From a clinical question to a clinical trial- Closing the gap between research and clinical practice in Radiotherapy skin care

Lena Sharp, RN, PhD
Chief Nursing Officer, Karolinska University Hospital, Dep. Of Oncology, EONS Board Member
How it started...

- A question from a patient to an RT nurse about Calendula cream for skin care (Nov 2008)
- I was asked for advice...
- Searched for evidence
- Found a RCT (Pommier et al 2004)
More questions…

- Frequency of ARSR at our department?
- Choice of assessment tool?
- Inter-observer agreement?
- Funding
Pilot study, study 1

- 93 patients, (Feb-March 2009)
- Standard skin care, 2 assessment tools
- Inter-observer agreement
- HRQoL, Sleep, Information needs
- PROM

Results
- Most patients experiences ARSR, mostly mild reactions
- Moderate agreement between observers, Need for education
- Assessment tools
Challenges before RCT

- Which version of assessment tool to use?
  - RTOG/EORTC (original vs modified version)
  - Translations
- Education to staff
- Funding, EONS Major Research Grant 2009
- Permissions and costs
- Studies with alternative products
- Informed consent procedure
Main study, study 2

- Blinded RCT, 420 patients
- 1st patient included March 2010
- Rapid inclusion rate, On-line randomisation
- Monitored as a clinical chemotherapy trial
Process

• Assessment at baseline, start, end, 10 days after RT
• Original version of the RTOG/EORTC scale
• Patient reported pain, burning, tenderness, pulling and itching (VAS)
• EORTC QLQ-C30
• MOS-SLEEP
• Smoking status (CO in expired air)
• Patients experiences on the used skin care product
Study 2 (RCT), Results

- No differences between Calendula cream and plain aqueous cream
- 23 % severe ARSR with Calendula cream
- 19 % severe ARSR with Essex cream
- More difficult to apply Calendula
Results, Study 2 (RCT) PROM

- **Pain**
- **Tenderness**
- **Burning**
- **Pulling**
- **Itching**
Study 2 (RCT)

Study 3

- Risk factors for ARSR
- 390 patients
- Treatment and patient-related risk factors
Study 3 (risk factors), results

- RT dose
- Smoking, High BMI independent risk factors
- Lower response rate and proportion of smokers
- Dilemma in studies on life style
Study 3 (risk factors)

- Smoking as an independent risk factor for severe skin reactions due to adjuvant radiotherapy for breast cancer. Sharp L, Johansson H, Hatschek T, Bergenmar M.
Study 4 (information needs)

- 88 women
- EORTC QLQ-C30, EORTC QLQ-INF025
Study 4, results

- 50% requested more information
- Patients treated with chemo reported less information
- Younger women less satisfied
- Positive assoc. between satisfaction with information and HRQoL
Study 4

Patients' perception of information after completion of adjuvant radiotherapy for breast cancer.
Bergenmar M, Johansson H, Sharp L.
Eur J Oncol Nurs. 2014 Mar [Epub ahead of print]
Conclusions

• Close collaboration between extremely dedicated clinical nurses, managers, a statistician and nursing researchers
• Successful implementation
• System not used to nurses performing clinical trials
• Funding a major issue
• Without the EONS Major Research Grant we would never have managed!
Thank you!