



# EORTC

European Organization for Research  
and Treatment of Cancer

## Development of an EORTC quality of life module for cholangiocarcinoma: UPDATE

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## AIMS

- To test the questions and issues of the LMC21 and the PAN26 in cholangiocarcinoma and gall bladder cancer patients and assess if either or both are adequate.
- If neither alone is thought to be adequate, then the EORTC protocol “guidelines for module development” will be adapted to develop a new module for cholangiocarcinoma patients.

# Investigators

## 5 UK Sites

- Basingstoke
- Liverpool
- Southampton
- Kings College  
London
- University College  
London

- Germany
- Taiwan
- Iran( pilot testing  
complete)
- Poland (await ethics  
approval)

# Phase 3 Recruitment

- Target 100
- 72 patients on data base
- 4 pending

# Provisional Statistical Methods

- Finding trends/correlations in comments
- Mean and SD of scores
- Range of responses
- Prevalence ratios/Negative responses
- Analyse data with clinical details

# Preferred questions

26 out of 47 items favoured

- 11 from PAN 26
- 15 from LMC21

# Trends in comments

- Repetitive issues from the QLQ-C30 are being discarded  
e.g. tiredness/bowel habit/social activity/anxiety
- Some questions are too similar  
e.g. some questions in the following scales -  
eating/ pain/ bowels/ body image

# Summary of patient responses

- EATING

- L31. Have you had trouble with eating?
- L32. Have you felt full up too quickly after beginning to eat?
- P36. Were you restricted in the types of food you can eat as a result of your disease or treatment?
- P37. Were you restricted in the amounts of food you could eat as a result of your disease or treatment?
- L34. Have you had problems with your sense of taste? ? OUT
- P38. Did food and drink taste different from usual? ? OUT
- P39. Have you had indigestion?

# Summary of patient responses

- **BOWELS**

- P46. Did you have frequent bowel movements? **? OUT**
- P47. Did you feel the urge to move your bowels quickly? **? OUT**

- **JAUNDICE**

- L41. Have your skin or eyes been yellow (jaundiced)?
- P44. Have you had itching?
- P45. To what extent was your skin yellow? **? OUT**
- X. Have you been worried about your skin being yellow? **? OUT**

# Summary of patient responses

- **TIREDNESS**

- L37. Have you been less active than you would like to be?
- L43. Have you felt “slowed down”?
- L44. Have you felt lacking in energy?

- **PAIN**

- L39. Have you had pain in your stomach area?
- L42. Have you had pain in your back? **? OUT**
- L40. Have you had discomfort in your stomach area?
- P31. Have you had abdominal discomfort? **?OUT**
- P34. Did you have pain during the night?
- P35. Did you find it uncomfortable in certain positions (e.g. lying down)?

# Summary of patient responses

- OTHER
- P50. To what extent have you been troubled with side-effects from your treatment?
- P42. Did you feel weak in your arms and legs? ? OUT
- L35. Have you had a dry mouth? ?OUT
- L36. Have you had a sore mouth or tongue? ? OUT
- F. Have you had any fevers? ? OUT
- L38. Have you had tingling hands or feet? ? OUT
- P32. Did you have a bloated feeling in your abdomen? ? OUT
- P40. Were you bothered by gas (flatulence)? ? OUT
  
- F. Have you had difficulties with drainage tubes/ bags? ? OUT

# Summary of patient responses

- **RELATIONSHIPS**

- L45. Have you had trouble having social contact with friends?
- L46. Have you had trouble talking about your feelings to your family or friends?
- P52. Were you limited in planning activities, for example meeting friends, in advance?
- P55. Have you felt less interest in sex? **? OUT**
- P56. Have you felt less sexual enjoyment? **? OUT**
- **During the past four weeks:**
- L51. Has the disease or treatment affected your sex life **? OUT**  
(For the worse)?

- **BODY IMAGE**

- **During the past week**
- P48. Have you felt physically less attractive as a result of your disease and treatment? **? OUT**
- P49. Have you been dissatisfied with your body? **? OUT**
- P41. Have you worried about your weight being too low?
- L33. Have you worried about losing weight?

# Summary of patient responses

- **ANXIETY**

- L47. Have you felt stressed?
- L48. Have you felt less able to enjoy yourself?
- L49. Have you worried about your health in the future?
- L50. Were you worried about your family in the future?

- **HEALTHCARE SATISFACTION**

- P53. Have you received adequate support from your health care professionals?
- P54. Has the information given about your physical condition and treatment been adequate?

# Plans

- Continue to recruit until reach target of 100 so sound decisions can be made on questions.
- During interviews, continue to ask patients to comment on which questions they wish to keep or remove.
- Analysis with clinical details and additional comments (e.g. rewording suggestions) pending.