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# **MEL-QOL Project**

**Improving quality of life measurement for  
melanoma patients and their family members:  
Validity and reliability study of QOL instruments  
in an Australian population**

**Associate Professor Julie Winstanley**



**The University of Sydney**

**MELANOMA** Institute Australia

# Melanoma Institute Australia, The Poche Centre



The University of Sydney

MELANOMA Institute Australia

# Update since QLG meeting, September 2009

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- EORTC Phase 1 – Generation of QL issues
- Literature searches conducted and collated
- QOL Interviews and content analysis completed
- Project plan and milestones agreed with core research team
- Expansion of team of international investigators in preparation for Phase 2 – Operationalisation



## Reminder of our patient group

- 5 year survival is high (88% male, 93% female)
- MIA sees about 1000 new patients a year
- Only about 10% of new patients are Stage 3 (~100) and <1% Stage 4 (~10) at first presentation
- Majority are physically fit and well
- Patients live with melanoma, rather than die from it
- Disease may progress by either recurrence or appearance of another primary
- Prognosis poor if disease recurs



# Comments from Professor John Thompson, Director of MIA

- Melanoma patients fall into two distinct groups, 'primary' and 'recurrent'; these two groups need very different things
- If a patient presents with a primary melanoma, 85% will not have any more problems once that melanoma is removed
- However, a 5 year disease free window does not mean they are cured (unlike other cancers)
- Melanoma can recur after many years (5,10,15 yrs)



# Comments from Professor John Thompson, Director of MIA

- Once there is a recurrence, the future is much more uncertain and they may die from the disease
- Some patients present with metastatic disease (~10%) at the first appointment
- When melanoma is diagnosed, family members are informed they have an increased risk
- After one melanoma is diagnosed, the risk of another is 5 times greater than the general population
- Patients have a deep fear of lymphoedema, even though not very common for melanoma patients



# Literature review – Ms Bridget Myles

## Systematic Review – Key Findings (Cornish 2009)

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- Showed about one third of melanoma patients experience considerable levels of distress, mostly at time of diagnosis and following treatment
- Timing of measurement, mode and completeness of data are important
- Suggests fear of recurrence, changed lifestyles, due to UV avoidance, are likely QOL domains of interest, not fully assessed in any of the HRQOL instruments



# Literature review – Ms Bridget Myles

## Systematic Review – Key Findings (Cornish 2009)

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- SF36 most widely used, but psychometric properties not tested in melanoma populations
- The combination of a generic and specific HRQOL instrument is most informative
- Melanoma patients experience few limitations to physical functioning, more affected psychologically
- Content of the FACT-M more appropriate for advanced melanomas, less for general population



## Rasch analysis FACT-M – Dr Julie Winstanley

- Rasch analysis of the FACT-G has previously been published; patient group was not melanoma specific
- Rasch analysis of the FACT-M has not been published in a large melanoma sample
- 298 patients recently completed the FACT-M as part of an MIA quality of care study
- Rasch analysis has been performed and results show problems with 5 point response format
- New study using 4 point scale in progress



# QOL interviews - Dr Edward White

	Interviewee						
	Patients				Relatives		
	Location				Location		
	MIA, Eden St		Other		MIA, Eden St		Other
	Group	One to One	CCC Westmead	Phone	Group	One to One	Phone
Mean (mins)	46	39	69	29	44	41	18
Number	2	9	1	7	2	5	1

Total interviewing time 1027 minutes – 17.1 hours

Number of interviewees 32 (22 patients, 10 relatives)



# Part 1 Interview participants

## Patients (n=22)

- 11 Females (50%) 11 Males (50%)
- Mean age 54 (SD=17, range 20 – 85)
- Mostly Australian born (n=20)
- All English speaking at home
- 12 Employed, 8 Retired, 2 Student
- Time since diagnosis, ranging from 1 week to 14 years
- Target group (Group 1, n=11; Group 2, n=8; Group 3, n=3)



# Part 1 Interview participants

## Relatives (n=10)

- Mostly Female (n=9), Male (1)
- Type of relative (5 Partners, 2 Sisters, 1 Daughter, 1 Son, 1 Friend)
- Mean age 46 (SD=20, range 21 – 73)
- All Australian born and English speaking
- 6 Employed, 4 Retired
- Target groups (Group 1,n=2; Group 2,n=5; Group 3,n=3)



# Analysis – Step 1

## 12 domains/themes (number of issues)

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- 1. Support (n=30)**
- 2. Information/Education staff (n=21)**
- 3. Dark thoughts (n=27)**
4. Global meaning of QOL (n=19)
5. Effects surgery drugs (n=11)
6. Clinical staff (n=11)



# Analysis – Step 1

## 12 domains/themes (number of issues)

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7. Resignation (n=9)
8. Life adjustments (n=4)
9. Information/Education (self taught) (n=7)
10. Change social activities(n=2)
11. Employment /financial (n=2)
12. Most helpful/unhelpful individual (n=2)



## Analysis – Step 2

- 145 issues revealed across 12 domains
- Some issues duplicated across several domains  
e.g. depression/anxiety appeared in overall meaning of QOL, support and dark thoughts
- Reduced 145 issues to 108 unique issues by assigning duplicate issues once only to the theme which was ‘most appropriate’
- Information ‘self’ and Information ‘staff’ merged
- ‘Helpful/unhelpful individual’ and ‘clinical staff’ merged



## Analysis – Step 3

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- 108 issues across 10 domains
- Existing EORTC modules examined for coverage of issues
  - QLQ – C30 (Core module)
  - INFO – 25 (Information)
  - PATSAT – 32 (Patient satisfaction)
  - H&N – 35 (Head and Neck)
- EORTC Item bank interrogated
- Core research team allocated items thought to adequately cover a range of pertinent issues



## Analysis – Step 4

- Remaining 45 issues may not be covered by existing items
- Unique to melanoma patient group?
- 45 items carried forward for clinician ratings of ‘Relevance’ and ‘Importance’
- 11 clinician interviews done so far (3 QOL specialist researchers, 4 MIA research staff, 2 plastic surgeons, 1 dermatologist, 1 Clinical trials manager)



# Discussion points from clinician interviews conducted so far in Sydney

- Many issues are 'generic' to any cancer group
- Melanoma is predominantly a 'surgical' disease
- Issues such as depression/anxiety addressed by many QOL instruments
- Information is one of the main issues for patients
- EORTC Information Module already exists
- Need to focus on the outstanding QOL issues for the new melanoma module



# Discussion points from clinician interviews conducted so far in Sydney

- Missing items to measure potential issues associated with melanoma surgery, lymphoedema, scarring, disfigurement, body image, intimacy
- Need items which probe how patients deal with the fact that there is no 'cure' for melanoma (fear of recurrence)
- Different QOL module may be required, depending on stage of melanoma



# Where to from here?

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- Translations required to complete Phase 1 (Spanish, Dutch, Italian, Other?)
- Collaborators for completing Phase 1
- Collaborators needed for Phase 2,3,4 study
- Application to EORTC for a Phase 2,3,4 study

***Thank you for participating today!***

