

## Developing an Outcome Measure

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## Background

- ◆ There are a wide number of outcome measures covering most health care states. Before developing a new measure a review (preferably systematic) of the available outcome measures should be undertaken BEFORE any development.

## Outcome measure

- ◆ In a RCT of HRT it was deemed that a relevant outcome to be measured should be sexual functioning.
- ◆ A systematic review was undertaken to identify a relevant questionnaire.

## Population

- ◆ Women in the study were 'normal' and were in a HRT study because of low bone density. They were not in the study because of poor sexual health or functioning.
- ◆ Many questionnaires identified in the review were too intrusive for use in this population (e.g., GRISS questionnaire).

## Suitable questionnaire?

- ◆ One questionnaire the Sabbatsberg Sexual Self-Rating Scale did not appear to be overly intrusive and was judged to have good face validity by a clinical psychologist working in the field.
- ◆ As far as we could tell, however, had not been validated properly in any population.

## SSRS

- ◆ The original q'naire had 14 questions, but two questions were deemed to be somewhat intrusive and were dropped. The amended version had 12 items.
- ◆ The questionnaire was piloted on an opportunistic sample of women passing through a clinic and these women were happy to answer the questions.

## Development

- ◆ We then gave the questionnaire to 148 women who were being recruited in the RCT.
- ◆ 48 did not respond (35%) of those who answered other QoL questions.
- ◆ As well as the SSSRS we also gave the women the SF36 and the Hospital Anxiety and Depression Scale (HADS).
- ◆ We measure oestrogen levels and sociodemographic variables.

## Item response

- ◆ Each question (item) had 5 possible responses. Guidelines suggest that the endorsement of each item should be less than 80% for it to be valid.
- ◆ In our study item endorsement ranged from 36% to 46%.
- ◆ Thus all items were retained for further analysis.

## Correlation

- ◆ If the questionnaire was measuring sexual functioning we would expect it to also correlate with other measures of health/wellbeing on the assumption that poor sexual functioning would, on average, have a negative impact on these other domains.
- ◆ As expected the questionnaire correlated in expected directions with 7 of the SF36 domains and both domains of the HADS.

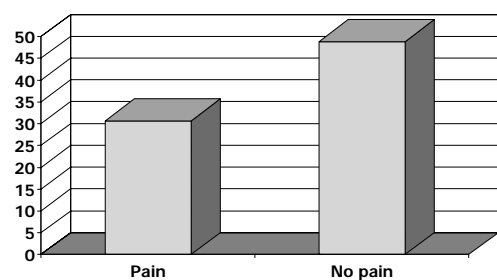
## Clinical measures

- ◆ Previous evidence suggests a correlation between sexual functioning and oestrogen levels. The SSSRS correlated with oestrogen levels in the expected direction.

## Group differences

- ◆ We would expect women who experience pain with sex to have lower scores than those who do not. This was the case with a difference of about 1 standard deviation.

## Score differences between those with dyspareunia or not



Garratt et al, BJOG 1995, 102:311.

## Statistical properties

- ◆ Scores tended to have a normal distribution.

## Conclusion

- ◆ The SSSRS appeared to be a valid measure of sexual functioning among a group of women aged between 45-49 years.