Questions		Levels	Type of Question
Physical impact	6	*Pain *Personal care *Mobility *Sleep	5	3 Severity 3 Frequency
Psychological impact	2	Mood	5	1 Severity 1 Frequency
Social impact	5	*Leisure *Social *Relationships *Clothes	5	4 Severity 1 Frequency
Ulcer specific	3	*Exudate *Smell	5	1 Severity 2 Frequency



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Stage 3. Refinement



Methods

- Need to reduced items
 - Redundant items
 - Important items
 - Max number ($n=7$) for valuation studies
- Item reduction techniques
 - Item performance
 - Factor Analysis
 - Item Response Theory - Rasch Analysis



RESULTS

- 266 questionnaires sent and repeated three weeks later
- 152 returned
- Response rate 57%
- 92 (61%) had a current ulcer
- Mean age 66.6 years (range 27 – 104), median age 70 years



Item selection

- 4 items dropped due to poor item performance
 - Poor completion rate
 - Floor ceiling effects
- 2 items dropped based on Rasch Analysis
 - Smell severity and leisure
- Needed to capture physical, psychological and social impact.



Questionnaire after item reduction

The Sheffield Preference-based Venous Ulcer – 5D:
The SPVU-5D

Parameter	No Questions	Item Description	Number of Levels
Physical Impact	2	1 Pain frequency item	4
		1 Mobility frequency item	4
Psychological Impact	1	1 Mood frequency item	5
Social Impact	1	Social Activities	3
Ulcer Impact	1	1 Smell frequency item	3



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Stage 4. Valuation of health states



Health State Valuation

- Needed to assign value to health states described by instrument.
- Number of potential health states based on number of items and levels.
 - 720 ($4^2 \times 3^2 \times 1^5$)
- Mapped onto 0 (death) 1 (full health) scale.
- Can be used to calculate QALYs



Methods - Valuation

- Time Trade-off (TTO)
 - 160 members of the general public
 - Interviewer administered
 - 26 selected health states valued
- Discrete choice experiment
 - 98 members general public and patients
 - Postal questionnaire
 - 25 choice sets valued



Time Trade-off

- Respondent asked to “trade” years of healthy life to escape health state
- Aims to force consideration of quality versus length of life
- Widely used and validated technique
 - EQ5-D.
- Chosen as time a factor in ulceration



Results - TTO

- 162 interviews
- Mean interview length 30 mins (range 15 – 80)
- Participants excluded if not trading.
 - Valued all health states same
 - Failed consistency test
- 141 included in analysis



Discrete Choice Experiment

Choice between two alternatives – variation in the levels

Health State A	Health State B
I notice a smell from my ulcer <u>most or all</u> of the time	I notice a smell from my ulcer <u>a little bit or some</u> of the time
I am down or depressed <u>most</u> of the time	I am down or depressed <u>all</u> of the time
I have problems with my mobility <u>all</u> of the time	I <u>do not</u> have problems with my mobility any of the time
I <u>very occasionally or occasionally</u> have limitations with my social activities	I have <u>no</u> limitations with my social activities
I have pain <u>none</u> of the time	I have pain <u>all</u> of the time
<input type="checkbox"/>	<input type="checkbox"/>



Regression Models

- Ordinary least squares (OLS)
 - Error mean zero and constant variance structure and independent error terms
 - Uses individual observations. Treats 141 respondents as though 1122 provided them.
- Fixed/ Random effects
 - Fixed = respondent specific effects and not random
 - Random = error term not independent of the respondent
- Aggregate health state values
 - Mean
 - Median

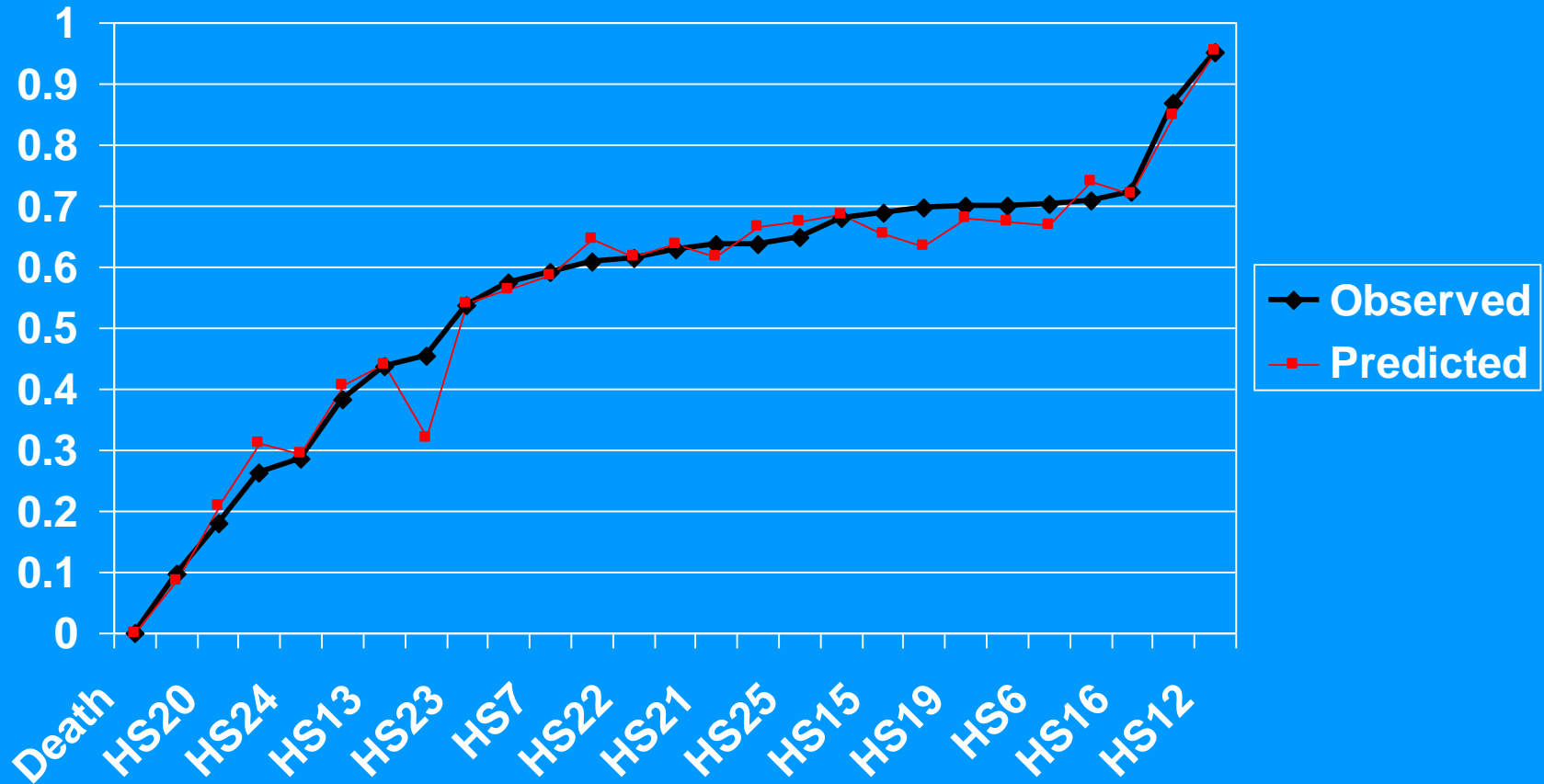


Model Performance

	Model			
	1	2	3	4
	OLS	Random Effects	Mean	Median
cons	0.955	0.956	0.955	1.05
pain2	-0.065	-0.053	-0.065	-0.066
pain3	-0.214	-0.198	-0.197	-0.184
pain4	-0.211	-0.206	-0.210	-0.225
smell2	-0.087	-0.067	-0.101	-0.055
smell3	-0.126	-0.114	-0.147	-0.134
mood2	-0.038	-0.055	-0.029	-0.058
mood3	-0.075	-0.078	-0.076	-0.068
mood4	-0.208	-0.229	-0.210	-0.223
mood5	-0.282	-0.285	-0.270	-0.272
social2	0.019	0.003	0.032	0.001
social3	-0.094	-0.098	-0.101	-0.134
mobility2	-0.073	-0.074	-0.075	-0.056
mobility3	-0.140	-0.134	-0.129	-0.129
mobility4	-0.157	-0.166	-0.143	-0.128
Number	1122	1154	26	26
RMSE	0.04	0.04	0.14	0.03
MAE	0.02	0.03	0.12	0.03
Adj R ²	0.300	n/a	0.973	0.970
Inconsistencies	1	1	1	1
Predictive performance				
No out of 26 within +/- 0.1	25	25	26	11
%< +/- 0.03	69.23	50.00	65.38	0
%< +/- 0.05	92.31	88.46	92.31	11.54
LB test	19.523	11.671	20.861	13.099

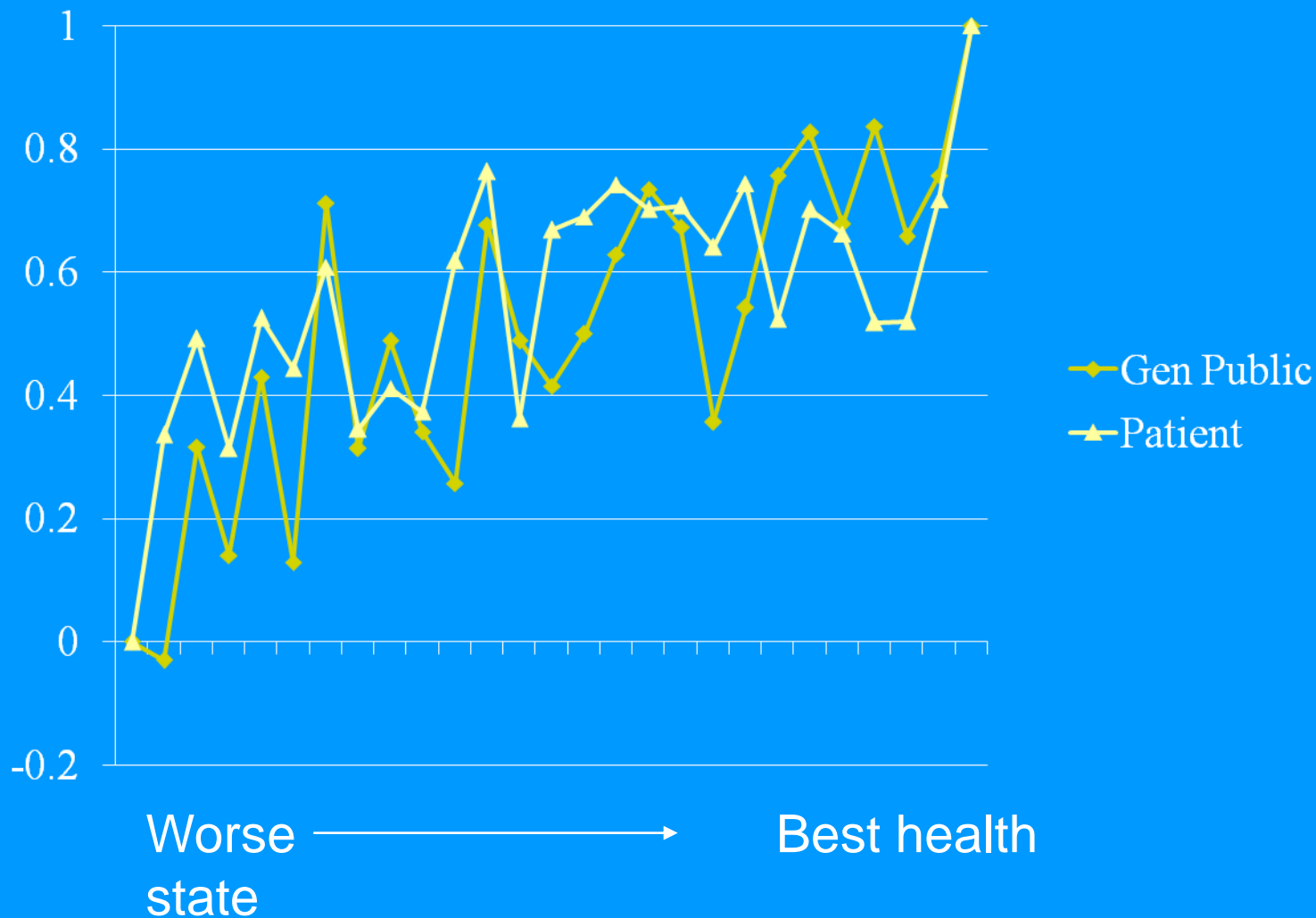


Prediction of Health State Values



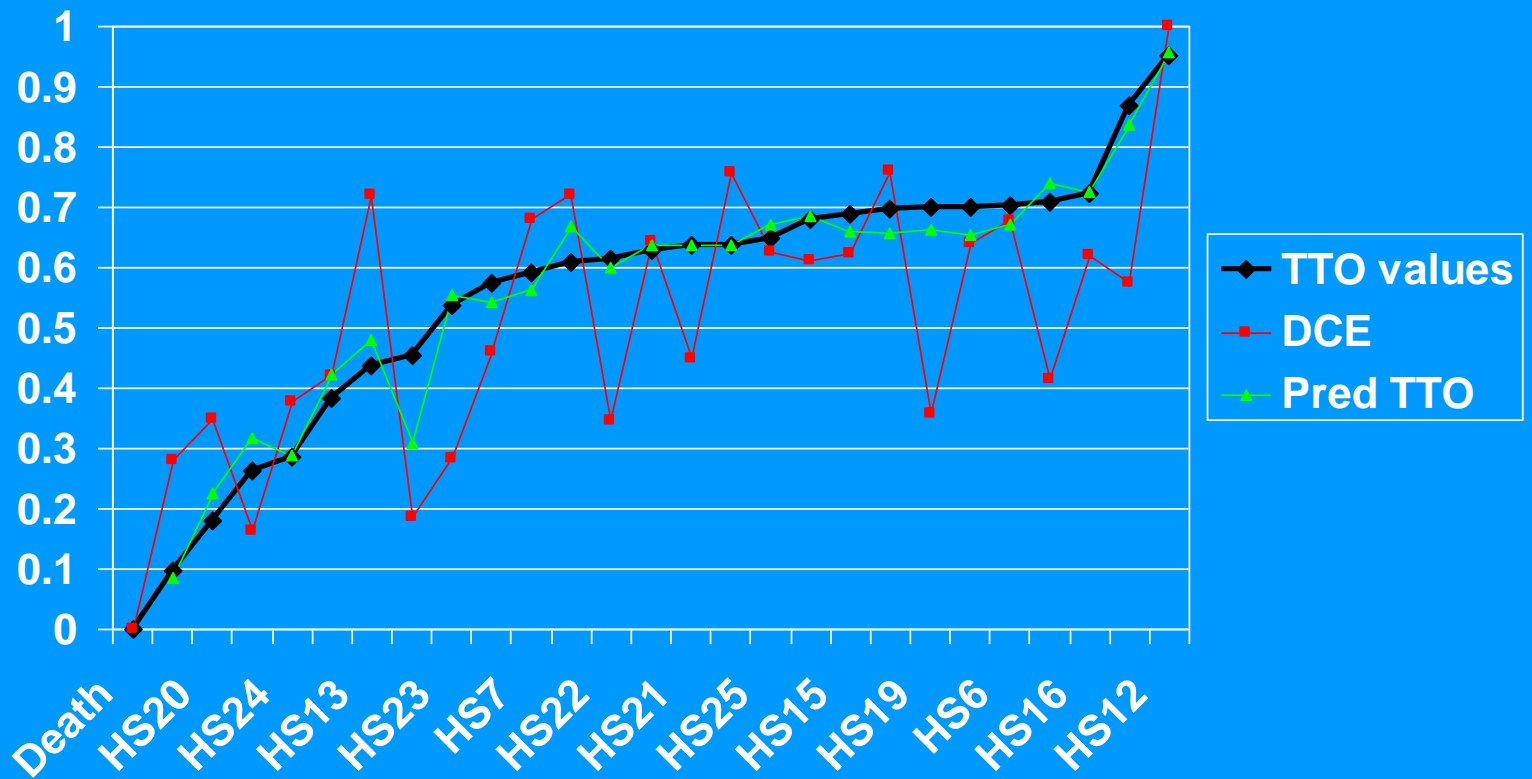


Comparison Public vs Patient Values





DCE vs TTO





Summary of Valuation

- TTO model best predictor of health state values
- Values have logical ordering
- TTO better predictor than DCE
- Confirms patients tend to give higher values to “worse” health states than the general public
- Produced an algorithm to calculate health states that compares with other studies



More information

- Palfreyman SJ et al (2007) Impact of intravenous drug use on quality of life for patients with venous ulcers. *Journal of Advanced Nursing* 58(5), 458–467
- Palfreyman SJ et al. (2007) Development of a tool to examine the effect of venous ulcers on patients' quality of life. *Nursing Standard* 21 (45), 57-69
- Palfreyman, S. (2008) Assessing the impact of venous ulceration on quality of life. *Nursing Times*; 104: 41, 34–37.
- Palfreyman SJ et al. Assessing current health related quality of life questionnaires administered to patients with venous ulcers: can they be used in economic evaluations? 2010 *Journal of Clinical Nursing* 19 (5)892-97



Discussion: Going to the PROM?

- PROMs are here to stay
- Nurses need to be able to demonstrate effectiveness
- There are challenges in developing PROMs
- Nursing needs to engage with the QIPP agenda
- If nurses don't lead then "others" will impose their own agenda.