

Communication about PROs in clinical practice

Professor Lesley Fallowfield
Sussex Psychosocial Oncology Group
Cancer Research UK



Primary purpose of all oncology treatment

- To improve the quality of patients' lives either by curing them of their disease and/or ameliorating their worst symptoms
- Without accurate monitoring of the impact that the disease and the treatments are having, management will not be optimal

Why don't doctors use information from QoL questionnaires routinely ?

- Clinicians will alter management on basis of a tumour marker score but unlikely to do so if questionnaire score changes
- They do not 'trust' them
- Are strangely over-confident in their ability to elicit problems with face-to face communication
- Are often uncomfortable discussing issues contained in q's
- Worry that they will initiate discussions about psychosocial and sexual problems for which they have no referral services

What needs to happen ?

- Challenge some of the assumptions
- Provide education about collection of PROs
- Demonstrate the unreliability and inaccuracy of data collection reported by clinicians
- Outline some of the problems that can occur if PROs are not identified
- Develop training interventions to assist in communication

How do PROs assist in the evaluation of therapeutic interventions ?

- They:-
- broaden and complement parameters of benefit beyond response, DFS and OS
- are a good prognostic indicators
- aid decision-making
- help determine supportive interventions needed to accompany efficacious treatments
- help inform resource allocation and health-care policy

Ability of doctors to detect probable psychological morbidity in cancer

(Fallowfield et al 2001, BJC)

- prior to seeing doctor patients completed GHQ12
- following consultation doctor indicated on visual analogue scale whether or not patient was psychologically distressed

GHQ12 scores of □4 in 2297 patients with cancer

all	837/2297 (36%)
male	300/881 (34%)
female	537/1416 (38%)
curative	293/933 (31%)
remission	61/215 (28%)
palliative	376/838 (45%)
uncertain	107/311 (34%)

Results from 143 doctors seeing 2,297 patients (Fallowfield et al BJC, 2001)

Patients with GHQ □4	837 (36.4%)
Sensitivity (true positives)	28.87%
Specificity (true negatives)	84.79%
Misclassification rate	34.7 %
Wrong assessment was probably made for 797	

Implications of findings

- much psychological morbidity of patients goes unrecognised and therefore untreated
- many health care professionals lack effective communication skills which would help them elicit psychosocial problems
- doctors have similar GHQ scores to patients making empathic communication difficult

Patients and clinicians may have different values

- although many cancer treatments offer good quality disease-free survival
- many also have at best unpleasant toxicities and at worst very serious side effects
- true benefits can be modest or uncertain due to limited follow-up
- decisions about desirable benefits and acceptable costs may differ between individual patients and also between patients and healthcare professionals

Discussing treatment options and aiding decision making

- we can only tell patients about things that we have systematically studied and recorded
- initially most novel therapies appear to have better profiles than the standard treatment
- manner in which all adverse events and side effects collected not especially reliable
- several studies have shown that side effects are often underestimated

Symptoms of tamoxifen self report vs. published data (%)

symptom	interview self-report	published pt self-reports	published clin. reports
hot flushes	75	56-78	2-64
fatigue	47	61-72	0-26
sweats	36	47-55	11
loss of libido	31	22	0

(Fallowes et al, Br.Ca.Res.& Tmt, 2001, 66:73-81)

Typical Case Report Form

✓ Signs/Symptoms	NCIC-CTC Grade 1-4
<input type="checkbox"/> Nausea (GI NAU)	_____
<input type="checkbox"/> Vomiting (GI VOM)	_____
<input type="checkbox"/> Headaches (NE HEAD)	_____
<input type="checkbox"/> Hot flushes (EN FLA)	_____
<input type="checkbox"/> Vaginal bleeding (code as for GU HEM)	_____
<input type="checkbox"/> Visual disturbances (NE VIS)	_____
<input type="checkbox"/> Dizziness (NE DIZ)	_____
<input type="checkbox"/> Insomnia (NE INS)	_____
<input type="checkbox"/> Fatigue (FL LET)	_____
<input type="checkbox"/> Sweating (FL SWE)	_____
<input type="checkbox"/> Thrombo-embolic disease (CD VEN)	_____
<input type="checkbox"/> Other	_____

Symptoms are ungraded or graded 1- 4 by clinicians according to severity

Tamoxifen symptoms rated 'severe' by women compared with clinicians

Symptom	QoL %	CRF (grade 3) %
hot flushes	38.2	3.6
weight gain	34.2	0
nights sweats	27.1	0.5
loss of libido	21.5	0
sleeping difficulties	19.2	0.4

Coombes et al, Proc.ASCO,2003

Concordance of Reporting the Presence of Symptoms

- ES & CRF data stratified into categories to compare clinician with patient self reports of the presence of endocrine symptoms
- Kappa statistics used to measure the degree of agreement

K=1 perfect agreement ****
K>0.8 good agreement ***
K<0.5 poor-fair agreement **
K=0 no better than chance *

Concordance of Symptom Reports of Any Severity

Symptoms	% Prevalence		Kappa	95% CI
	CRF	QoL		
Hot flushes	49.8	73.5	0.73**	.70 - .75
Fatigue	21.0	71.5	0.72**	.41 - .47
Insomnia	17.9	69.4	0.45*	.42 - .48
Headaches	15.8	48.7	0.66**	.63 - .69
Dizziness	9.5	32.1	0.72**	.69 - .75
Vaginal bleeding	2.7	5.4	0.97***	.96 - .98

Why PROs may be more accurate than those on CRFs

- reporting by physicians on CRFs often inaccurate and in busy clinics data may not be collected systematically
- focus is often on life-threatening adverse events
- ascertainment bias
- leading, multiple questioning
- research nurses transferring medical records onto CRFs
- patients may fail to attribute SEs to treatment or be too embarrassed to mention some issues

Impact of side effects on adherence

- non-life threatening side effects that go unrecognised or untreated may compromise adherence
- >40% women in a chemoprevention trial failed to take tablets (Fallowfield et al JCO, 2001)
- similar numbers in an adjuvant EBC (Partridge et al, JCO, 2003, Ann Oncol, 2006, Lash, BCRT, 2006)
- even women with more advanced disease admit to forgetting (49%) or choosing (13%) not to take their drugs (Fallowfield et al Ann Oncol, 2005, Atkins EJC, 2006)

Why do we need this information ?

- to stimulate ameliorative intervention research
- if not patients will not adhere or take non-prescription drugs that could seriously interfere with anti-cancer drugs. Often this information is not disclosed to doctors
- 53% women in a recent study were regularly taking vitamins, oils, minerals, glucosamine, Chinese herbs, black cohosh (Catt et al, EJCC, 2006)
- >80% pts in Phase I trials at Mayo clinic were taking above despite this being an exclusion criterion (Dy et al, JCO, 2004)

Some reasons to be concerned

- a herbal remedy containing black cohosh, dong quai, red clover and Mexican yam for menopausal symptoms can cause retinal vein thrombosis and visual problems (Cheung, 2005)
- even prescribed drugs could influence response. >35% women with breast cancer are depressed and many take SSRIs for this and for vasomotor complaints
- recent research on tamoxifen metabolism with ER+ women suggests that genetic variation in CYP2D6 and its inhibition by SSRIs influences response and relapse (Knox et al, JCO, 2006)

Can we change doctors communication skills ?

- plenty of good evidence that we can improve skills in key areas e.g (Fallowfield et al, Lancet, 2002)
- that psychosocial attitudes and beliefs alter and change behaviour (Jenkins et al, JCO, 2002)
- that these improved skills endure over time (Fallowfield et al, BJC, 2003)
- training programmes being developed and evaluated by Galina Velikova's group are aimed at improving communication with patients about their responses to touchscreen completed q's