

# Validation of the Revised Incontinence and Patient Satisfaction Tools

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# Refining Contenance Measurement Tools

- Used the 2004 SAHOS data to assess the psychometric properties of the Urogenital Distress Inventory-6, the Incontinence Severity Index (UI); the Wexner and faecal items (FI).
- Psychometric analyses of the data used both Classical Test Theory and Modern Test Theory (IRT) approaches
- Revised 5 item measures of incontinence were derived
  - Revised Urinary Incontinence Scale
  - Revised Faecal Incontinence Scale

## Validating Tools in Clinical Settings

- This project, funded by DoHA, assessed these tools in clinical settings – 11 clinics across 4 states
- Descriptive statistics, reliability, factor structure, correlations with other measures are examined
- Also examined type of treatment variables – continence advising, physiotherapy, surgical interventions and responsiveness to change over time

## Revised Urinary Incontinence Scale

Do you experience and how much are you bothered by:

- Urine leakage related to the feeling of urgency?
- Urine leakage related to physical activity, coughing or sneezing?
- Small amounts of urine leakage?

Responses = not at all, slightly, moderately, greatly (0-3)

- How often do you experience urine leakage?

Responses = never to every day/night (0-4)

- How much urine do you lose each time?

Responses = none, drops, small splashes, more (0-3)

Scores range from 0-16

# RUIS : Descriptive Statistics

## Females

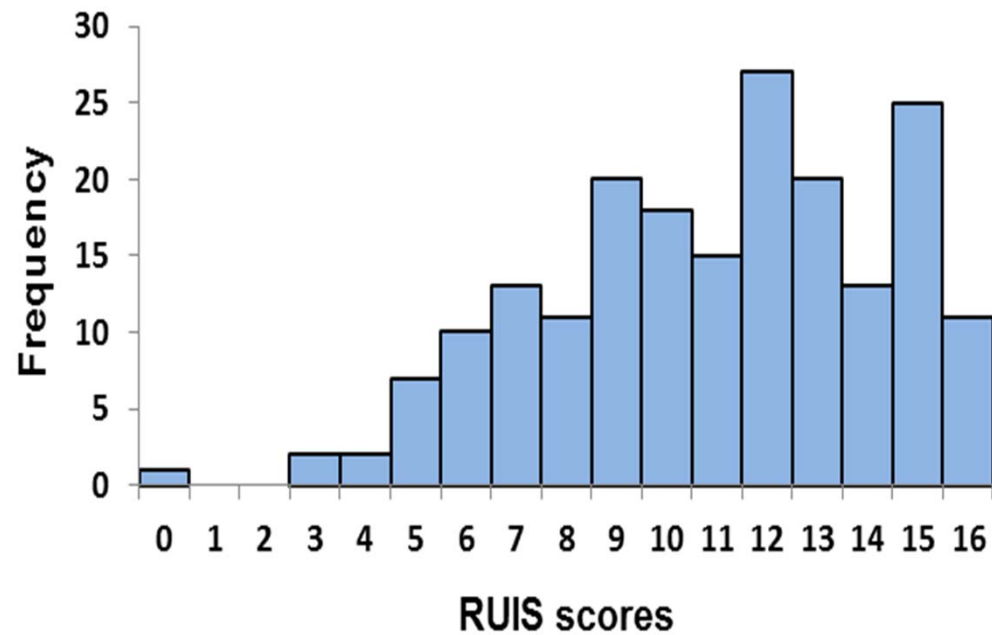
	N	Mean	SD	Actual Range	
<b>RUIS-SAHOS</b>	<b>1712</b>	<b>2.47</b>	<b>3.31</b>	<b>0</b>	<b>16</b>
<b>RUIS Clin PS Retro*</b>	<b>163</b>	<b>11.56</b>	<b>3.31</b>	<b>1</b>	<b>16</b>
<b>RUIS Clin Prosp.*</b>	<b>167</b>	<b>10.9</b>	<b>3.33</b>	<b>3</b>	<b>16</b>

## Males

	N	Mean	SD	Actual Range	
<b>RUIS-SAHOS</b>	<b>1203</b>	<b>0.70</b>	<b>1.97</b>	<b>0</b>	<b>14</b>
<b>RUIS Clin Prosp.*</b>	<b>28</b>	<b>11.07</b>	<b>4.18</b>	<b>0</b>	<b>16</b>

\* = *Clinical samples at pre-treatment*

# RUIS-Score Distribution (Clinical Sample)



**N = 195; Mean 10.92; SD 3.33;**

**Mode = 12; Median = 11**

**Males = 11.07; Females 10.90**

## Reliability Estimates RUIS Cronbach's Alpha

Data Source	Pre-treatment	Post-treatment
SAHOS all-RUIS	0.91	NA
PS Retro study (women)	NA	0.85
Current Study-UI	0.73*	0.90
Current Study-all	0.84	0.91

\*Pre-treatment alpha for UDI-6 = **0.64**; ICIQ-SF = **0.65**;  
ISI = **0.54**

# Factor Structure: PCA

	<i>Urinary Incontinence Patients (N = 195)</i>	<i>Community Survey (N = 2915)</i>
	<i>Factor</i>	<i>Factor</i>
<b>RUIS Items</b>	<b>1 (49%)*</b>	<b>1 (74%)*</b>
RUIS1 - Urge	<b>0.64</b>	<b>0.80</b>
RUIS2 - Stress	<b>0.67</b>	<b>0.83</b>
RUIS3 – leak small amounts	<b>0.80</b>	<b>0.88</b>
RUIS4 – leak frequency	<b>0.72</b>	<b>0.91</b>
RUIS5 – leak volume	<b>0.64</b>	<b>0.90</b>

\* Proportion of variance explained

# Factor Structure

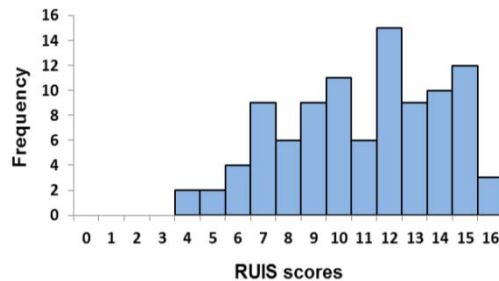
*Rotated Factor Matrices for Urinary Incontinence Items*

		<i>Community Survey 2006 N = 3015</i>		<i>Clinical Survey 2011 N = 195</i>	
<i>Scale</i>		<i>Factor</i>		<i>Factor</i>	
		<i>1</i>	<i>2</i>	<i>1</i>	<i>2</i>
Freq Urination		0.48	0.49	0.41	0.54
Urgency Leakage	RUIS1	<b>0.74</b>	0.33	<b>0.60</b>	0.41
Stress Leakage	RUIS2	<b>0.82</b>	0.09	<b>0.66</b>	-0.04
Leak Small Amount	RUIS3	<b>0.85</b>	0.22	<b>0.77</b>	0.23
Emptying Bladder		0.14	<b>0.76</b>	-0.06	<b>0.76</b>
Pain Lower Abdominal		0.09	<b>0.75</b>	-0.07	<b>0.71</b>
Leakage Frequency	RUIS4	<b>0.89</b>	0.16	<b>0.72</b>	0.01
Leakage Amount	RUIS5	<b>0.89</b>	0.13	<b>0.65</b>	-0.13

*Note: Principal Components Analyses with Varimax Rotation were employed in both studies.*

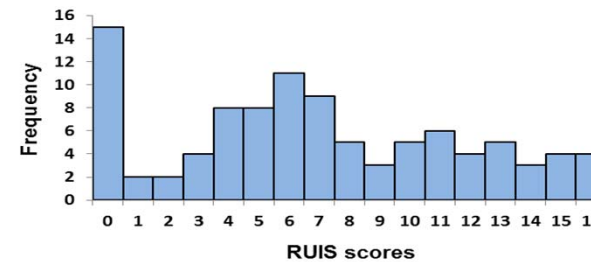
# RUIS: Before and After Treatment

## Pre-Treatment



Mean 11.02; SD .08; N = 100

## Post-Treatment

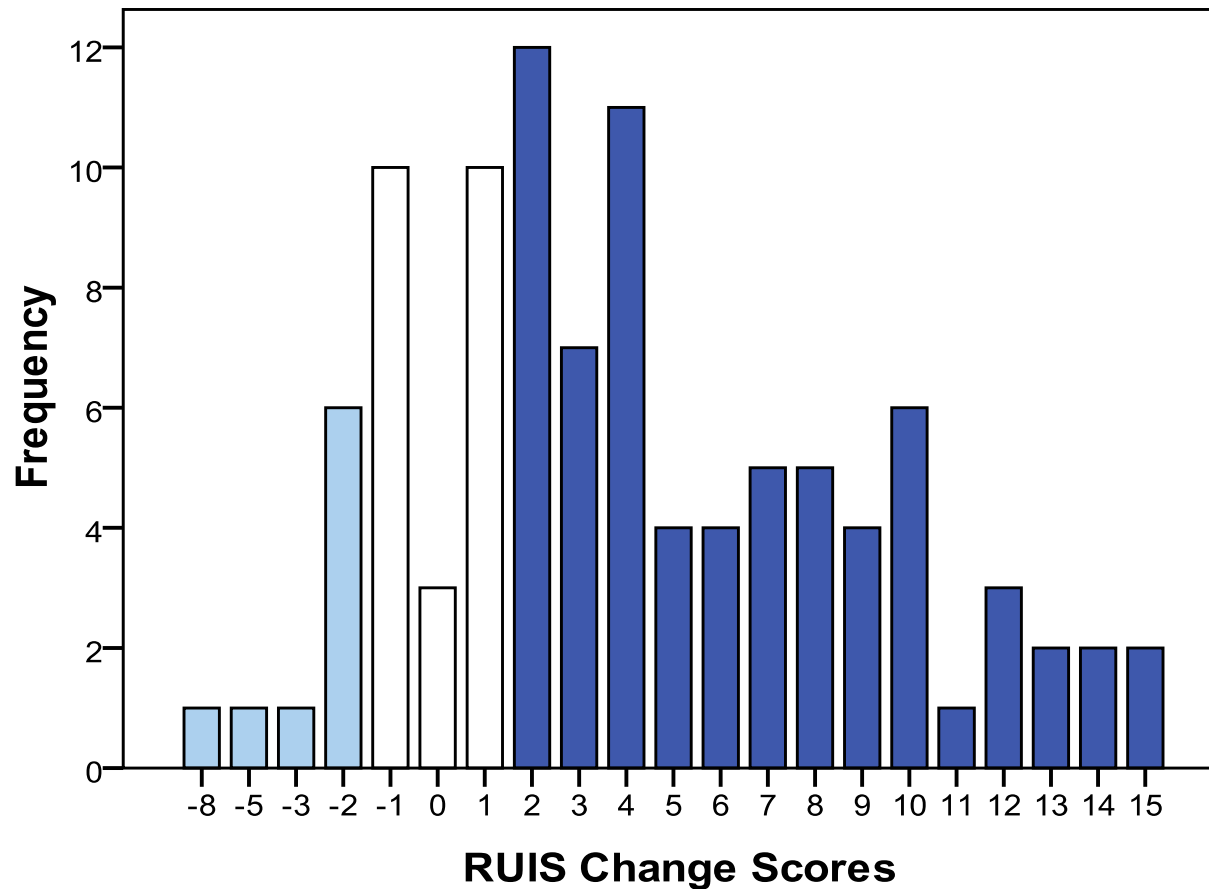


Mean = 6.95; SD 6.95, N = 100

At follow up the mean RUIS score was 6.95, (SD = 4.77, N = 100). For females the mean was 6.91 and for males the mean was 7.21.

Examination of pre-post scores revealed a statistically significant improvement of **4.07** points (SD = 4.76, N = 100) (paired t-test,  $t = 8.56$ ,  $df = 99$ ,  $p < 0.01$ ).

# RUIS: Change with Treatment



Dark Blue = Improved; White = Little or No Change; Light Blue = Worse

# Effect of Treatment

- RUIS scores improved significantly (4.07) with treatment
- There was a significant difference by **type of treatment**. Mean improvement for CA = 2 (n = 11); for Physiotherapy = 3.09 (n = 55) and for Surgery = 7.07 (n = 29) - but note that surgical patients have higher RUIS pre-treatment scores
- An analysis of RUIS change by Global Rating of Improvement suggests the **mean minimal detectable difference** for patients and clinicians is estimated at **2 RUIS** change scores, at the group level.
- Analyses suggest changes of 3-4 scores or greater are statistically and clinically more meaningful for patient monitoring

# Associations with Other Measures

	UDI-6	ISI	Wei Symptom	ICIQ-SF	IIQ (impact)	PR Severity
RUIS* (Pre)	0.76	0.76	0.72	0.74	0.53	0.62

\* All correlations  $p < 0.01$

**Clinical Severity Ratings** – RUIS mean score for mild = 9.22, for moderate = 11.79 and severe = 12.13 (F 16.99; df 2,191;  $p < 0.01$ ). **Patient Severity Ratings** – RUIS mean score for mild = 8.36; moderate = 11.60; severe = 14.03 (F 80.46; df 2, 109.07;  $p < 0.01$ )

**Daily Pad Use** – RUIS mean for <1 per day = 8.06, for >1 per day = 11.55 (t = -6.22; df 192;  $p < 0.01$ ).

**ICIQ number of symptoms severity index** – RUIS mean scores for 2 or less symptoms = 8.60; 3-4 symptoms = 11.46, 5 or more symptoms = 13.21 (F Welch = 43.84; df 2, 125.42;  $p < 0.01$ )

RUIS scores were also higher for those having **surgical treatment**, for those experiencing **double incontinence** and those with **mixed incontinence type**

# Suggested Cut Points

**Summary** + reliability, +/- responsiveness; +/- discriminatory power, unidimensional

Based on the sample distributions, clinician and patient ratings and comparison with other indicators the following cutpoints for interpretation are suggested:

- **0-3:** no urinary incontinence or extremely mild or occasional incontinence symptoms
- **4-8:** mild urinary incontinence
- **9-12:** moderate urinary incontinence
- **13-16:** severe urinary incontinence (scores of 15 -16 could be considered very severe)
- For screening we suggest a score of **4** would warrant further assessment.

## Revised Faecal Incontinence Scale

- Do you leak, have accidents or lose control with solid stool? (Wexner)
- Do you leak, have accidents or lose control with liquid stool? (Wexner)
- 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? (Wexner)

*Response Categories: Never/ Rarely, i.e. < once in the past four weeks/ Sometimes, i.e. < once a week, but > once in the past four weeks/ Often or usually, i.e. < once a day but > once a week/ Always, i.e. > once a day or whenever you have a bowel movement*

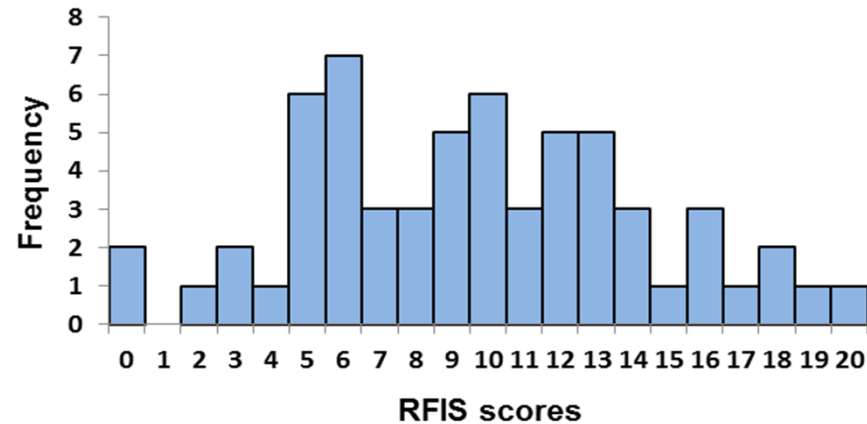
***Item scores range from 0-4 and the Scale Score ranges from 0-20***

# RFIS: Psychometric Properties

	N	Mean	SD	Actual Range	
<b>Females</b>					
RFIS-SAHOS	1714	0.43	1.56	0	18
RFIS – CLIN.	51	9.76	4.86	0	20
<b>Males</b>					
RFIS-SAHOS	1201	0.25	1.04	0	12
RFIS – CLIN.	10	9.10	3.6	3	16

# RFIS Distributions

## RFIS pre-treatment scores (all)

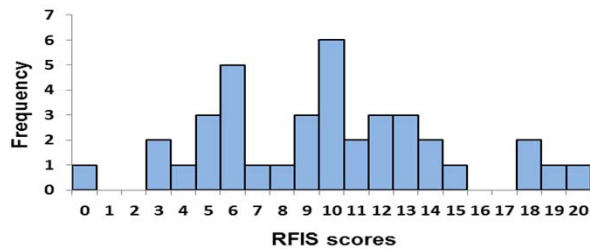


**N = 61**

**Mean = 9.66**

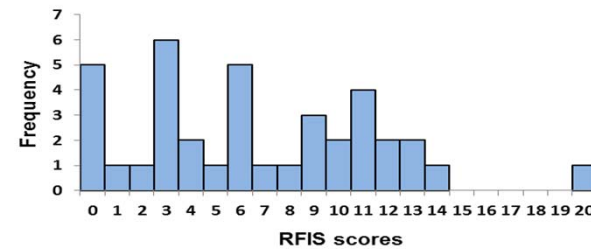
**SD = 4.66**

## RFIS pre-treatment (post sample)



**N = 38, Mean = 9.79, SD = 4.68**

## RFIS post-treatment scores



**N = 38, Mean = 6.68, SD = 4.82**

# Faecal Incontinence

- A significant improvement of **3.11** points (SD = 4.92) (t paired = 3.89, df = 39,  $p < 0.001$ ). No difference in improvement between surgical and conservative treatments – **all groups improved**
- The internal consistency reliability (ICR) for the **RFIS** pre-treatment is **0.78 (faecal sample)**. By comparison pre-treatment alphas for **Wexner = 0.65** and **St Marks = 0.66** which are considered inadequate. The ICR of **RFIS = 0.91** (total sample)
- Retest reliability is good = **0.79 - 0.80** (ICC) and better than other measures
- RFIS scores discriminated by clinician and patient severity ratings, pad use and size, duration of symptoms and other severity indices
- Factor structure suggest RFIS is a uni-dimensional scale - the general faecal incontinence factor explains **54%** of variance

# Suggested Cut Points

Based on the sample distributions, clinician and patient ratings and severity indicators the following cutpoints for interpretation are suggested

- **0-3:** no faecal incontinence or extremely mild or occasional incontinence symptoms
- **4-6:** mild faecal incontinence
- **7-12:** moderate faecal incontinence
- **13-20:** severe faecal incontinence (scores above 16 could be considered very severe)
- For screening we suggest a score of **4** would warrant further assessment.
- (flatus assessment is a separate exercise)

## Conclusions

- Data indicates both the RFIS and the RUIS have good psychometric properties (reliability, validity) and are sensitive to detecting change in patients' incontinence status (responsiveness). Overall better properties than comparable scales – some problem items in some scales
- The RUIS and RFIS are very short and simple to use and provide reliable estimates of the extent of the patient's incontinence and the extent of their improvement from treatment
- Good for quality improvement – easy to use in routine practice – an online collaboration?

# Theory

***“Patient satisfaction may be considered to be one of the desired outcomes of care, even an element in health status itself. An expression of satisfaction or dissatisfaction is also the patient’s judgment on the quality of care in all its aspects, but particularly as concerns the interpersonal process.”***

(Donabedian, 1998, p. 1746)

- Seven key domains: effectiveness, information, technical skill, participation, relationship, access & facilities, satisfaction general.

# Original Patient Satisfaction Study

- Arising from Hawthorne (2006) **Review of patient satisfaction measures** for continence services and treatments
- Post treatment design (*Then-Test Procedure*)
- Survey – 4 patient satisfaction measures (Client Satisfaction Q -18, Consultation Satisfaction Q, Patient Satisfaction Index, Genito-Urinary Treatment Satisfaction Scale);
- Incontinence symptoms e.g. RUIS, plus other items about treatment (e.g. expectations).
- St George Hospital, Sydney and Royal Women's Hospital, Melbourne (and associated private clinics)
- Women only; Urinary patients; N = 178
- Treatments = surgery or physiotherapy or combined

# Results

- An examination of the psychometric properties of the four instruments found **some evidence of item redundancy, response bias and poor responsiveness.**
- Non-responsive & poorly worded items were deleted and the remaining items (n = 49) were used to develop a **pooled patient satisfaction estimate.**
- Used **Item Response Theory (IRT)** to examine and select the items with the best fit with the pooled patient satisfaction estimate. In this iterative analysis we were looking for the best fitting model consistent with the 7 domains of patient satisfaction. A 7 item draft SAPS was developed

## Summary

- The draft SAPS had an excellent coverage of patient satisfaction model and was a strong uni-dimensional scale (Loevinger H = 0.55).
- The draft SAPS was more sensitive than any other instrument to the pooled patient satisfaction estimate.
- Internal consistency reliability (Cronbach's alpha) = 0.86
- The draft SAPS correlated well with other measures of patient satisfaction and with other indicators of treatment outcomes – most improved had higher satisfaction scores

## Current Study

- Pre and post treatment design (prospective study)
- Survey - continence symptoms, clinical ratings, quality of life measures and satisfaction items
- Tested some changes to the wording of the original SAPS items e.g. replacing 'how happy' with 'how satisfied' for two items
- Tested the order of response categories (very satisfied – very dissatisfied) for some items
- Tested some additional Qs – re success and outcomes of treatment, expectations and patient global improvement

# Short assessment of patient satisfaction (SAPS)

Effectiveness: How satisfied are you with the effect of your treatment ?

Information: How satisfied are you with the explanations the doctor or other health professional has given you about the results of your treatment ?

Technical Skill: The doctor or other health professional was very careful to check everything when examining you?

Participation: How satisfied were you with the choices you had in decisions affecting your health care ?

Relationship: How much of the time did you feel respected by the doctor or other health professional ?

Access & facilities: The time you had with the doctor or other health professional was too short?

Satisfaction: Are you satisfied with the care you received in the hospital or clinic ?

# SAPS Summary Statistics 2011

<b>Study 1</b>	<b>SAPS Total %</b>		
<b>Group</b>	<b>Mean</b>	<b>SD</b>	<b>N</b>
<b>Women - Urinary</b>	<b>82.52</b>	<b>15.12</b>	<b>176</b>

<b>Study 2</b>	<b>SAPS Total %</b>		
<b>Group</b>	<b>Mean</b>	<b>SD</b>	<b>N</b>
<b>Women - Urinary</b>	<b>76.86</b>	<b>18.29</b>	<b>86</b>
<b>Men - Urinary</b>	<b>81.11</b>	<b>16.07</b>	<b>14</b>
<b>Women - Faecal</b>	<b>80.75</b>	<b>17.04</b>	<b>31</b>
<b>Men - Faecal</b>	<b>84.82</b>	<b>7.57</b>	<b>8</b>
<b>All incontinence</b>	<b>78.43</b>	<b>17.32</b>	<b>139</b>

*Cronbach's alpha = 0.85*

# SAPS Data

Figure 2: SAPS score distribution

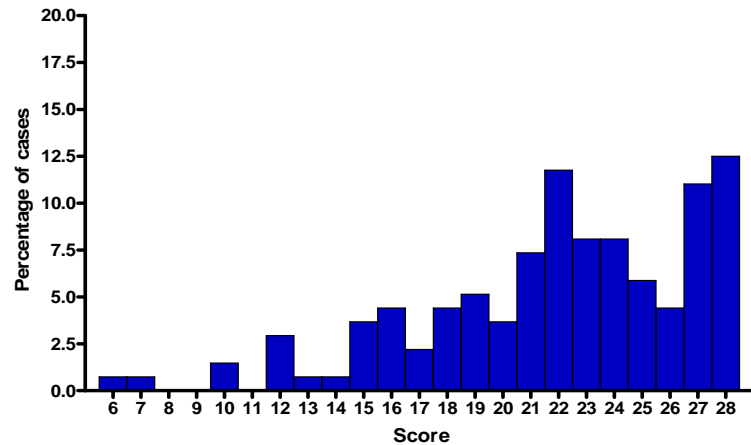
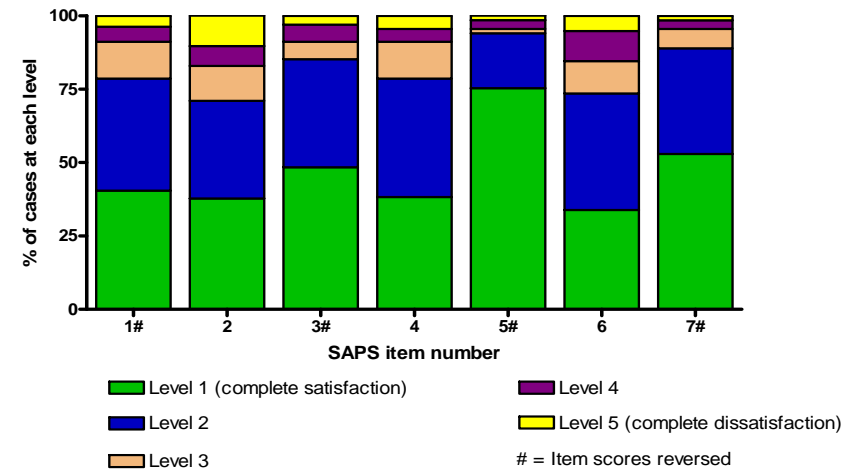


Figure 5.1: SAPS item data distribution



0-10 very dissatisfied; 11-18 dissatisfied; 19-26 satisfied; 27-28 very satisfied.

Mean 21.96, SD 4.85 (N = 139 all incontinence patients)

## Summary: SAPS

- Statistically significant differences in mean SAPS scores by **type of treatment** (surgical patients more satisfied), **clinician and patient rated severity** at post-treatment (normal/mild more satisfied) and post-treatment general health status (fair/poor health least satisfied)
- No significant differences by gender, age group, educational attainment or incontinence type
- SAPS demonstrates good discriminant validity
- Easy to use for quality improvement activities

# Thanks to Participating Clinics

- **ACT Continence Promotion Centre**
- **Colorectalsurgery SA**
- **Lemongrove Community Health Centre NSW**
- **Royal Prince Alfred Colorectal Clinic**
- **Royal Women's Hospital**
- **Royal Women's Hospital**
- **St George Pelvic Floor Clinic**
- **St George Anorectal Clinic**
- **St George Surgery**
- **St George Surgery**
- **Women's and Men's Health Physiotherapy  
and the patients and the Project Steering Group**