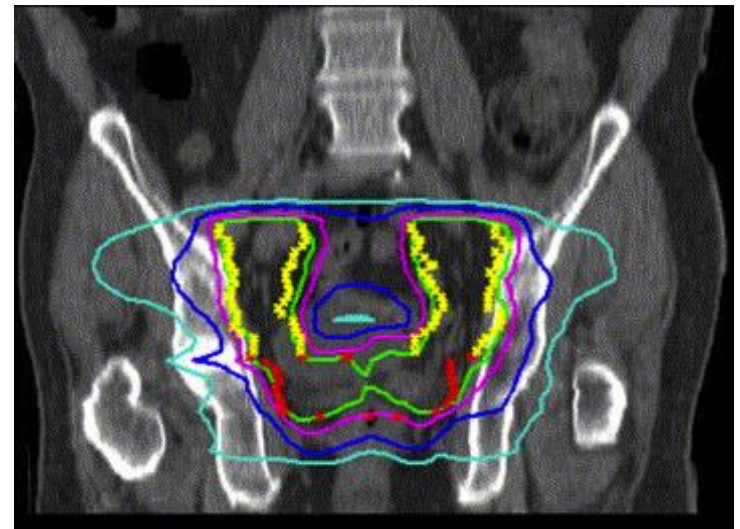




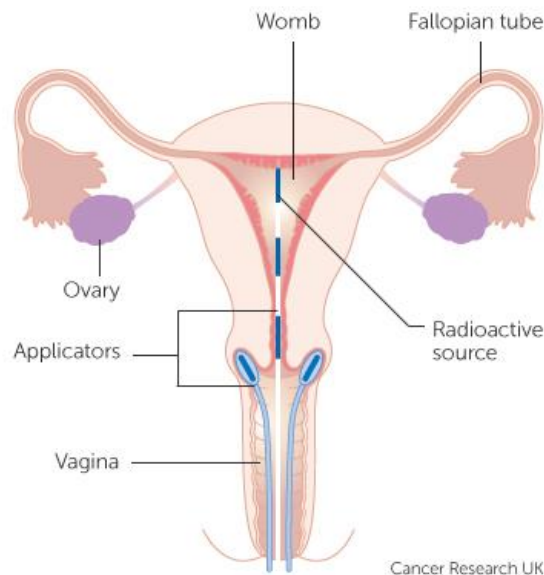
# Using Patient Reported Outcomes to Improve Radiotherapy Treatment

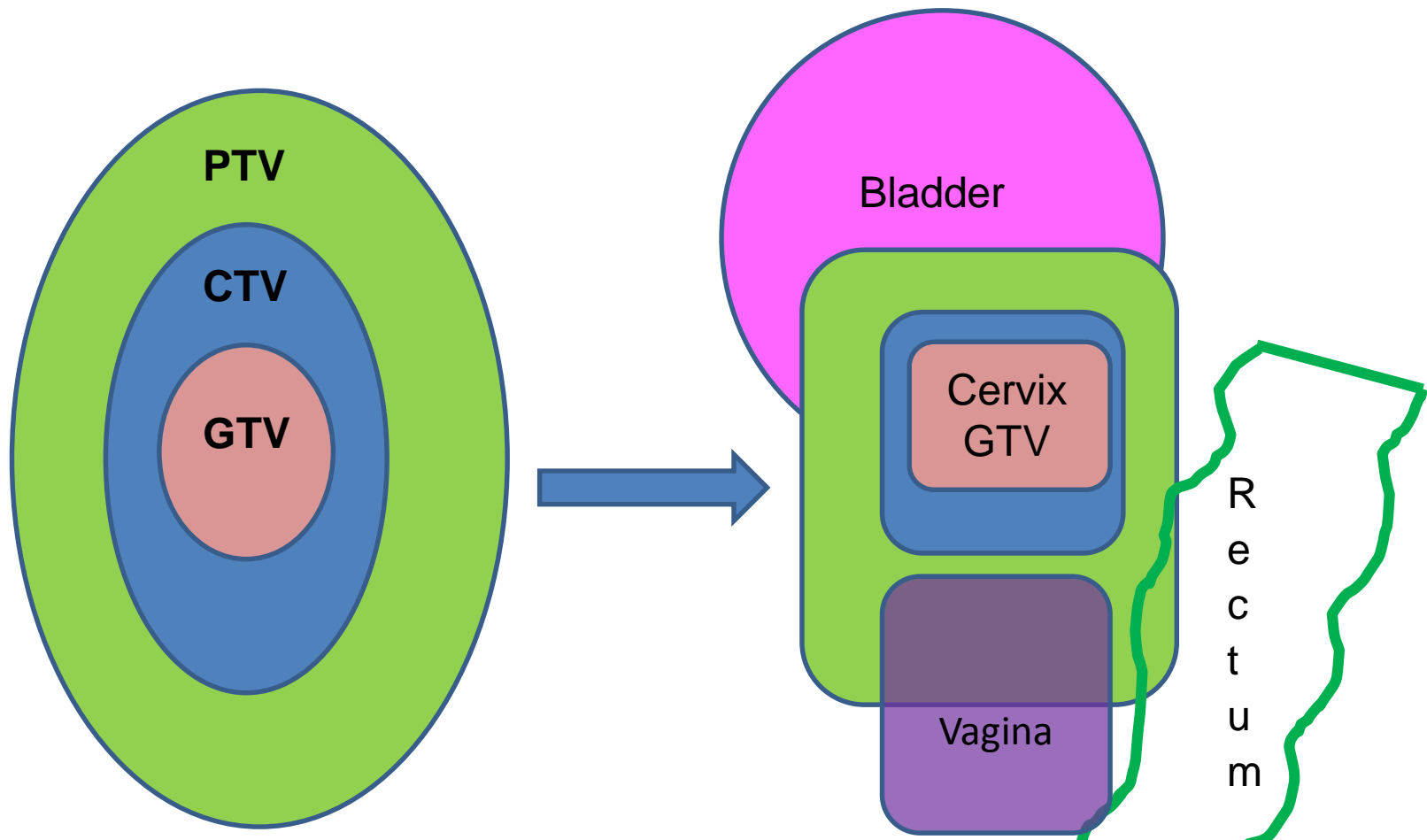
Dr Alexandra Gilbert

NIHR Academic Clinical  
Lecturer Clinical Oncology  
St James's Hospital, Leeds



- Radiotherapy - destroys cancer cells
- Used in the management of 40% of patients treated curatively for cancer
- **Internal** radiotherapy (brachytherapy): internal radioactive source placed inside the body
- **External** beam radiotherapy: high energy x-rays

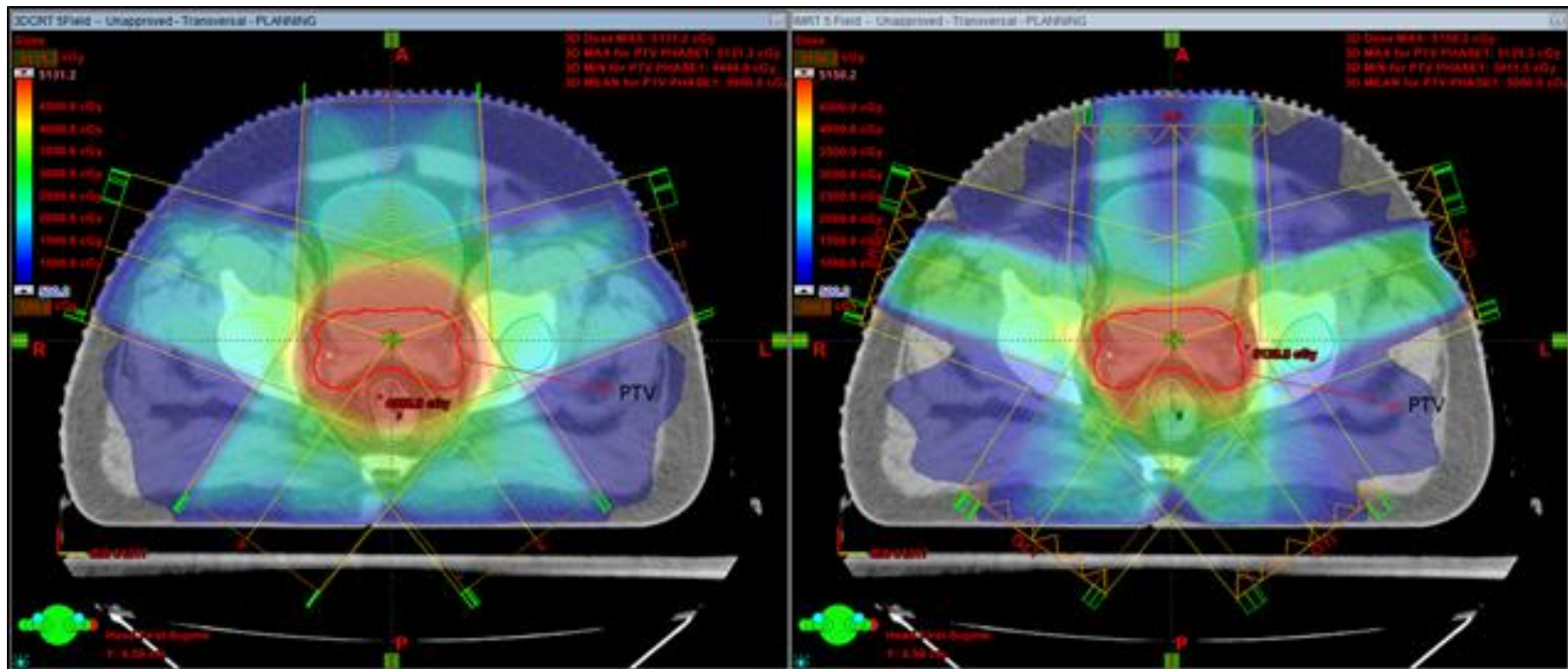


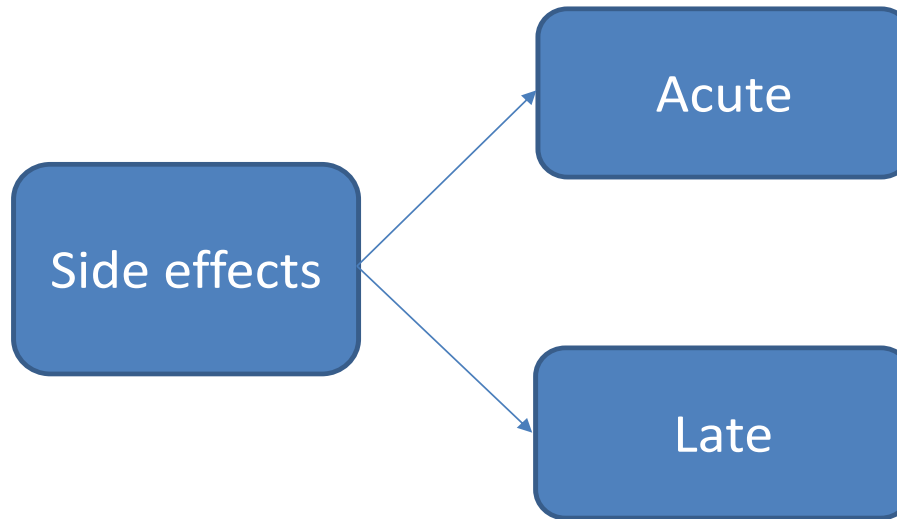


- Radiotherapy is a balance between:
  - Delivering the maximum possible dose to the tumour
  - Minimising dose to the surrounding normal tissues
- Normal tissue surrounding the tumour will receive a proportion of the radiation dose delivered

Newer precision radiotherapy techniques allow us to:

- target the tumour more accurately
- avoid more normal tissue





- Symptoms are underreported:

**No systematic method to document radiotherapy side effects**

- Challenging to support patients, put in useful interventions and modify treatments



Electronic PROs will enable integration into patient electronic records for use in clinic

# Implementing in practice



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## CROSS SECTIONAL STUDY

Late effects

ANAL

CERVICAL

ENDOMETRIAL

RECTAL

**N=315**

Establish  
relationship  
between  
radiotherapy dose  
and volume to  
normal tissues,  
patient factors and  
toxicity

**N=315**

## PROSPECTIVE, LONGITUDINAL STUDY

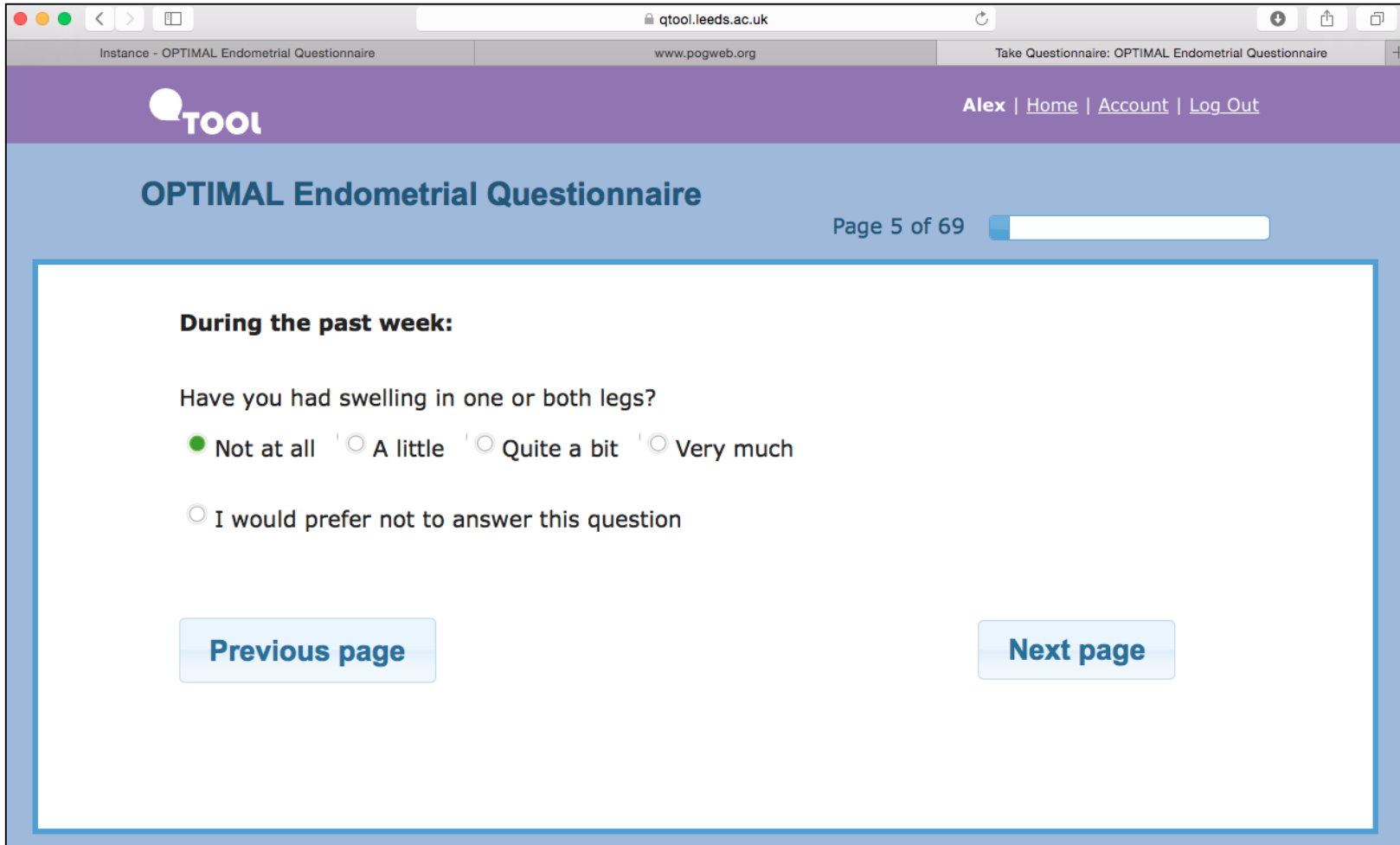
Baseline, acute  
and early late  
effects

Feasibility

**N=129**

**Electronic and paper PRO data collection**

# Electronic platforms



The screenshot shows a web browser window with the URL `qtool.leeds.ac.uk`. The page title is "OPTIMAL Endometrial Questionnaire". The user is logged in as "Alex" and has navigation links for "Home", "Account", and "Log Out". The page is "Page 5 of 69". The main content area contains the following text:

**During the past week:**

Have you had swelling in one or both legs?

Not at all    A little    Quite a bit    Very much

I would prefer not to answer this question

At the bottom of the content area, there are two buttons: "Previous page" and "Next page".

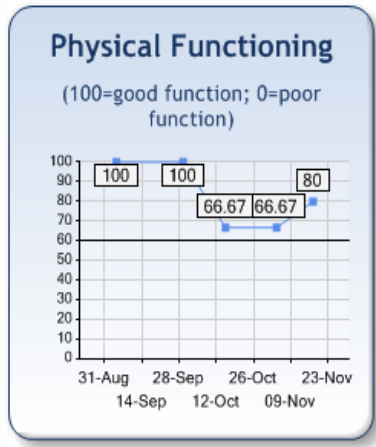
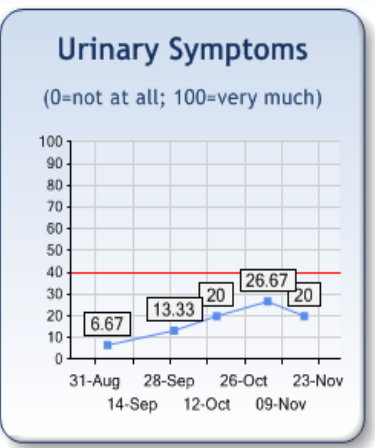
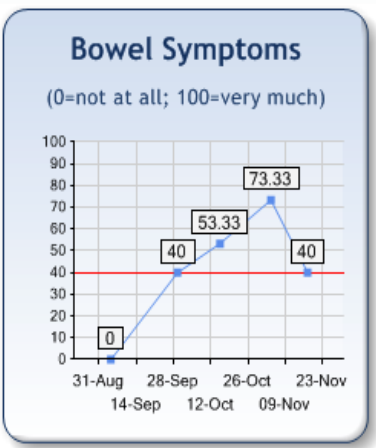
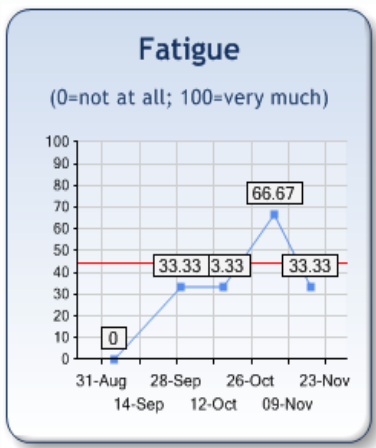
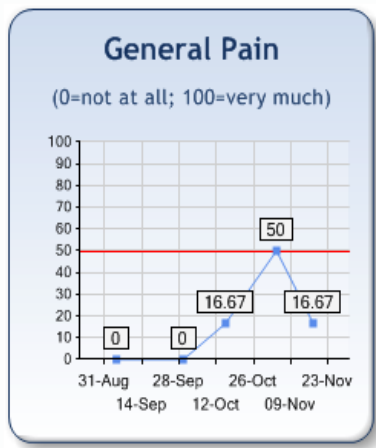


# Female, T4N2M0 SCC anal cancer, treated with 50Gy in 25 with MMC and 5FU



## OPTIMAL Lower GI Female Questionnaire (1.6)

### Scores



**FUNCTION ITEMS**  
Lower scores = worse function

**SYMPTOM ITEMS**  
Higher scores = worse symptoms

# Integration into electronic health records: individual level



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## OPTIMAL Cervix Questionnaire (1.7)

Scores	24-Aug-2015	03-Jun-2015	09-Mar-2015	27-Jan-2015	10-Jan-2015	19-Dec-2014
General Pain (0=not at all; 100=very much)	0	50	0	16.67	16.67	16.67
Fatigue	0	33.33	16.67	33.33	33.33	33.33

## Scores

24-Aug-2015

03-Jun-2015

General Pain  
(0=not at all; 100=very much)

0

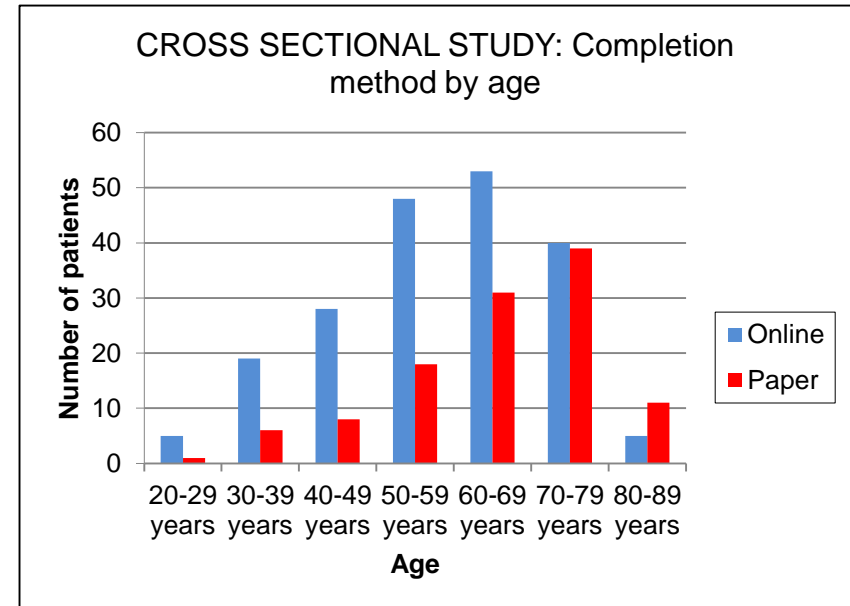
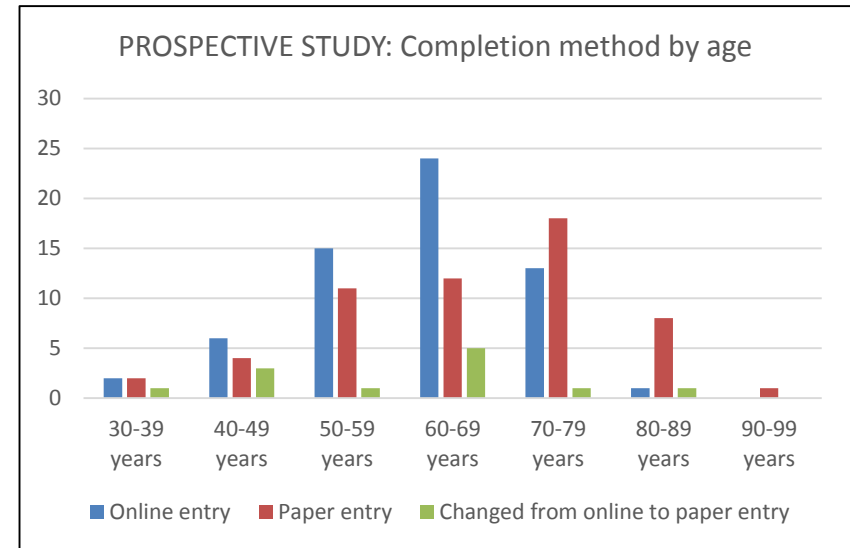
50

Pain (0=not at all; 100=very much)	0	66.67	0	33.33	33.33	33.33
Pain affecting ADLs (0=not at all; 100=very much)	0	33.33	0	0	0	0
Low back pain (0=not at all; 100=very much)	0	33.33	33.33	33.33	0	0
Nausea Vomiting (0=not at all; 100=very much)	0	16.67	0	0	16.67	16.67
Diarrhoea (0=not at all; 100=very much)	0	0	0	0	66.67	66.67
Constipation (0=not at all; 100=very much)	0	0	0	0	33.33	33.33
Bowel Urgency (0=not at all; 100=very much)	0	0	0	0	33.33	0
Faecal Incontinence (0=not at all; 100=very much)	0	0	0	0	33.33	33.33
Abdominal cramps (0=not at all; 100=very much)	33.33	66.67	0	33.33	0	33.33
PR bleeding (0=not at all; 100=very much)	0	0	0	0	33.33	0
Buttock Pain (0=not at all; 100=very much)	0	0	0	33.33	66.67	33.33

# Observational studies



- PROSPECTIVE STUDY:
  - N=129 (16% declined)
  - Completion at 6 months 62%
  - Median follow up 9 months
- CROSS SECTIONAL STUDY
  - N=315 (18% declined)
- Electronic methods are feasible and allow integration into clinical consultations



## Patients

...it's good to see all the problems that you don't have when you're feeling unwell

...it's about patient education and empowerment

I wouldn't have brought up the [sexual] problems I have with the consultant if I hadn't completed the questionnaire

## Health professionals

It's really useful to help structure the consultation in advance

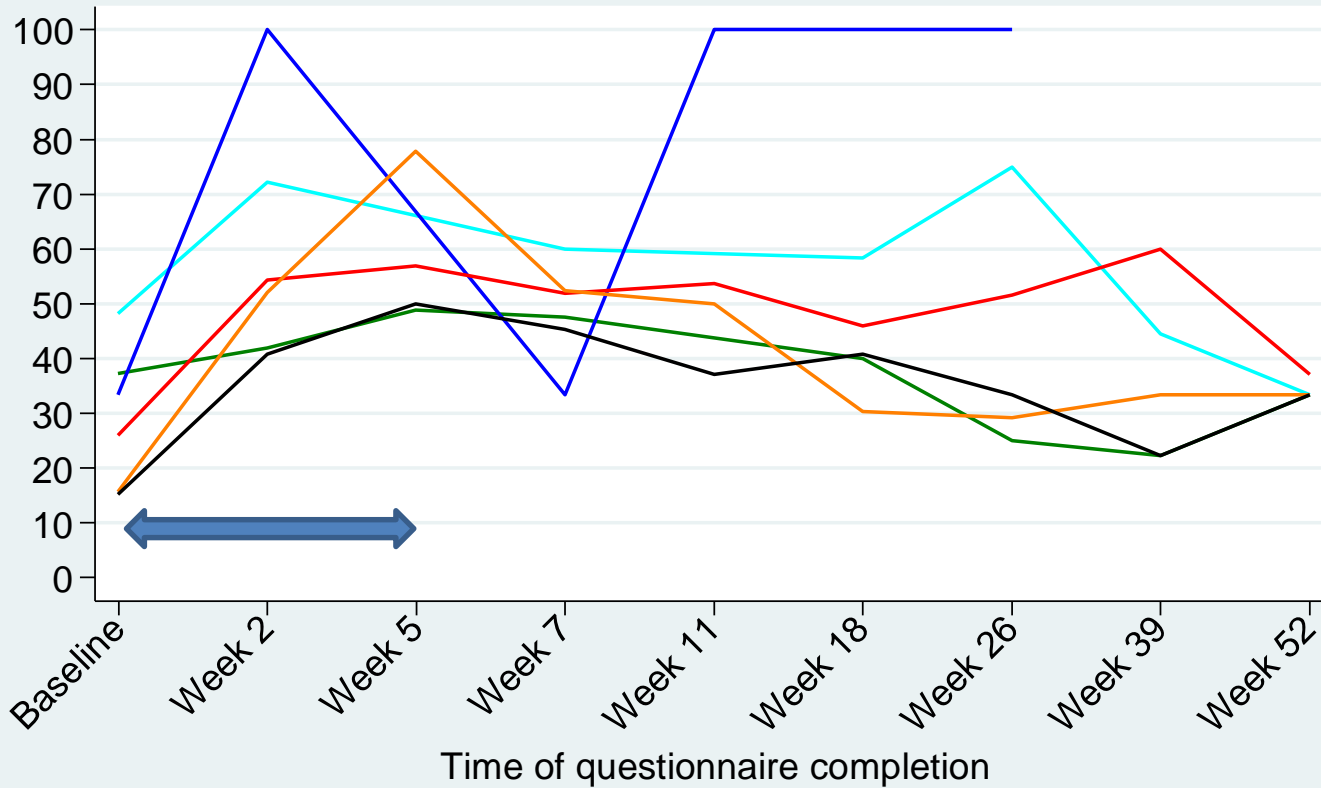
It makes it easier to bring up sensitive topics like sexual problems

I find it really helpful to prepare for the clinic

# Bowel urgency using EORTC QLQ module



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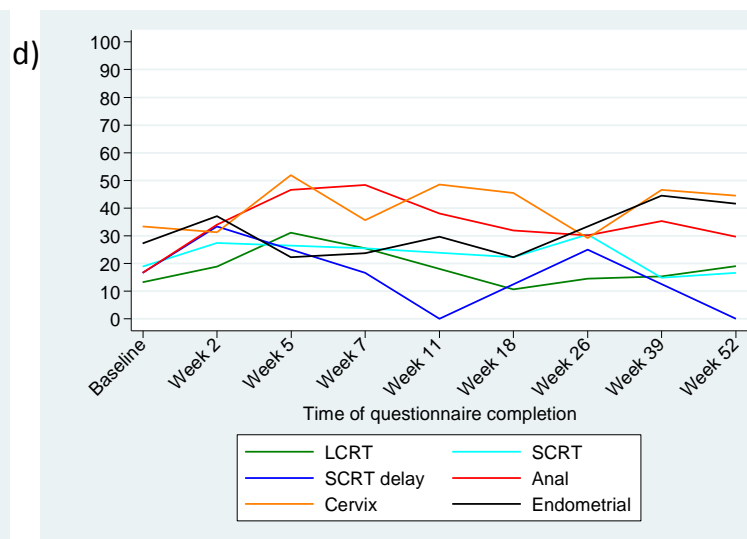
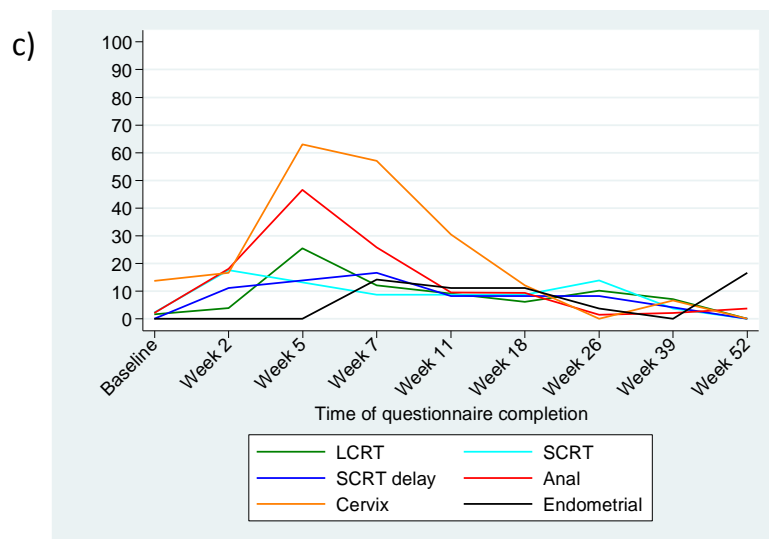
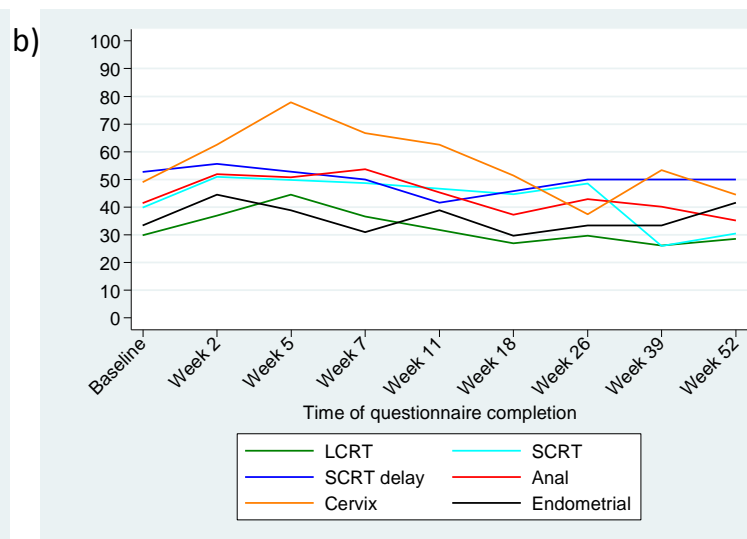
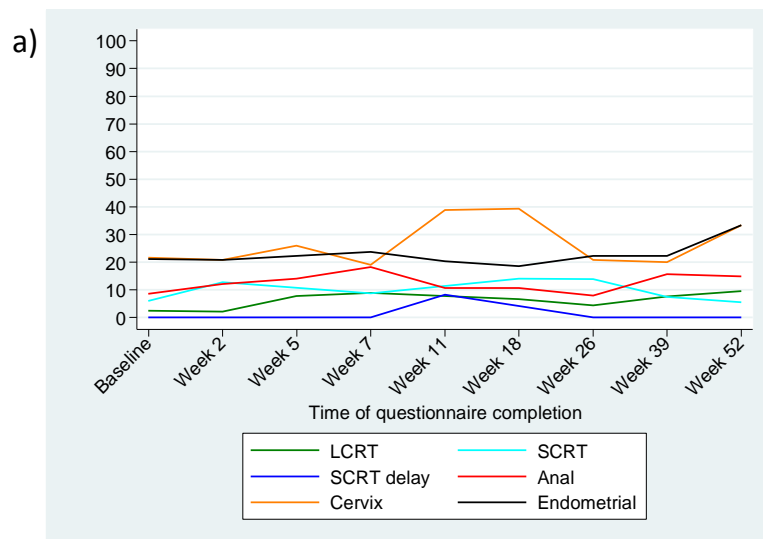
Mean score  
30.9  
increased to  
44.9  
(moderate  
difference)

Treatment  
duration 5  
weeks for  
all except  
SCRT

# Urinary symptoms using EORTC QLQ modules



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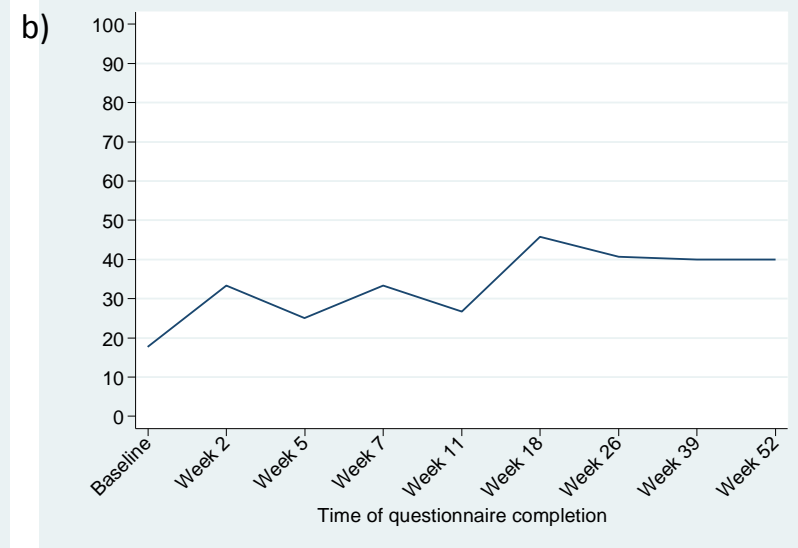
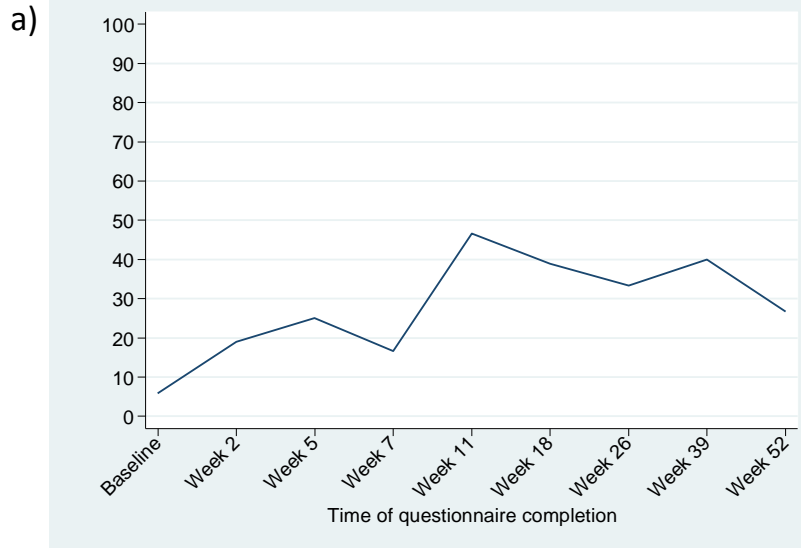


Minimal change from baseline for all urinary scores

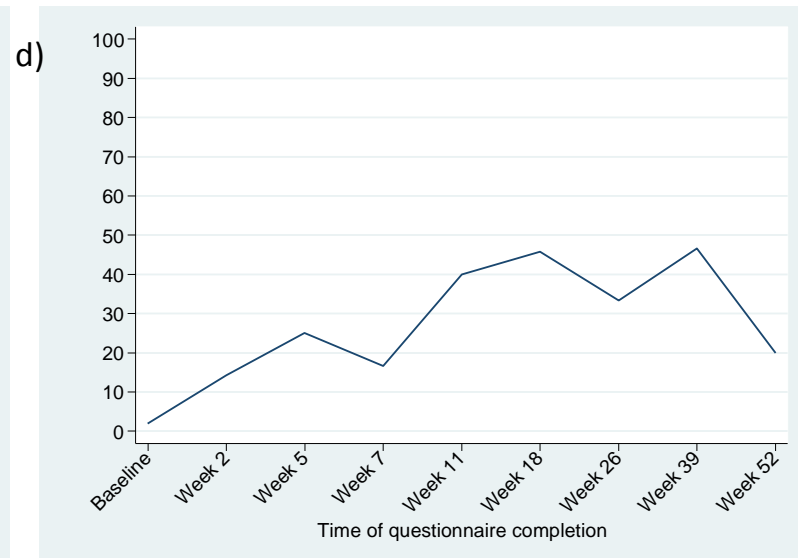
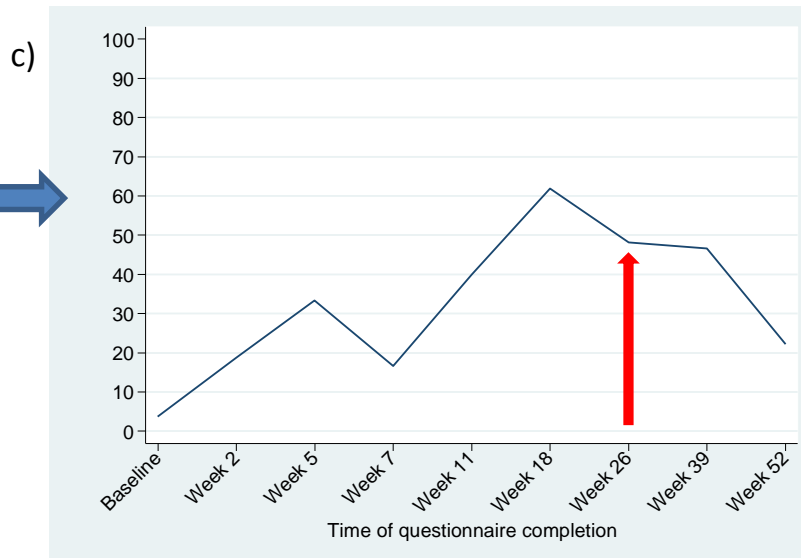
# Vaginal symptoms using EORTC QLQ modules (n=17/78 sexually active; 23%)

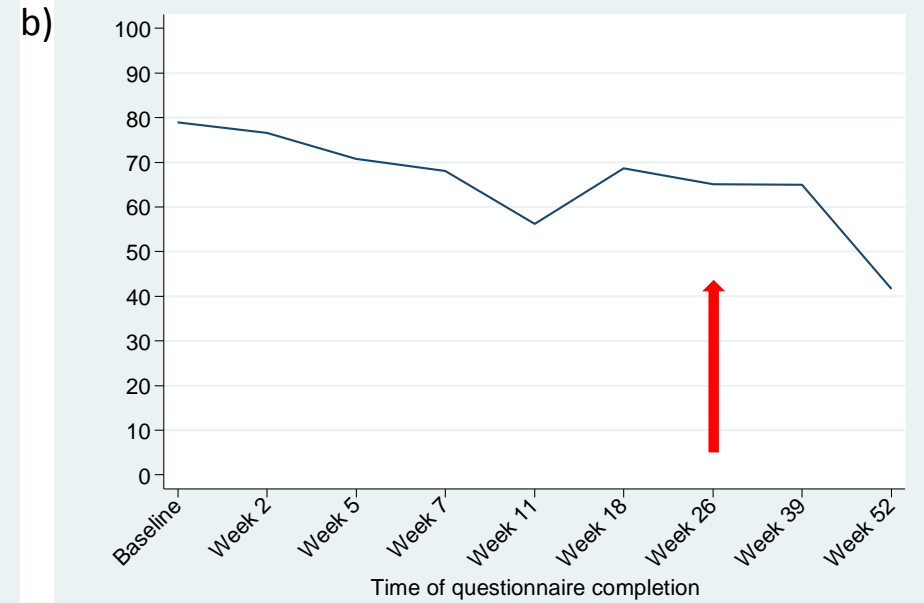
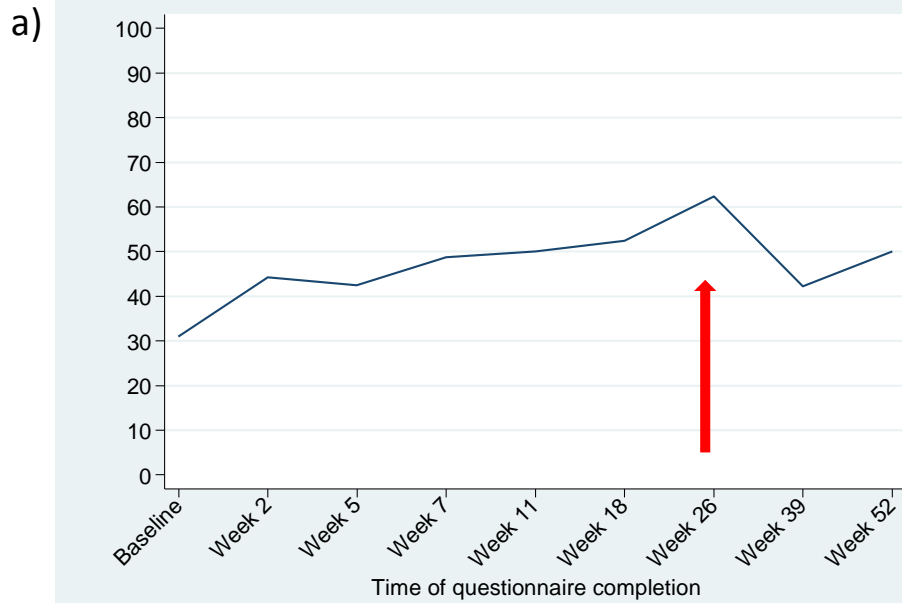


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Mean 3.7  
increased  
to 48.1  
(large  
difference;  
n=9)





- AT 6 MONTHS:
  - n=43 impotence item (mean 31.0 to 62.3; large difference)
  - n=13/51 sexually active: 31% - also large differences in ejaculation problems and reduction in sexual enjoyment

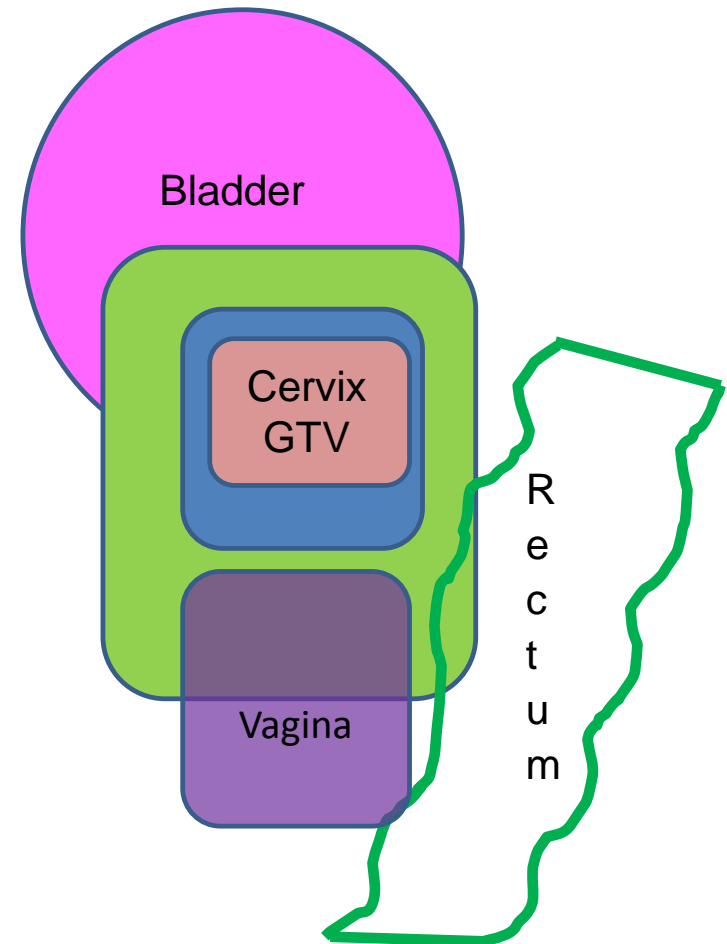


- QOL deteriorates during treatment but is improving by 6 months
- Symptoms are worst at week 5 and improving by week 7
- Bowel urgency and sexual dysfunction have the greatest change from baseline at 6 months
- These symptoms were also most severe in cross sectional study (median 2 year)

# Use in normal tissue complication probability (NTCP) modeling



- Relationship between dose and volume of these normal tissues treated and patient reported symptomatic toxicity
  - Intestinal cavity
  - Rectum
  - Bladder
  - Vagina
  - Female external genitalia
  - Male external genitalia
  - Penile bulb
  - Sacrum



## FEMALE SEXUAL DYSFUNCTION: N= 75

- Clinical factors: HRT, increasing age (better scores)
- **Vagina:** increase relative volume of organs receiving doses greater than 40Gy associated with vaginal stenosis, dyspareunia and vaginal dryness
- **Female external genitalia:** increase relative volume doses greater than 30Gy associated with reduction in enjoyment of sex

PROSPECTIVE STUDY: FURTHER  
VALIDATION OF MODELS

- Routine toxicity collection in clinical practice is key to improving our practice in radiotherapy
- PROs provide a robust method to collect symptomatic toxicity data
- Benefits to patients established
- Electronic methods of data collection and integration into EHR is feasible
- Longest follow up in the literature using electronic PRO collection (9 months)
- Data used in NTCP modeling

Thank you



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**NHS**  
*National Institute for  
Health Research*



**Radiotherapy  
Research Group**

