Institution:
Cardiff University

Unit of Assessment:
UoA1

Title of case study:

The Dermatology Life Quality Index: the leading patient–orientated dermatology outcome measure used worldwide.

1. Summary of the impact

The Dermatology Life Quality Index (DLQI) questionnaire is a clinical and research tool, which has fundamentally shifted dermatology from being doctor-centred to patient-centred. Previously, no standard method to quantify the impact of skin disease on patients existed. The DLQI was created by interviewing people with skin disease and made clinically useful through development and validation of score bands. NICE/SIGN require UK dermatologists to use the DLQI when assessing severe psoriasis and hand eczema. DLQI is used in national psoriasis guidelines in 14 countries, is available in 91 language translations, has been used in 678 clinical research studies and generated £881,236 in royalties to Cardiff University.

2. Underpinning research

Patients' attitudes to their skin disease vary widely and the degree of disability experienced is a key influence on clinical decision-making. It was clear that a dermatology-specific measure was needed that could be used for assessment of all dermatology diseases. In 1994, PhD student Dr Gul Karim Khan supervised by Dr Andrew Finlay (Sen Lect 92-99, Prof 99-09, post retirement in '09 taken on again as Professor of Dermatology with fixed term contract until 2015) and co-supervisor Dr Sam Salek (Lect 85-96, Sen Lect 96-04, Reader 04-06, Prof 06-present, School of Pharmacy) asked 130 patients in Cardiff with a range of skin diseases how their disease had affected their life, and distilled the answers to create 10 questions, scored from 0-30. We designed the DLQI to be simple for use in a busy clinic; questions fitting on one sheet with very simple scoring [3.1]. We established copyright (Library of Congress, Washington) and carried out initial validation.

We demonstrated in Cardiff the utility of the DLQI in assessing in-patient therapy [3.2], Behcet's disease, general practice and hair loss studies (carried out by Finlay with dermatology registrars Dr Habib Kurwa and Dr Diane Williamson, dermatologist Dr Sharon Blackford, and general practitioner Dr Dilys Harlow in 1996-2001, all NHS employees). This work demonstrated the practical value of the measure and worldwide use of the DLQI rapidly developed.

Scores from quality of life (QoL) measures used to be published without description of their meaning. Our study of 1,993 patients with skin disease determined validated descriptive score bandings, allowing the DLQI to be useful in informing clinical decisions (carried out in 2002-2004 by research fellow Dr Yan Hongbo and dermatology registrar Dr Charles Thomas (NHS employees), supervised by Salek and Finlay, published in 2005) [3.3]. The DLQI could then be used to enhance appropriateness of clinical decisions, to audit dermatology services, to assess new drugs and to inform resource allocation.

We sought to make the DLQI useful in daily practice. By proposing in 2005 the Rule of Tens[3.4] as a clinical definition of severe current psoriasis, Finlay enabled dermatologists to learn to interpret DLQI scores, and to recognise that a score over 10 means major impact on life quality [3.3]. This Rule also embedded for the first time a QoL measure into skin disease severity definition. This concept influenced the development of national guidelines for the use of Biologics in psoriasis in 2005 and 2009[3.5] in the UK and abroad.

The very widespread use of the DLQI resulted in many validation studies being published worldwide. We undertook a detailed review identifying all aspects of validation to assist DLQI users. Two School of Pharmacy students supervised by Dr M Basra (Research Fellow 04-12), Salek and Finlay carried out this work in 2007, published in 2008[3.6].

A further essential aspect to interpretation of scores is the magnitude of the Minimal Clinically Important Difference (MCID) for DLQI scores. A Cardiff study in 2002 provisionally established the value and we have submitted for publication new data demonstrating the MCID. Basra with Salek and Finlay carried out this work in 2009-2012.

3. References to the research

3.1. **Finlay AY, Khan GK**. Dermatology Life Quality Index (DLQI) - A simple practical measure for routine clinical use**.** *Clinical and Experimental Dermatology*, 1994; 19: 210-216. PMID: 8033378 DOI: 10.1111/j.1365-2230.1994.tb01167.x (supplied on request) (1,029 citations, Web of Knowledge).

3.2. Kurwa HA, **Finlay AY**. Dermatology inpatient admission greatly improves life quality. *British Journal of Dermatology*, 1995; 133: 575-578. PMID: 7577587 DOI: 10.1111/j.1365-2133.1995.tb02708.x (supplied on request) (84 citations)

3.3. **Hongbo Y**, Thomas C L, **Harrison M A, Salek M S, Finlay A Y**. Translating the science of quality of life into practice: what do Dermatology Life Quality Index scores mean? *Journal of Investigative Dermatology* 2005; 125: 659-664. PMID: 16185263 DOI: 10.1111/j.0022-202X.2005.23621.x (supplied on request) (133 citations)

3.4. **Finlay A Y**. Current severe psoriasis and the Rule of Tens. *British Journal of Dermatology* 2005; 152: 861-867. PMID: 15888138 DOI: 10.1111/j.1365-2133.2005.06502.x (supplied on request) (123 citations)

3.5. Smith C H, **Anstey A V**, Barker J N W N, Burden A D, Chalmers R J G, Chandler D, **Finlay A Y**, Griffiths C E M, Jackson K, McHugh N J, McKenna K E, Reynolds N J, Ormerod A D. **British Association of Dermatologists' guidelines for use of biologic interventions for psoriasis 2009.** *British Journal of Dermatology* 2009; 161: 987-1019. DOI: 10.1111/j.1365-2133.2009.09505.x (103 citations)

3.6. **Basra M K A**, **Fenech R, Gatt R M** , **Salek M S, Finlay A Y**. The Dermatology Life Quality Index 1994-2007: A comprehensive review of validation data and clinical results. *British Journal of Dermatology* 2008; 159: 997-1035. DOI: 10.1111/j.1365-2133.2008.08832.x (85 citations) (see Table 17, p 1020-1026 to back up the claim of usage of DLQI in Phase II and III studies)

4. Details of the impact

Generation of Income

In 1998 the DLQI was established as the leading dermatology measure, planning long-term income generation. We allow its use without charge except for studies funded by for-profit companies. **IMPACT:** 83 pharmaceutical companies/divisions have used the DLQI. The total income generated for Cardiff University from the DLQI has been £881,236 (equivalent to 176,000 patients); the total income from Aug 2008 – June 2013 was £617,778.

Establishment of guidelines

The breakthrough in making the DLQI useful to clinicians was our 2005 simple score interpretation method, the Banding Descriptor concept [3.3], and the psoriasis severity "Rule of Tens" [3.4].
IMPACT: Development of NICE (2006-9) and SIGN (2010) guidelines for the Biologics infliximab, adalimumab and ustekinumab in psoriasis [5.1, 5.2] and (NICE) (2009) for treatment of severe hand dermatitis [5.1]. Adoption within guidelines by national organisations and national registries in 11 countries, e.g. Sweden [5.3] (8 since 2008). Chren commented [5.4] on our Banding Descriptor paper [3.3] and another: "These papers are important for several reasons. First, both studies examine instruments that were developed and refined by Andrew Finlay and his colleagues in Cardiff, highlighting the seminal and sustained effects of their work on improving the measurement of complex constructs in dermatology."

Reach
We have supervised 91 validated translations of the DLQI (51 since 2008), reviewing back translations to ensure accuracy. The DLQI section of the Dermatology Department website (www.dermatology.org.uk), has since 1999 been an essential part of our strategy to make the DLQI easily accessible worldwide. This is constantly updated. All translations are available and instructions for use are given. The website was accessed for DLQI information by 22,703 visits from Nov 2011 – June 2013, bringing web-users to the Cardiff University site. A Google search for DLQI records 183,000 results. The original article [3.1] has been cited 1,029 times.

IMPACT: The DLQI is used internationally and can therefore be used effectively for multi-centre studies e.g. DLQI was used as an outcome measure in Phase III studies of cyclosporine and of all biologics in psoriasis [3.6].

IMPACT: In 2012 alone, publications described DLQI usage in 105 studies of 37 diseases in 25,785 patients in 29 countries (review of all 2012 publications identified by PubMed). The DLQI has been used in over 678 research studies (PubMed review). The DLQI has been of great benefit to dermatology research teams worldwide. Pharmaceutical companies use the measure widely in Phase II and Phase III studies [3.6], as reported in >148 publications (PubMed review). The DLQI is the most frequently used adult QoL measure in psoriasis and in atopic dermatitis [5.5].
We continue to make the DLQI more accessible and useful for clinicians. With Janssen Pharmaceuticals, we have upgraded a free iPhone and iPad app “360 Psoriasis” to include the DLQI and a graphic score readout with meaning. When released in 2014, >6,000 current users will be able download this.

IMPACT: The DLQI in standard software will be used daily by GPs to support decisions such as referral to secondary care and by dermatologists to assist decisions concerning systemic therapy.

Clinicians and healthcare providers benefit
The DLQI assists clinicians to understand their patients and justify their clinical decisions.

IMPACT: Since 2008, all patients with severe psoriasis or with severe hand eczema are assessed with the DLQI (as recommended by NICE) [5.1, 5.2] and this directly influences whether the patient has access to biologics. The DLQI may be helpful to health care providers to identify conditions that need additional clinical support, and DLQI data is used to support clinicians’ requests for additional funding for individual patient therapy. For example people with the condition hidradenitis suppurativa have high scores, reflecting major but unrecognised QoL problems.

Patient benefit
Patient support groups in several countries**,** such as the Finnish Psoriasis Association and the UK Ichthyosis Support Group, give patients access online to the DLQI, so they can use the questionnaire in discussions with their doctor, leading to more appropriate clinical decisions.

IMPACT: When used routinely, 13.8% of clinical decisions in general clinics were influenced by knowing the DLQI score, usually in patients with scores >10 and who were consequently treated more aggressively [5.6].

All dermatologists in the UK and in 10 other countries are required to use the DLQI routinely to support decisions relating to the use of biologics in psoriasis. DLQI usage has resulted in a measureable shift to patient-centred dermatology [5.7].

IMPACT: It has become normal for dermatologists to think of QoL and to measure it to assist their decisions, fundamentally altering the practice of dermatology to a more patient-orientated speciality. Since 2008, 100% of dermatology clinicians in Wales stated that QoL was an influence on their clinical decisions. DLQI scores have become integral to European S3-guidelines [5.8], in defining treatment goals in psoriasis [5.9] and for pharmaco-economic analysis [5.1]. By highlighting the major impact of skin involvement in other conditions, such as HIV/AIDS [5.10], DLQI data may further influence appropriate management.

Competitors and additional Cardiff measures

Other research teams have created similar questionnaires to compete with the DLQI, but the DLQI is the most frequently used measure in research and in clinical practice (PubMed review). We have demonstrated the DLQI's many strengths in comparison [5.7]. Other measures developed in Cardiff by Finlay and colleagues from 1993 to present include the Children's-DLQI, Dermatitis Family Impact (DFI) and Infant's Dermatitis Quality of Life (IDQoL). These are the most frequently used QoL measures in children [5.5]. They are available on the Dermatology Department website (www.dermatology.org.uk), increasing the exposure of the DLQI.

Conclusions

The DLQI as described by the indicators outlined above claims economic impact, impact on the practice of health-care professionals and on health and welfare outcomes for patients.

5. Sources to corroborate the impact

5.1. **Basra MK**, Chowdhury MM, Smith EV, Freemantle N, **Piguet V**. A review of the use of the dermatology life quality index as a criterion in guidelines and health technology assessments in psoriasis and hand eczema. *Dermatol Clin* 2012; 30: 237-44. DOI: 10.1016/j.det.2011.11.002 (Backs up the claim of establishment of guidelines)
5.2. NICE and SIGN guidelines: Psoriasis**:** Infliximab TA134 (2008), pages 4,6,8-13,15-16, available at http://www.nice.org.uk/nicemedia/live/11910/38954/38954.pdf and SIGN Guideline 121: diagnosis and management of psoriasis and psoriatic arthritis in adults. Paragraph 4.3.1, available at http://www.sign.ac.uk/guidelines/fulltext/121/section4.html (Backs up the claim of establishment of guidelines)
5.3. Norlin JM, Steen Carlsson K, Persson U, Schmitt-Egenolf M. Analysis of three outcome measures in moderate to severe psoriasis: a registry-based study of 2450 patients. *Br J Dermatol* 2012; 166: 797-802. DOI: 10.1111/j.1365-2133.2011.10778.x (Backs up the claim of adoption within guidelines by national organisations and national registries)
5.4. Chren M. Measurement of vital signs for skin diseases. *J Invest Dermatol* 2005; 125 (4): viii-ix, available at http://www.nature.com/jid/journal/v125/n4/full/5603538a.html (Backs up the involvement of Professor Finlay and colleagues in Cardiff in improving the measurement of complex constructs in dermatology)
5.5. Rehal B, Armstrong AW. Health outcome measures in atopic dermatitis: a systematic review of trends in disease severity and quality-of-life instruments. *PLoS One* 2011; 6(4): e17520. DOI: 10.1371/journal.pone.0017520 (Backs up the impact of patient benefit)
5.6. **Salek S, Roberts A, Finlay AY**. The practical reality of using a patient-reported outcome measure in a routine dermatology clinic**.** *Dermatology* 2007; 215: 315-9. PMID: 17911989 DOI: 10.1159/000107625 (DLQI influenced decision taking in 37 (13.8%) consultations out of 268. Backs up the impact of patient benefit)
5.7. **Finlay AY, Basra MKA, Piguet V, Salek MS**. The DLQI a paradigm shift to patient-centered outcomes. *J Invest Dermatol* 2012; 132: 2464-5. DOI: 10.1038/jid.2012.147 (Backs up the impact of patient and clinician benefit)
5.8. Pathirana D, Ormerod AD, Saiag P et al. European S-3 guidelines on the systemic treatment of psoriasis vulgaris**.** *J Eur Acad Dermatol Venereol* 2009; 23 (Suppl 2): 1-70. DOI: 10.1111/j.1468-3083.2010.03671.x (Backs up the impact of patient benefit)
5.9. Mrowietz U, Kragballe K, Reich K et al. Definition of treatment goals for moderate to severe psoriasis: a European consensus. *Arch Derm Res* 2011; 303; 1-10. DOI: 10.1007/s00403-010-1080-1 (Backs up the impact of patient benefit from having defined patient-orientated treatment goals)
5.10. Shittu RO, Odeigah LO, Mahmoud AO, Sani MA, Bolarinwa OA. Dermatology Quality of Life impairments among newly diagnosed HIV/AIDS-infected patients in the University of Ilorin Teaching Hospital (UiTH), Ilorin, Nigeria. *J Int Assoc Provid AIDS Care 2013* Jun 14 (epub ahead of print) (Backs up the impact of patient and clinician benefit)