

This is an Open Access document downloaded from ORCA, Cardiff University's institutional repository:<https://orca.cardiff.ac.uk/id/eprint/124472/>

This is the author's version of a work that was submitted to / accepted for publication.

Citation for final published version:

Ali, F.M., Salek, M.S., Finlay, A.Y. and Piguët, V. 2019. Validation of the electronic Psoriasis Area and Severity Index application: establishing measurement equivalence. *Journal of The American Academy of Dermatology* 81 (6) , pp. 1439-1441. 10.1016/j.jaad.2019.04.073

Publishers page: <http://dx.doi.org/10.1016/j.jaad.2019.04.073>

Please note:

Changes made as a result of publishing processes such as copy-editing, formatting and page numbers may not be reflected in this version. For the definitive version of this publication, please refer to the published source. You are advised to consult the publisher's version if you wish to cite this paper.

This version is being made available in accordance with publisher policies. See <http://orca.cf.ac.uk/policies.html> for usage policies. Copyright and moral rights for publications made available in ORCA are retained by the copyright holders.



1 Title Page

2

3 Validation of the electronic PASI application: establishing measurement equivalence

4 FM Ali¹ (MBChB), MS Salek^{2,3} (PhD), AY Finlay¹ (MBBS), V Piguet^{1,4} (MD),

5

6 ¹Department of Dermatology and Academic Wound Healing, Division of Infection and

7 Immunity, School of Medicine, Cardiff University, Cardiff, UK

8 ²School of Life and Medical Sciences, University of Hertfordshire, Hatfield, UK

9 ³Institute for Medicines Development, Cardiff, UK

10 ⁴Division of Dermatology, Department of Medicine, University of Toronto; Division of

11 Dermatology, Women's College Hospital, Toronto, Canada

12

13

14 Running head: Validation of electronic PASI

15

16 *Correspondence:

17

- 18 • Dr Faraz Ali, Department of Dermatology, Division of Infection and Immunity,
19 School of Medicine, Cardiff University, 3rd Floor Glamorgan House, Heath
20 Park, Cardiff CF14 4XN, UK

21 email: AliFM@cardiff.ac.uk, tel: +44 29 2074 5874

22

23 **Funding:** The study was supported by a research grant from Janssen-Cilag Limited

24

25

26 **Conflicts of Interest**

27 FA has received travel expenses for attending AAD meetings from Janssen-Cilag
28 Limited. FA has received lecture fees from Leo Pharmaceuticals.

29

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,
35 Almirall and Celgene. He has received departmental support from AbbVie, Bausch
36 Health, Celgene, Janssen, LEO Pharma, Lilly, NAOS, Novartis, Pfizer, Pierre-Fabre,
37 and Sanofi.

38

39 Keywords: electronic, validation, equivalence, PASI, clinical outcome measures

40

41 **Letter word count: 498**

42 **Manuscript table count: 1**

43 **Manuscript figure count: 1**

44

45 **ORCID Numbers:**

46

47 Faraz Ali: 0000-0002-4184-2023

48 Sam Salek: 0000-0002-4612-5699

49 Andrew Finlay: 0000-0003-2143-1646

50 Vincent Piguet: 0000-0001-6079-4517

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.

88

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.

97

98

99

100 REFERENCES

- 101 1. Ashcroft DM, Wan Po AL, Williams HC, Griffiths CEM. Clinical measures of
102 disease severity and outcome in psoriasis: a critical appraisal of their quality.
103 *Br J Dermatol* 1999;**141**:185-191.
- 104 2. Campbell N, Ali F, Finlay AY *et al.* Equivalence of electronic and paper-based
105 patient-reported outcome measures. *Qual Life Res.* 2015;**24**:1949-61.
- 106 3. Coons SJ, Gwaltney CJ, Hays RD *et al.* Recommendations on Evidence
107 Needed to Support Measurement Equivalence between Electronic and Paper-
108 Based Patient-Reported Outcome (PRO) Measures: ISPOR ePRO Good
109 Research Practices Task Force Report. *Value Health.* 2009;**12**:419-29
- 110 4. Gill JM, Ewen E, Nsereko M. Impact of an electronic medical record on quality
111 of care in a primary care office. *Del Med J* 2001;**73**:187-94.
- 112 5. Ali FM, Johns N, Finlay AY, Salek MS, Piguet V. Comparison of the paper-
113 based and electronic versions of the Dermatology Life Quality Index: evidence
114 of equivalence. *Br J Dermatol* 2017;**177**:1306-15.

115

116

117

118

119

120

121

122

123 **TABLES**

124

125

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)†		

128

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

135

136

137

138

139

140

141

142

143

144

145

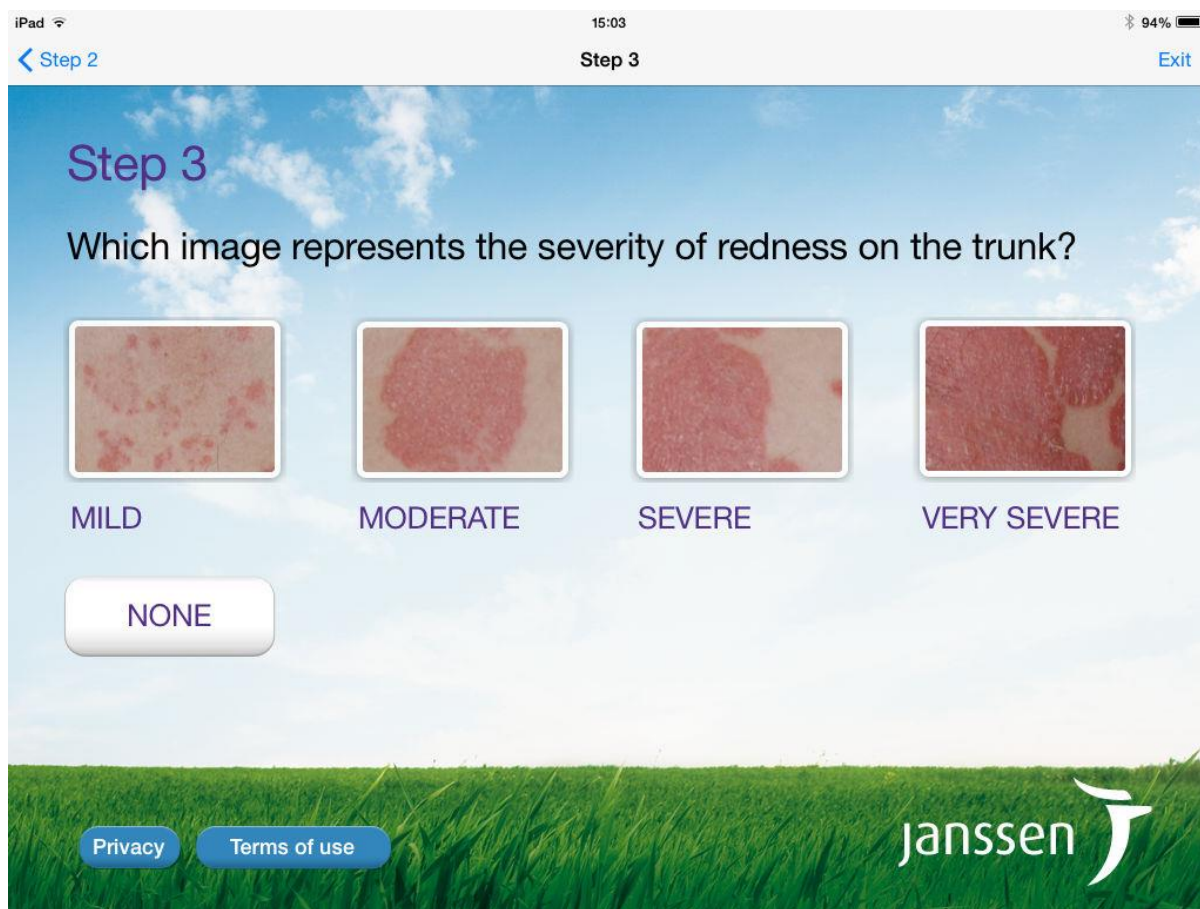
146

147 **Figures**

148

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

150



151

152

153

154