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## Title Page

Comparison of the paper-based and electronic versions of the Dermatology Life Quality Index (DLQI): evidence of equivalence

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Running head: Validation of electronic DLQI

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## Conflicts of Interest

AYF is joint copyright owner of the DLQI: Cardiff University and AYF receive royalties.

## What's already known about this topic?

- The use of patient reported outcome measures (PROs) in electronic format has been increasing.
- Electronic formats are usually not validated or compared to their original paper-based formats, but are assumed without evidence to be comparable.
- The benefits of using electronic PROs include portability, real-time monitoring of patients' quality of life and improved data capture.

## What does this study add?

- There is equivalence between completing the DLQI on paper and in an electronic format.
- Patients prefer the electronic format to the paper version: the electronic format takes slightly longer to complete.
- This equivalence testing of the electronic format of the DLQI with the paper version will reassure and encourage such use in clinical and research settings.

Keywords: electronic, validation, ePRO, equivalence, DLQI, quality of life measures

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## ABSTRACT

### Background

The use of patient-reported outcome measures in electronic format has been increasing. However, these formats are usually not validated or compared to the original paper-based formats, so there is no evidence that they are completed in the same way.

### Objectives

The aim of this study was to compare the conventional paper version and a web-based application version (iPad®) of the DLQI to assess equivalence of scores.

### Methods

The study employed a randomized cross-over design using a within-subjects comparison of the two formats of the questionnaire. International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidelines were followed. Subjects aged over 18 years with any confirmed skin condition were recruited from a teaching hospital dermatology outpatient clinic. Expected Intra-class correlation coefficient (ICC) was 0.9 ( $\alpha = 0.05$ )

### Results

A total of 104 patients were recruited, median age=53.5 years (IQR=37.3-67.8, 43% male). The Intraclass correlation coefficient (ICC) showed high concordance between the total DLQI scores from paper and iPad® versions (ICC = 0.98; 95% CI 0.97-0.99). Patients took a median of 78 seconds to complete the electronic version and 73 seconds for paper ( $p=0.008$ ): 76% preferred the electronic version and perceived completion to take a shorter time.

### Conclusions

There is high concordance, and thus equivalence, between the iPad and paper versions of the DLQI, with an ICC of 0.98, and a clear patient preference for the iPad version.

## INTRODUCTION

There is increasing interest in utilising technology within clinical medicine: innovations include computerised data entry<sup>1,2</sup>, communication initiatives<sup>3</sup> and virtual reality<sup>4</sup>. Within dermatology, there have been several innovations using electronics and information technology<sup>5-7</sup>. The use of patient reported outcome measures (PROs) in electronic format has also been increasing<sup>8</sup>. However, these formats are usually not validated or compared to their original paper-based versions. This may result in data that is incomparable between the two formats due to the lack of equivalence<sup>9</sup>. Coons et al.<sup>10</sup> have proposed guidelines detailing the level of evidence required to demonstrate equivalence, depending on the amount of modification to the original PRO.

The Dermatology Life Quality Index (DLQI)<sup>11</sup> is the most commonly used dermatology-specific quality of life (QoL) measure in clinical trials<sup>12-14</sup>. The DLQI is easy to use in clinical practice due to its brevity and simplicity<sup>15</sup> with an average completion time of two minutes<sup>16</sup>. In the current era of widespread use of digital devices such as Tablets and smartphones, clinicians, researchers and patients often substitute non-validated electronic versions in place of the original paper version. However, there is an underlying concern whether such data is comparable to two decades of data gathered via the validated paper DLQI,<sup>11,14</sup> posing several challenges in data analysis and interpretation. The availability of a DLQI application that had been validated would alleviate such concerns and contribute to better management of patients with skin conditions by having an easy tool for regular monitoring of disease severity from the patient's own perspective. Moreover, this tool could potentially be used by general practitioners to decide which patients need to be referred, as well as provide reassurance for users of electronic QoL measures across dermatology and other medical fields.

This study aimed at comparing the conventional paper-based and a novel web-based application version of the DLQI, following International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidelines<sup>10</sup>, concerning patient acceptability and preference and in terms of consistency of scores. We also assessed whether there was a carryover effect depending on which format patients completed first (paper versus iPad).

## METHODS

### *Study participants*

The study employed a randomized cross-over design using a within-subjects comparison of the two formats of the questionnaire. The study was conducted at the Dermatology outpatient department, University Hospital of Wales, Cardiff, UK. Inclusion criteria were: patients aged 18 years or older with any confirmed skin condition and the ability to read and understand English. The exclusion criteria were patients who were not able to read and or understand written English, or having a co-existing medical or second dermatological condition of considerable severity as

determined by the investigator, or physical deformities which would prevent writing or use of an iPad. The study protocol was approved by a local Ethics Committee (Ref: 14/SW/0085, NRES Committee, South West-Central Bristol, UK) and the Cardiff and Vale University Health Board Research & Development Department. Written informed consent was completed by each subject prior to entering the study.

### ***The Dermatology Life Quality Index iPad® App***

The DLQI consists of 10 questions concerning a dermatological patient's perception of the impact of their skin disease on different aspects of their QoL over the last week. The items of the DLQI include symptoms and feelings, daily activities, leisure, work or school, personal relationships and the side effects of treatment. Each item is scored on a 4-point scale: not at all/not relevant, a little, a lot and very much. Scores of individual items (0-3) are added to yield a total score (0-30); higher scores mean greater impairment of patient's QoL. The DLQI has been shown to be a strong instrument with respect to its internal consistency, reproducibility, validity and sensitivity to change<sup>14,15,17-19</sup>.

The DLQI was developed into an electronic application on the iPad® by Janssen EMEA® in conjunction with the original copyright holder (AYF, Cardiff University). Only this particular iOS version was tested for the purpose of studying equivalence. The individual items and their response categories/scale were unchanged, allowing users to select options using touch. The application (Psoriasis 360©) is available without charge and may be downloaded from the Apple App Store: <https://appsto.re/gb/-JlFw.i>. It is also available on the Google (Android) App Store: [https://play.google.com/store/apps/details?id=com.sapnagroup.p360&hl=en\\_GB](https://play.google.com/store/apps/details?id=com.sapnagroup.p360&hl=en_GB). Example screenshots of the paper and iPad app versions are given in Figures 1a and 1b respectively.

### ***Study procedure***

Eligible patients were asked to complete the DLQI (both paper and electronic versions). The order of completing of the questionnaires (paper version first versus an iPad® version first) was randomized using a random number generator. After 30 minutes patients were asked to complete the other format (Figure 2). Thirty minutes interval was used to minimise patient waiting time and burden, as following up patients to complete the study at a later date would result in a higher cost and increase the chances of change in disease severity<sup>10</sup>. The research team ensured that patients read a magazine, talked to staff or used their phones to browse in between testing as forms of distraction.

Training to operate the electronic application was given in person to every subject by a member of the research team, who remained with the patient throughout the duration of completion in case the subject needed assistance. The electronic application also has basic instructions on the home screen and all patients were given time to read this prior to completion. Prior to completing either format of the DLQI, patients also completed a short demographic questionnaire on age, gender, literacy levels, visual and tactile impairments, diagnosis, and previous use of tablet computers or the DLQI. Completion of both versions were conducted in a similar environment, both completions for the same subject were either before or after



meeting the doctor, in order to reduce the effect of the doctor's consultation upon patient reported QoL. The time taken by participants to complete the DLQI using the paper version and the application was recorded. Patients were asked to also complete a short questionnaire asking about their perception, attitude and experience with the paper-based and web-based methods, concerning ease or difficulty of administration, acceptability, time requirement, feasibility and being comfortable with disclosing personal information using the novel application-based method.

### **Sample Size**

Sample size was calculated in accordance to ISPOR guidelines<sup>10</sup>. The study power was set at 95%, with an expected intra-class correlation coefficient (ICC) of 0.9 ( $\alpha = 0.05$ ), resulting in a target sample size of 104 patients.

### **Data analysis**

Data analysis was conducted using SPSS version 20®. The concordance of DLQI scores between paper-based and the application-based data was analysed using a two way fixed effects ICC model, which is the most commonly utilised statistical measure in equivalence studies of this nature<sup>20</sup>. Wilcoxon signed rank test was used to compare DLQI scores and completion times between the two formats; both variables were found to be non-normally distributed using Shapiro-wilk. A more stringent score difference of 1 point (3%) between the two versions was considered equivalent, though a majority of studies target a maximum of 5% difference<sup>20</sup>. Sub-analysis was conducted to identify any carryover effect depending on which format of the DLQI patients completed first. Bland-Altman plots were drawn to measure the limits of agreement between the two formats. Equivalence was considered with limits of agreement  $\leq 4$ , which is the minimal clinically important difference (MCID) for the DLQI<sup>21</sup>.

Descriptive analysis was used to present demographic data of the patients and their feedback on the preference and experience of using the tools. Linear regression techniques were used to identify correlation of iPad completion times with age.

## **RESULTS**

### **Socio-demographic characteristics of the study participants**

A total of 104 patients were recruited, mean age 52 years (SD  $\pm$  18.7, 43% male): demographic details are given in Table 1. The most common diagnoses were psoriasis (39%), 'skin lesion' (19%) and eczema (13%). The majority of patients (61%) had their highest level of education at school. 17% of patients had never used a tablet before and 46% stated that they were "a little" or "not" comfortable with a tablet prior to participating in this study.

### **Comparisons of validity and reliability**

As shown in Table 2a, the ICC shows high concordance between the total DLQI

scores from paper and iPad® versions (ICC = 0.98; 95% CI 0.97-0.99). The median difference of scores was also within the hypothesized difference of  $\pm 1$  point ( $p=0.006$ , Figure 3). The lower and higher limits of agreement were -3.1 and 4.1, respectively (Figure 4). Patients took a slightly longer time to complete the DLQI on the iPad® than on paper. The median of the individual time differences was 9 seconds (IQR=-25-13 seconds,  $p=0.008$ ). However, as shown in Table 2b, there was no carryover effect on scores ( $p=0.56$ ) or completion times ( $p=0.76$ ) regardless of which format of the DLQI was used first. Linear regression demonstrated that the time taken to complete the iPad version was weakly correlated in a positive way with age, with older patients taking slightly longer ( $R^2=0.257$ ,  $p=0.012$ ). The estimated increase was 7.99 seconds for each 10 year increase in age.

### ***Comparisons of applicability and practicality***

Patients were asked: 'On a scale of 1 to 10, where 1 is very uncomfortable and 10 is very comfortable, how comfortable were you using the iPad application version of the DLQI?'. In addition patients were also asked: 'On a scale of 1 to 10, where 1 is very difficult and 10 is very easy, how easy did you find it to use the iPad application version of the DLQI?'. Both questions were also asked about the paper version of the DLQI. Patients found both paper and iPad® versions were easy (mean  $9.4 \pm 1.3$  for paper and  $9.6 \pm 1.3$  for iPad®) and comfortable to use (mean  $9.4 \pm 1.1$  for paper and  $9.6 \pm 1.4$  for iPad®) (Table 3). Overall, 57% of patients reported perceived time to complete the iPad® version as shorter than that of the paper version. The format of the questionnaire used first has an effect on the perceived time of iPad® completion; more patients perceived shorter time with iPad® when paper was used first than when iPad® used first (70% vs. 43%;  $p=0.023$ ). The feedback results in other areas were the same whether paper or iPad® was completed first. The majority of patients (76%) preferred iPad® over the paper version. The patients' demographics or previous experience with Tablets did not have any effect on the choice of preference and completion of the questionnaire.

## **DISCUSSION**

PROs are increasingly being used in electronic formats over their paper counterparts due to their inherent benefits, including a more streamlined process as well as increased reliability of data<sup>20</sup>. If not validated alongside the paper format, several new PROs are being validated initially in electronic format<sup>22, 23</sup> to facilitate easier and higher quality data analysis and to reduce the overall cost of administration and storage. Paper-based instruments have a number of limitations such as higher rate of missing values, higher error rates in selecting multiple responses for single option items, data entry error<sup>24</sup> in transferring responses from a paper form to the electronic databases and higher costs associated with administration, collection and processing the data<sup>25</sup>. These issues can be avoided by the use of computer-based administration (CBA) of QoL questionnaires.

However, CBA of PROs presents several challenges<sup>26, 27</sup>. In routine clinical practice, assessment (at each visit) of disease severity and of QoL is labour intensive, requiring a major commitment of resources. Ease of use is one of the most important



factors necessary for assessing QoL as part of routine clinical practice. Furthermore, patients may not be accustomed to such input devices or may be hindered by the lack of Internet connectivity<sup>8</sup>.

CBA of QoL measures such as in the form of web-based applications using touchscreen computers, also called Tablets (e.g. iPad®), is one of the ways that more frequent assessments can be conducted with minimal burden on patients and clinical staff in addition to meeting the requirements outlined above. This method, that includes not only CBA, but also scoring and presentation of QoL results, eliminates the need for a test (interviewer) administrator, as usually needed for traditional paper and pencil formats, while providing immediate "real-time" feedback. Information from assessments can be displayed in graphic reports as visual aids that help guide discussions about treatment options and care planning. The availability of electronic versions of QoL instruments on various computer-based devices has the potential to reduce both the respondent burden and administrative time required to transfer the results of these patient-reported outcomes e.g. QoL scores to the clinician's desk enhancing the feasibility and logistics of integrating real-time QoL assessment data for immediate use into routine clinical care to aid decision-making. A further benefit of electronic data capture is the ability to record time and date stamps, in contrast to paper capture whereby completion may occur at a different time to that recorded or intended; a feature particularly useful for diary data. The computer-based measurement of QoL was well accepted by patients who felt that this method was a useful tool to inform the clinician about their problems<sup>28</sup>. Data are more complete on the electronic questionnaires compared with paper questionnaires, data handling is greatly simplified and the majority of patients prefer electronic completion<sup>29</sup>. The availability of an electronic format of the DLQI could potentially streamline referral systems from primary care, allowing more appropriate allocation of appointments and resources. For example, the DLQI is integral to guidelines assessing the severity of psoriasis<sup>30</sup> and chronic hand eczema<sup>31</sup> and referrals could potentially be triaged according to DLQI severity. In the research setting the availability of a web-based application would facilitate more efficient data collection in multicentre clinical trials and for longitudinal assessments of disease severity.

In response to the increasing demand, a web-based application of the DLQI has been developed to encourage its further uptake in the current modernised clinical and research settings in many countries. Although computerised administration of QoL tools in other specialities has been shown to have numerous advantages over traditional paper-based tools<sup>32</sup>, this method of QoL assessment to present an overall disease severity idea has not yet been widely used in dermatology.

Level of education and literacy are important to consider when conducting PRO studies<sup>33</sup>: this study is representative of the general population with the study subjects' education ranging from secondary school (22.9%) to university level (37.6%). Previous experience with use of a Tablet device did not affect results, with 17.3% of patients having never used one before and 46.2% stating that they were 'a little comfortable' or 'not comfortable' with using a Tablet. Overall, 76% of patients preferred the iPad version to the paper version, and found it easier to use and more comfortable. Furthermore, 93% of patients perceived that the iPad was quicker to complete or took the same time as the paper version, despite on average being

slower by a median of 9 seconds ( $p < 0.008$ ). Similar findings have been reported in many studies comparing the electronic and paper PROs<sup>9, 20, 34</sup>. However, patients were aware they were being timed when completing both versions of the DLQI, which could be a potential source of bias. Slower completion times could also be attributed to the lack of familiarity of navigating on the iPad and occasional non-responsiveness of the touch screen. Investigators reported that various patients did not know how to 'touch' the screen appropriately and often searched for a 'next' button rather than scrolling down, despite instructions provided to the user on every occasion. This may be attributed to a simple design flaw in the application itself whereby navigation may be updated to become more intuitive. This study indicates that patients enjoy using the iPad more and the extra time spent had a negligible impact on patient experience. One concern exhibited by a few patients included potential infection risk with shared iPads, though this may be less of an issue where personal electronic devices are used to monitor QoL changes over a period of time.

There are some limitations to the study. For example, a 30 minutes washout period may be considered too short and result in a carryover, or 'training', effect, though there was no statistical evidence of this (Table 2b). Theoretically, this only may have occurred when the iPad was administered first, as patients spent longer on average completing it, therefore possibly having more time to remember the questions and answers. This effect however was counteracted by the cross-over study design, and reading material was provided to patients as a 'distraction'. Nevertheless, there is no consensus on the ideal interval period between PRO administrations when carrying out test-retest validation: intervals used have ranged from one minute to seven years<sup>35</sup>. Other studies have also used 30 minutes as a washout period<sup>36</sup>. In order to reduce patient time and travel burden, as well as to ensure that disease severity did not fluctuate in between administrations, the shorter washout period of 30 minutes was used. Touch screen surfaces are also prone to accidental touches, which may result in unintentional item responses subsequently contributing to final score differences. The electronic version of the DLQI utilised in this study does not allow completion until all items are answered, which may impact validity if patients are coerced into answering questions they may have otherwise skipped on a paper format. This could have ethical implications from not giving patients the choice of not responding to a question if they do not wish to do so. In the DLQI, this issue is partly addressed by having a 'not relevant' option in eight of the ten questions. The median score difference of '0' is unlikely to be clinically significant and strong correlation suggests that the two formats may be used interchangeably. Though the significant p-value of 0.006 for median total score difference is statistically significant, this is likely due to the large sample size<sup>37</sup>. Furthermore, the MCID for the DLQI is four<sup>21</sup> and therefore the difference in scores is negligible in a clinical context. The limits of agreement from the Bland-Altman plots (-3.4 to 4.1) are also similarly reassuring. Differential item functioning (DIF) was not assessed as the DLQI total score is most relevant in clinical decision-making<sup>14</sup>.

Touchscreen devices offer many advantages including portability and real-time assessment of QoL status<sup>38</sup>. Though this study did not involve full psychometric evaluation of the DLQI, there is evidence to suggest that where minimal modifications have been made, psychometric properties remain intact and need not be tested again<sup>10, 20, 39</sup>. Whilst cognitive debriefing is suggested for equivalence

studies of electronic PROs where only minor modifications are made<sup>10</sup>, this requirement was circumvented by using a higher threshold for testing equivalence (i.e. by comparing scores). It is hoped this will provide further reassurance for users who may have had concerns regarding the validity of scores from the use of the DLQI in the previously non-validated electronic formats that have been used for many years. Formally testing such measures in this novel format provides confidence for end users who might otherwise have been reluctant to consider use of such formats because of concerns about validity or applicability. Thus such studies may have wider and reassuring implications not just for the DLQI, but also for other PROs within dermatology and across other medical specialties, encouraging early simultaneous validation of electronic and paper versions. Several challenges remain, including interface design decisions, data collection<sup>40</sup> and adapting electronic PROs to target populations, particularly in patients with physical disabilities or other impairments<sup>41</sup>. Nevertheless, this study has demonstrated that when the DLQI is migrated to an electronic format, the scores are equivalent, despite an overall slower completion time, which will become negligible with increased use and improvements to the application (app) interface. This study provides evidence of equivalence for this electronic application in particular (Psoriasis 360©), and future/other iterations of the electronic DLQI may not necessarily be equivalent. However, in most cases the changes to font size and layout are minor and thus repeated equivalence studies may be deemed unnecessary<sup>10</sup>.

The majority of patients preferred the electronic DLQI over the paper format, reflecting the findings of many similar studies<sup>30, 42-43</sup>. This study demonstrates equivalence in the measurement properties of paper and electronic formats, providing confidence for the use of electronic format of the DLQI in both clinical and research settings, thereby paving the way for the digital era into current practices. The digital era in medicine will continue to be fuelled by a new generation of healthcare professionals who have been trained in this new platform. Patients and healthcare professionals are becoming more comfortable communicating and delivering their clinical expertise within a digital environment. In this context the electronic DLQI would be a valuable instrument in professionals' digital healthcare toolbox.

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## TABLES

**Table 1** Demographic characteristic of the study participants (DLQI study)

	All (n=104)		Paper First (n=57)		iPad First (n=47)	
<b>Age</b>	Mean ± sd Median (IQR) Min and max (n=96)	51.5 ± 18.7 53.5 (37.3-67.8) 20 - 89	Mean ± sd Median (IQR) Min and max (n=53)	51.5 ± 19.3 54 (33-68) 20 - 89	Mean ± sd Median (IQR) Min and max (n=43)	51.4 ± 18.2 50 (38-67) 20 - 85
<b>Sex</b>	Male Female	43.3% (45) 56.7% (59)	Male Female	50.9% (29) 49.1% (28)	Male Female	34.0% (16) 66.0% (31)
<b>Nationality</b>	British Other	91.3% (95) 8.7% (9)	British Other	91.2% (52) 8.8% (5)	British Other	91.5% (43) 8.5% (4)
<b>First Language</b>	English Welsh Other	90.4% (94) 1.9% (2) 7.7% (8)	English Welsh Other	87.7% (50) 3.5% (2) 8.8% (5)	English Welsh Other	93.6% (44) - 6.4% (3)
<b>Education</b>	Secondary School University	60.6% (63) 37.6% (41)	Secondary School University	57.9% (33) 42.1% (24)	Secondary School University	63.8% (30) 36.2% (17)
<b>Visual Impairment</b>	None Glasses Other condition Unspecified Missing data	59.6% (62) 29.8% (31) 5.8% (6) 1.9% (2) 2.9% (3)	None Glasses Other condition Unspecified Missing data	64.9% (37) 24.6% (14) 5.3% (3) 3.5% (2) 1.8% (1)	None Glasses Other condition Unspecified Missing data	53.2% (25) 36.2% (17) 6.4% (3) - 4.3% (2)
<b>Tactile Impairment</b>	Yes No	9.6% (10) 90.4% (94)	Yes No	8.8% (5) 91.2% (52)	Yes No	10.6% (5) 89.4% (42)
<b>Diagnosis</b>	Unknown Skin Lesion Psoriasis Eczema/Dermatitis Alopecia Vitiligo Infection Acne/Folliculitis Cyst Non-skin cancer Allergy Hidradenitis Autoimmune/inflammatory condition ... Missing data	2.9% (3) 19.2% (20) 38.5% (40) 13.5% (14) 1.0% (1) 1.9% (2) 3.8% (4) 6.7% (7) 2.9% (3) 1.9% (2) 1.0% (1) 1.9% (2) 1.9% (2) ... 2.9% (3)	Unknown Skin Lesion Psoriasis Eczema/Dermatitis Alopecia Vitiligo Infection Acne/Folliculitis Cyst Non-skin cancer Allergy Hidradenitis Autoimmune/inflammatory condition ... Missing data	5.3% (3) 22.8% (13) 33.3% (19) 14.0% (8) - 1.8% (1) 3.5% (2) 5.3% (3) 3.5% (2) 1.8% (1) 1.8% (1) 3.5% (2) 1.8% (1) ... 1.8% (1)	Unknown Skin Lesion Psoriasis Eczema/Dermatitis Alopecia Vitiligo Infection Acne/Folliculitis Cyst Non-skin cancer Allergy Hidradenitis Autoimmune/inflammatory condition ... Missing data	- 14.9% (7) 44.7% (21) 12.8% (6) 2.1% (1) 2.1% (1) 4.3% (2) 8.5% (4) 2.1% (1) 2.1% (1) - - 2.1% (1) ... -
<b>Tablet Use</b>	Daily Less Often Never	49.0% (51) 32.7% (34) 17.3% (18)	Daily Less Often Never	40.4% (23) 43.9% (25) 14.0% (8)	Daily Less Often Never	59.6% (28) 19.1% (9) 21.3% (10)

<b>Tablet Comfort</b>	<i>Missing data</i>	1.0% (1)	<i>Missing data</i>	1.8% (1)	<i>Missing data</i>	-
	Very Comfortable	52.9% (55)	Very Comfortable	54.4% (31)	Very Comfortable	51.1% (24)
	A Little Comfortable	30.8% (32)	A Little	29.8% (17)	A Little	31.9% (15)
	Not Comfortable	15.4% (16)	Comfortable		Comfortable	
<b>Used DLQI before?</b>	<i>Missing data</i>	1.0% (1)	Not Comfortable	14.0% (8)	Not Comfortable	17.0% (8)
	Yes	9.6% (10)	<i>Missing data</i>	1.8% (1)	<i>Missing data</i>	-
	No	89.4% (93)	Yes	7.0% (4)	Yes	12.8% (6)
	<i>Missing data</i>	1.0% (1)	No	93.0% (53)	No	85.1% (40)
			<i>Missing data</i>	-	<i>Missing data</i>	2.1% (1)

**Table 2a** Equivalence analysis of paper and electronic DLQI overall mean scores and mean completion time

	Paper	iPad®	ICC* (95% CI)	Difference (P – I)	Limits of agreement‡	
					lower	upper
<b>DLQI scores (n=104)</b> <i>Median (IQR)</i>	5.0 (1-12)	4.0 (1-11)	0.98 (0.97 – 0.99)	0.0 (0-1)†	-3.1	4.1
<b>DLQI times (mins:seconds)</b> <i>Median (IQR)</i>	1:13 (00:56-01:36)	1:18 (01:03-01:39)	0.59 (0.39 – 0.72)	-0:09 (00:25-00:13)†		

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

P-I = Paper - iPad®

\* Hypothesizing coefficient of  $\geq 0.9$

† p value < 0.05 calculated by Wilcoxon Signed Rank test

‡ Limits of agreement calculated from Bland-Altman plots (Figure 4)

**Table 2b** Equivalence and carryover analysis of paper and electronic DLQI

	All (n=104)	Paper First (n=57)	iPad® First (n=47)
<b>Paper Score:</b>			
Median (IQR)	5 (1-12)	5 (1-12.5)	6 (1-12)
Min and max	0 – 30	0 - 26	0 – 30
<b>iPad® Score:</b>			
Median (IQR)	4 (1-11)	4 (0.5-10)	6 (1-12)
Min and max	0 - 27	0 - 26	0 – 30
<b>Paper Time (mins:seconds):</b>			
Median (IQR)	01:13 (00:56-01:36)	01:24 (01:06-01:40)	01:03 (00:50-01:29)
Min and max	00:28 – 04:15	00:28 – 04:15	00:30 – 02:49
<b>iPad® Time (mins:seconds):</b>			
Median (IQR)	01:18 (01:03-01:39)	01:13 (00:58-01:27)	01:25 (01:09-01:53)
Min and max	00:35 – 08:24	00:35 – 08:24	00:49 – 02:49
<b>Score difference:</b>			
Median (IQR)	0 (0-1)	0 (0-1.5)	0 (0-0)
Min and max	(-3) – 11	(-2) -11	(-3) – 5
p value	0.006†		0.56†
Carryover effect			
<b>Time difference (mins:seconds):</b>			
Median (IQR)	-00:09 (-00:25-00:13)	00:09 (-00:09-00:23.5)	-00:26 (-00:46-00:11)
Min and max	(-06:45) – 00:58	(-06:45) – 00:58	(-01:53) – 00:16
p value	0.008†		0.76†
Carryover effect			

† p-value calculated by Wilcoxon Signed Rank test

**Table 3** Comparisons of applicability and practicality of paper and electronic versions of the DLQI

	All (n=104)		Paper First (n=57)		iPad® First (n=47)	
	Paper	iPad®	Paper	iPad®	iPad®	Paper
<b>Ease of use:</b>						
Median	10	10	10	10	10	10
(IQR)	(9-10)	(10-10)	(10-10)	(10-10)	(9-10)	(9-10)
<b>Comfort:</b>						
Median	10	10	10	10	10	10
(IQR)	(9-10)	(10-10)	(9-10)	(10-10)	(10-10)	(9-10)
<b>Perceived time to complete iPad®</b>						
Shorter than paper	57.7% (60)		70.2% (40)		42.6% (20)	
The same as paper	35.6% (37)		26.3% (15)		46.8% (22)	
Longer than paper	5.8% (6)		3.5% (2)		8.5% (4)	
Missing data	1.0% (1)		-		2.1% (1)	
<b>Preference</b>						
Paper	13.5% (14)		15.8% (9)		10.6% (5)	
iPad®	76.0% (79)		75.4% (43)		76.6% (36)	
No preference	10.6% (11)		8.8% (5)		12.8% (6)	

Score: 10 = very easy or very comfortable, 1 = very difficult or very uncomfortable

## Figures

Figure 1a The original DLQI questionnaire<sup>11</sup>

DERMATOLOGY LIFE QUALITY INDEX				DLQI
Hospital No:	Date:	Score:	<div style="border: 1px solid black; width: 40px; height: 20px; display: inline-block;"></div>	
Name:	Diagnosis:			
Address:				
<p><b>The aim of this questionnaire is to measure how much your skin problem has affected your life OVER THE LAST WEEK. Please tick <input type="checkbox"/> one box for each question.</b></p>				
1.	Over the last week, how <b>itchy, sore, painful</b> or <b>stinging</b> has your skin been?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
2.	Over the last week, how <b>embarrassed</b> or <b>self conscious</b> have you been because of your skin?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
3.	Over the last week, how much has your skin interfered with you going <b>shopping</b> or looking after your <b>home</b> or <b>garden</b> ?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not relevant <input type="checkbox"/>
4.	Over the last week, how much has your skin influenced the <b>clothes</b> you wear?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not relevant <input type="checkbox"/>
5.	Over the last week, how much has your skin affected any <b>social</b> or <b>leisure</b> activities?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not relevant <input type="checkbox"/>
6.	Over the last week, how much has your skin made it difficult for you to do any <b>sport</b> ?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not relevant <input type="checkbox"/>
7.	Over the last week, has your skin prevented you from <b>working</b> or <b>studying</b> ?	Yes No	<input type="checkbox"/> <input type="checkbox"/>	Not relevant <input type="checkbox"/>
	If "No", over the last week how much has your skin been a problem at <b>work</b> or <b>studying</b> ?	A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
8.	Over the last week, how much has your skin created problems with your <b>partner</b> or any of your <b>close friends</b> or <b>relatives</b> ?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not relevant <input type="checkbox"/>
9.	Over the last week, how much has your skin caused any <b>sexual</b> <b>difficulties</b> ?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not relevant <input type="checkbox"/>
10.	Over the last week, how much of a problem has the <b>treatment</b> for your skin been, for example by making your home messy, or by taking up time?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not relevant <input type="checkbox"/>

Please check you have answered EVERY question. Thank you.  
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**Figure 1b** Example screenshot from the DLQI iPad app

The screenshot shows the DLQI iPad app interface. At the top, the status bar indicates 'iPad', signal strength, time '15:10', and battery level '93%'. Below the status bar, a progress indicator shows '0/10 Questions Answered' and an 'Exit' button. The main content area features two questions with radio button options, set against a background image of a green field under a blue sky with clouds.

1. Over the last week, how itchy, sore, painful or stinging has your skin been?

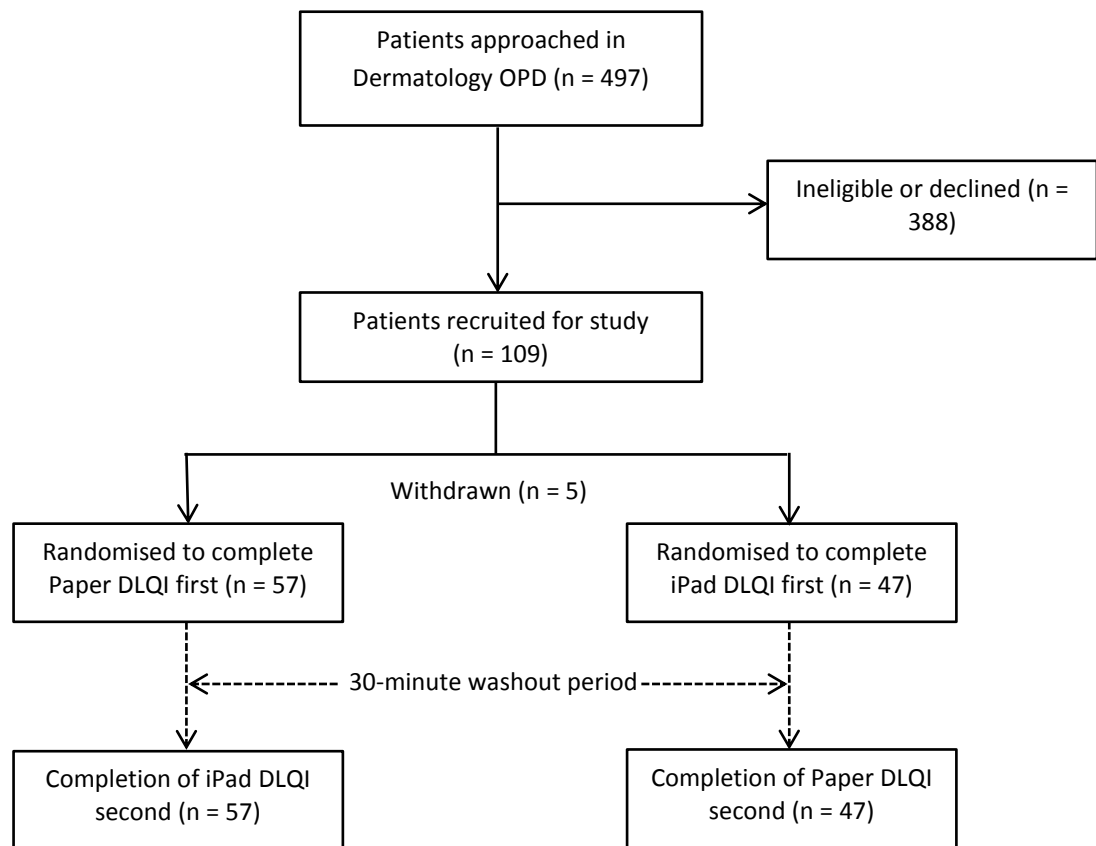
- ☐ Very much
- ☐ A lot
- ☐ A little
- ☐ Not at all

2. Over the last week, how embarrassed or self conscious have you been because of your skin?

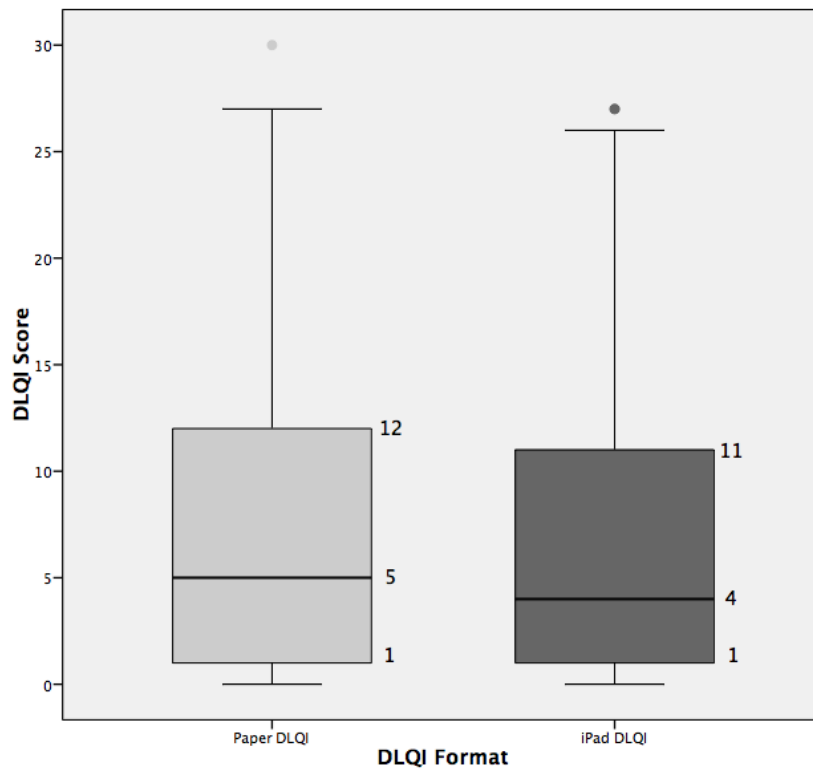
- ☐ Very much
- ☐ A lot
- ☐ A little
- ☐ Not at all

At the bottom, there are two blue buttons labeled 'Privacy' and 'Terms of use', and the Cardiff University logo on the right.

**Figure 2** Flow diagram of the study procedure



**Figure 3** Box plot demonstrating the score distribution of both paper and iPad DLQI formats



The bottom whisker represents the lowest value, and the upper whisker represents the highest value. The dot represents 'one outlier'. The upper level of the box represents the 75<sup>th</sup> percentile and the lower level of the box represents the 25<sup>th</sup> percentile. The broad horizontal line in the middle of the box represents the median.

**Figure 4** Bland-Altman plot demonstrating Paper and iPad DLQI score agreement

