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3 Validation of the electronic PASI application: establishing measurement equivalence

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14 Running head: Validation of electronic PASI

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26 **Conflicts of Interest**

27 FA has received travel expenses for attending AAD meetings from Janssen-Cilag
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30 AYF is joint copyright owner of the DLQI. Cardiff University and AYF receive
31 royalties. AYF is a member of a Novartis Advisory Board and has received lecture
32 fees and travel expenses from Novartis.

33

34 VP undertakes personal advisory work for Pfizer, AbbVie, Janssen, UCB, Novartis,
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51 Despite its many shortcomings, the Psoriasis Area and Severity Index (PASI)
52 remains the standard method worldwide for psoriasis assessment¹. Several studies
53 have implemented electronic versions without evidence of formal validation, raising
54 the possibility of lack of equivalence with the paper counterpart². This study aimed at
55 comparing the conventional paper-based and a novel electronic application version
56 of the PASI (Figure 1). International Society for Pharmacoeconomics and Outcomes
57 Research (ISPOR) guidelines³ were followed to assess rater preference and
58 consistency of scores.

59

60 The study employed a randomized cross-over design using a within-subjects
61 comparison of the two formats of the PASI. The study was conducted at the
62 dermatology outpatient department, University Hospital of Wales, Cardiff, UK.
63 Inclusion criteria were: patients aged 18 years or older with a clinical diagnosis of
64 chronic plaque psoriasis from a dermatologist and the ability to read and understand
65 English. Raters ranged from medical students to senior trainees and received
66 standardised clinical training for PASI assessment to ensure uniformity of rating. The
67 study power was 80%, with an expected intra-class correlation coefficient (ICC) of
68 0.9 ($\alpha = 0.05$), resulting in a target sample size of 44 patients.

69

70 All three raters showed high correlation in test scores (Pearson-correlation 0.949,
71 $p < 0.05$, $n = 5$) demonstrating standardisation of the assessment criteria. Forty-four
72 patients were recruited, mean age 45 years ($SD \pm 16$, 59.1% male). The mean
73 duration of chronic plaque psoriasis diagnosis was 19.2 years ($SD \pm 14.8$,
74 interquartile range, IQR, 8-30), with PASI severity ranging from 0.7 to 28.5. The ICC
75 showed high concordance between the total PASI scores from paper and iPad

76 format (ICC = 0.993; 95% CI 0.988-0.996, Table 1). The median difference in PASI
77 scores was also within the hypothesized difference of CC = 0.993 (p=0.72). The
78 lower and higher limits of agreement were -1.4 and 1.4, respectively.

79 The PASI iPad® version demonstrated reduced inter-rater variability compared to
80 the paper version (Pearson correlation 0.982 vs 0.949, number of patients
81 assessed=5). There was no carryover effect demonstrated with scores (p=0.82) or
82 time to completion (p=0.16) regardless of which format of the PASI was used first.
83 The raters, using a stopwatch, took a median of 147 seconds (iPad®) versus 152
84 seconds (paper), not including calculation time (p=0.81). Raters reported that the
85 iPad version was easier to use compared to the paper version due to the visual
86 nature of the application allowing accurate assessment and calculation of severity
87 scores, though suggestions were made to improve the user interface.

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89 The future of medical practice is intricately anchored within the evolution of digital
90 technology. There is high correlation, and thus equivalence, between the PASI
91 iPad® and paper versions. The raters preferred the iPad version due to the visual
92 nature of the scoring process and the reduced likelihood of calculation errors. The
93 higher inter-rater reliability and the inherent advantages of electronic tools⁴ further
94 re-enforces the superiority of the digital format. The validated Psoriasis 360
95 application®, together with the previously validated DLQI⁵ component, has the
96 potential to be of considerable value to clinicians, researchers and patients.

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123 **TABLES**

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126 **Table 1** Equivalence analysis of paper and electronic PASI overall mean scores and
 127 mean completion time

	Paper	iPad®	ICC* (95% CI)	Difference (P – I)	Limits of agreement‡	
PASI scores (n=104)					lower	upper
<i>Median (IQR)</i>	5.7 (2.1-10.7)	5.8 (2.7-9.3)	0.993 (0.988 – 0.996)	0.0 (-0.3 – 0.4)†	-1.4	1.4
PASI times (mins:seconds)						
<i>Median (IQR)</i>	2:32 (01:55-03:07)	2:27 (01:54-03:00)	0.444 (0.148 – 0.665)	-00:10 (-00:31-00:40)†		

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129 CI = confidence interval, ICC = intraclass correlation, IQR = interquartile range, SD =
 130 standard deviation

131 P-I = Paper - iPad®

132 * Hypothesizing coefficient of ≥ 0.9

133 † p value > 0.05 calculated by Wilcoxon Signed Rank test

134 ‡ Limits of agreement calculated from Bland-Altman plots

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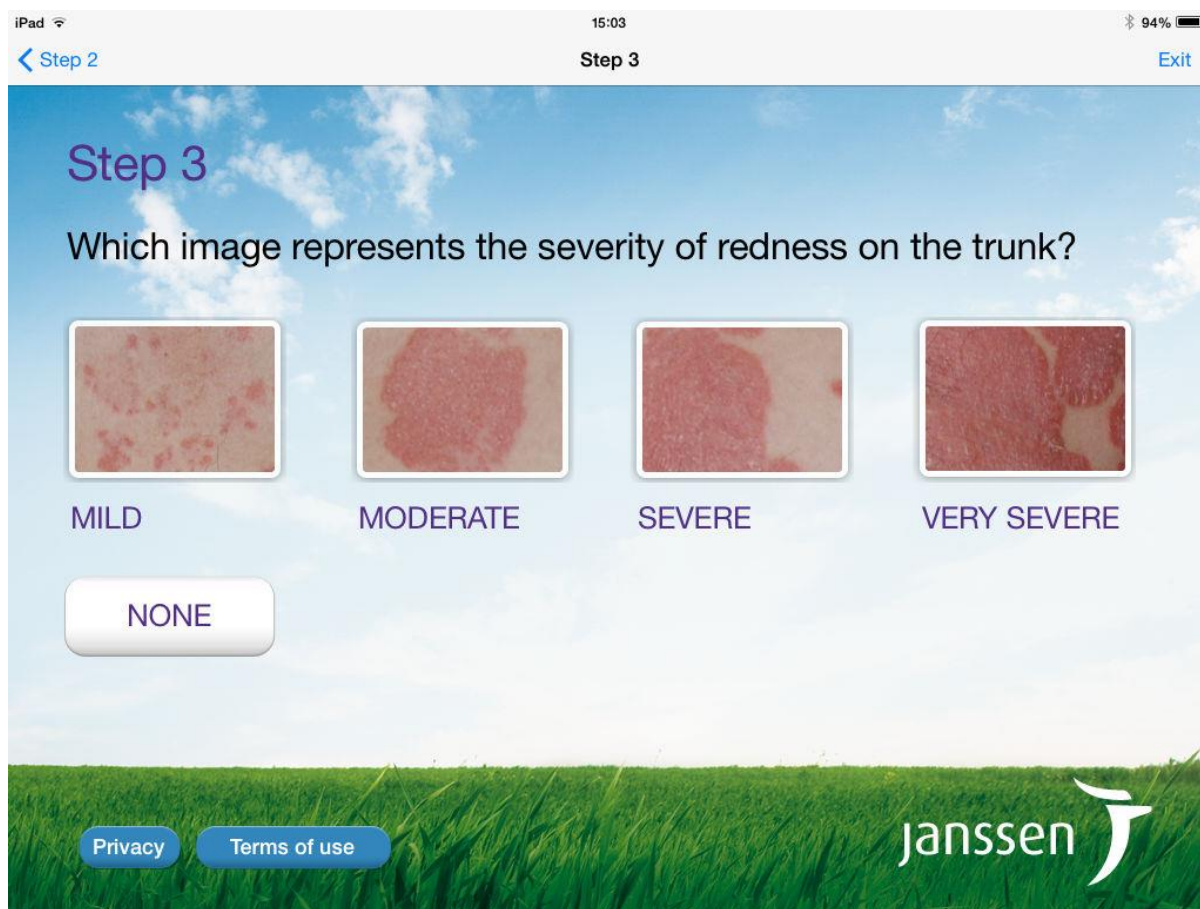
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147 **Figures**

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149 **Figure 1** Example screenshot from the PASI iPad App

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