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Designing a faecal incontinence instrument using survey data

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Recently the Wexner Faecal Continence Grading Scale (Jorge and Wexner, 1993) and a number of other items pertaining to faecal incontinence were included in the 2004 South Australian Health Omnibus Survey (SAHOS). The performance of these faecal incontinence items in SAHOS will be used as examples to demonstrate some of the key design issues.

Keywords

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Abstract

The development of instruments for the measurement of faecal incontinence symptoms and quality of life impact is at an early stage in psychometric terms (Thomas et al., 2006). The absence of large scale studies and clinical data makes the selection of reliable and valid measures difficult. Issues surrounding the actual content of questionnaires and scoring systems are also hotly debated. Some of these issues include: What do you mean by the severity of symptoms (Flatus, Liquid, or Solid Stool)? How do you measure the frequency of symptoms? Do you include questions about the use of pads? Do you ask questions about the impact of faecal incontinence? This paper examines these content issues in detail, in order to offer some useful pointers for questionnaire revision and development in the future.

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Introduction

A Continence Outcome Measurement Suite (COMS) Project was commissioned by the Australian Government Department of Health and Ageing, National Continence Management Strategy Research Program with the goal of recommending a suite of continence outcome measures to be used by clinicians and researchers in Australia. This project was finalised in early 2006 (Thomas et al., 2006). Recommendations from this report led to a related project *Measuring Incontinence in Australia* (Hawthorne, 2006) which assessed a number of the recommended measures (Urogenital Distress Inventory 6 (Uebersax et al., 1995), Incontinence Severity Index (Sandvik et al., 1993), and the Wexner Faecal Continence Grading Scale (Jorge and Wexner, 1993)) by including them in the autumn 2004 South Australian Health Omnibus Survey (Harrison Health Research, 2004). This study provided Australian prevalence estimates for both faecal and urinary incontinence based on this community survey data.

For urinary incontinence, the results suggested that the preferred urinary incontinence measure was the Incontinence Severity Index (ISI). It was found to possess superior measurement properties in comparison with the Urogenital Distress Inventory (UDI-6). Because the UDI-6 measures the impact of urinary incontinence on peoples' lives rather than incontinence per se, and may contain items that may be endorsed by those without urinary incontinence, the UDI-6 may overstate incontinence prevalence and the impact of this on peoples' lives (defined as their health status and their quality of life). Given its poor psychometric properties, there was a case for major revision of the UDI-6. Although the ISI was the preferred measure, it violated the assumptions of classic psychometric theory relating

to scale stability as it contained only two items, so further research into its properties was also recommended.

Regarding the measurement of faecal incontinence, as Hawthorne (2006) indicated the current definition of faecal incontinence by the International Continence Society (ICS) excludes flatus, yet this is included in the Wexner Faecal Continence Grading System (Wexner FCGS). In addition to this definitional inconsistency, the evidence from Hawthorne (2006) and AIHW (2006) suggested that the inclusion of the flatus item led to overestimates of faecal incontinence prevalence. It was recommended that further work on the Wexner FCGS be undertaken to remove the flatus item and to improve the measurement properties of this scale.

The main purpose of the *Refining Continence Measurement Tools* project was to undertake further analysis of the SAHOS dataset to refine the incontinence measures to provide better instruments for the assessment of urinary and faecal incontinence in Australia

This paper examines the psychometric properties of the Wexner FCGS (Jorge and Wexner, 1993) and ancillary faecal incontinence items included in the SAHOS dataset for the purpose of refining the measurement of faecal incontinence.

Methods

Data Items

The Jorge and Wexner FCGS was developed to provide clinicians with a means of assessing faecal incontinence severity (Jorge and Wexner, 1993). The Wexner FCGS requires assessment on leakage/accidental faeces for solid, liquid, and gas, the need to wear a pad and alterations to lifestyle. The Wexner FCGS items are presented on Slide 6.

There are a number of studies supporting the construct validity and the discriminative validity of the Wexner FCGS (Sanson et al., in press). Vaizey et al. (1999) reported that the test-retest reliability of the Wexner FCGS score was $r = 0.75$ (in a clinical sample) which falls within an acceptable range (Streiner and Norman, 2003).

However, Thomas et al. (2006) and Hawthorne (2006) have both commented that an obvious difficulty with the Wexner FCGS is that it is unconventional to sum symptoms and symptom effects; a procedure that gives rise to double counting. In the Wexner FCGS, stool leakage and its consequence on lifestyle are both counted.

Vaizey et al. (1999) has also criticized the Wexner FCGS for the pad wearing question, arguing this was a measure of patient fastidiousness or urinary co-morbidity. There are also no items included in the scale that address the issue of urge incontinence (Deutokom et al., 2005; Hawthorne, 2006; Thomas et al., 2006; Vaizey et al., 1999).

Another issue with the Wexner FCGS is the inclusion of an item on flatus which is equally weighted with other items in the scale. Thus a person who endorses daily flatus and no other item will receive the same score as another who endorses only daily incontinence for liquid or solid stool which might be considered a more severe condition. Thus its measurement of severity may be confounded by flatus. This problem associated with the Wexner FCGS, and

indeed a number of other faecal incontinence scales, has been commented on by both Hawthorne (2006) and AIHW (2006).

Given some of the concerns raised above a number of ancillary items for faecal incontinence were also included in the 2004 SAHOS. These items were devised by a clinician, Dr Kate Moore and addressed issues such as bowel pattern, frequency, faecal urgency and soiling.

Slides 4 and 5 summarise the methods of data collection for the 2004 SAHOS. Slide 6 depicts the items from the Wexner FCGS and Slide 7 depicts the ancillary faecal incontinence items included in the 2004 SAHOS.

Data Analysis

The first approach taken was to examine the items and scales using classical test theory (CCT) (Streiner and Norman, 2003). The following steps were undertaken and for these analyses unweighted survey data from 2004 SAHOS (Harrison Health Research, 2004) were utilized:

1. Explore basic item properties such as means, medians and distributions
2. Item analysis – examine item endorsement and discrimination
3. Item analysis – examine item total correlations and internal consistency reliability
4. Content Validity – relate the items back to their construct(s) using exploratory factor analysis
5. Select items for ‘refined measures’ and compare with IRT (Item Response Theory) approaches
6. Examine the relationship of the items and the refined scales with other constructs, namely health utilization, disability and self-reported health status

It was also decided to use a sample of adults, 18 years of age and over.

The second approach to refining incontinence measures was to use modern test theory (MTT), specifically Item Response Theory Analysis (IRT). This presentation will allude to the results of the IRT analysis but full details of this can be found in Sansoni et al., in press.

Results

Slide 8 shows the descriptive statistics for the Wexner FCGS. The sample comprised 2915 persons; 1713 females and 1202 males. Scores on the Wexner FCGS can range from 0-20. The mean for females was 0.94, the standard deviation was 1.77 and the scores ranged from 0-18. The mean for males was 0.65, the standard deviation was 1.28 and the scores ranged from 0-10. These figures are not surprising as faecal incontinence is not common in the community. Plus, it should be noted, that elderly persons (aged 75 years and over) are more likely to reside in nursing homes and they are therefore excluded in a community household survey.

An examination of the faecal incontinence items and their endorsement patterns show:

- Similar patterns of endorsement of the “Normal” or “Never” category for males and females (within 10 percent). This indicates that the presence of faecal incontinence is not common amongst males or females

- Across all age groups a high proportion of survey participants (greater than 80 or 90 %) endorse the “Normal” or “Never” category for most faecal incontinence items. This indicates the presence of faecal incontinence is not common across age groups
- There were lower levels of responding with “Normal” or “Never” (around 50 or 60%) for items X3 (urgency) and X6 (leak gas). This would indicate that these symptoms are more common in the community than the other faecal incontinence symptoms. Slides 9 and 10 depict the non endorsement rate for leakage of solid stool and leakage for gas (flatus).

The Cronbach’s alpha for Wexner FCGS in this sample was $r = 0.57$. This is far less than reported by Vaizey (1999) and is considered to be in the unacceptable range (Streiner and Norman, 2003). Slide 11 provides a table of the corrected item total correlations and Cronbach’s alpha if each item were deleted from the Wexner FCGS. This table shows that item X6 (leak gas) has a low corrected item - total correlation, just above the acceptable range of 0.20 (Streiner and Norman, 2003). The Cronbach’s alpha data also suggests that if item X6 (leak gas) is deleted then Cronbach’s alpha moves to an acceptable level of 0.77.

Slides 13 and 14 present the correlation matrix for the faecal items and the rotated factor matrix for the faecal incontinence items. (The method of exploratory factor analysis used was principal components analysis for extraction [eigenvalues > 1.00] with varimax rotation.)

The factor analysis of the faecal incontinence items indicated that a 3 factor structure resulted explaining 61% of the variance. According to Norman and Streiner (2003) this percentage represents an acceptable solution. The items that load highly on the first factor are mainly items concerning soiling / wearing a pad, leakage and the effect of leakage on lifestyle (refer Slides 14 and 18). This factor may be considered to be a ‘general faecal incontinence’ factor, as all items are concerned with leakage and soiling.

The items that loaded highly on the second factor were the flatus leakage item from the Wexner FCGS, a question about type of bowel pattern (normal, constipation, diarrhoea, alternating) and a question concerning faecal urge (Do you experience an urgent need to have a bowel movement that makes you rush to the toilet?). These items appear to be tapping ‘other bowel symptoms’ that do not appear to be related to faecal incontinence / leakage per se (refer Slide 14).

The only item that loaded on the third factor is ‘frequency of bowel motions’ (Item X2) and this item has extremely low loadings on the other two factors. It appears to be unrelated to faecal leakage or soiling (refer Slide 14).

Further analysis of the corrected item-total correlations for the Wexner FCGS indicates that the item concerning flatus has a low corrected item-total correlation and that Cronbach’s alpha would be improved if this item were removed from the scale. Both the Hawthorne (2006) and AIHW (2006) reports recommended this item should be removed from the Wexner FCGS as it confounds prevalence estimates and is outside the current ICS definition of anal incontinence (Norton et al., 2002; 2005). The factor analysis results discussed above would also suggest a refined faecal incontinence scale should not include this item.

Although clinicians (Moore et al., 2006) had suggested the inclusion of a faecal urgency item this item (Do you experience an urgent need to have a bowel movement that makes you rush to the toilet?). It only had a low loading on the ‘general faecal incontinence’ factor and

loaded highly on the second 'other bowel symptoms' factor. Its endorsement pattern was quite different from the other faecal incontinence items with far fewer respondents endorsing 'never' in relation to this item. This might suggest that bowel urgency is a relatively more common symptom in the community and thus may be endorsed by those not experiencing faecal incontinence. For these reasons this faecal urgency item is not considered for inclusion in the refined scale. However, the item 'Do you leak stool if you don't get to the toilet in time?' loads highly on the general faecal incontinence factor and does contain an urge component.

The item concerning type of bowel pattern loaded most highly on the second factor (other bowel symptoms) and has a low loading on the 'general faecal incontinence' factor. Similarly, the question concerning frequency of bowel movements loaded poorly on the general factor and thus these items were not included in the revised scale.

An issue concerning item redundancy might be considered by comparing the following items:

- Do you need to wear a pad to protect your underwear from stool? (Wexner FCGS)
- Does stool leak so that you have to change your underwear?

The pad question from the Wexner FCGS has previously been criticized by Vaizey (1999) as it may relate more to patient fastidiousness rather than faecal incontinence / soiling per se. Given these considerations and its similarity to the soiling item above, in loading on the general faecal incontinence factor (0.78 vs. 0.71, refer Slide 14), it is suggested this item be excluded from the Revised Faecal Incontinence Scale.

The proposed scale that results from CTT analysis is the Revised Faecal Incontinence Scale (RFIS) and it contains the following items:

1. Do you leak, have accidents or lose control with solid stool? (Wexner FCGS)
2. Do you leak, have accidents or lose control with liquid stool? (Wexner FCGS)
3. Do you leak stool if you don't get to the toilet in time?
4. Does stool leak so that you have to change your underwear?
5. Does bowel or stool leakage cause you to alter your lifestyle? (Wexner FCGS)

As part of this study an IRT analysis of the faecal incontinence items was also undertaken (refer Slide 20). There were similarities between the CTT and MTT analyses concerning a number of items that should be excluded from a faecal incontinence scale. These included the items of flatus leakage (Wexner FCGS) and items concerning the number of bowel movements and bowel pattern which loaded poorly of the 'general incontinence factor' and were also found to be problematic in the IRT analyses.

Analyses using Modern Test Theory approaches (IRT) came to a 4 item solution for faecal incontinence which contains items 1-4 above. IRT is used to find the model with the best fit to the data within the minimum number of items and it is a process commonly used to shorten scales. Item 5 from the RFIS above (the Wexner FCGS lifestyle item) is not included in this solution as the other items fitted the model better and thus is excluded from the Faecal Continence Assessment scale below (see Sansoni et al, in press). However, it is thought that clinicians may prefer the inclusion of the lifestyle question and thus it is recommended that both these scales be tested in clinical settings.

The Faecal Continence Assessment (FCA) scale resulting from Modern Test Theory Analyses is provided below.

1. Do you leak, have accidents or lose control with solid stool? (Wexner FCGS)
2. Do you leak, have accidents or lose control with liquid stool? (Wexner FCGS)
3. Do you leak stool if you don't get to the toilet in time?
4. Does stool leak so that you have to change your underwear?

It is important to note that the revised scales, in conjunction with the original scales, need to be assessed in clinical field trials as part of their validation.

Conclusion And Recommendations

The Wexner FCGS is currently used widely in clinical settings. If the Wexner FCGS is to continue to be used it is recommended that the item concerning flatus should be deleted from this scale. It is suggested it then be referred to as the Australian Modified Wexner Faecal Incontinence Scale to prevent confusion between this scale and other modifications of the Wexner FCGS.

Both the 5 item Refined Faecal Incontinence Scale (RFIS) and the 4 item Faecal Continence Assessment scale (FCA) need to be tested in clinical populations where a greater spread of incontinence symptoms (and scores) will be found.

It is thought the RFIS may be more acceptable to clinicians as it includes the effect of faecal incontinence on lifestyle. However, this remains to be ascertained in clinical trials.

The 4 item FCA or a 2 item faecal incontinence index (AIHW, 2006) based on the leakage of liquid and solid stool questions from the Wexner FCGS may be the preferred instruments to use in prevalence studies.

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Appendix 1: Revised Faecal Incontinence Scale

Do you leak, have accidents or lose control with solid stool?
Do you leak, have accidents or lose control with liquid stool?
Do you leak stool if you don't get to the toilet in time?
Does stool leak so that you have to change your underwear?
Does bowel or stool leakage cause you to alter your lifestyle?

The response scale for each item is

Never

Rarely, i.e. less than once in the past four weeks

Sometimes, i.e. less than once a week, but more than once in the past four weeks

Often or usually, i.e. less than once a day but more than once a week

Always, i.e. more than once a day or whenever you have a bowel movement