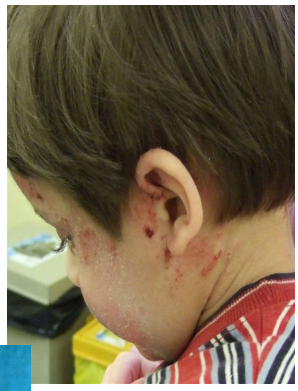
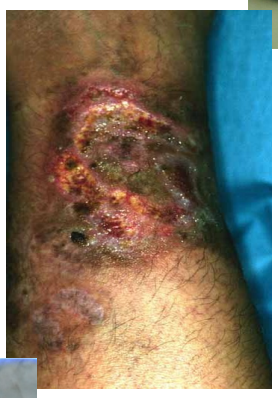
The University of Nottingham

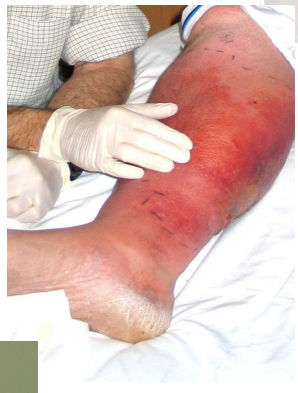
Centre of Dermatology Evidence Based

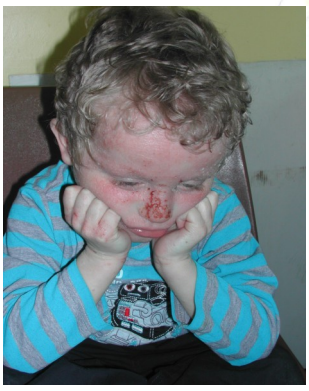
The Centre of Evidence Based Dermatology

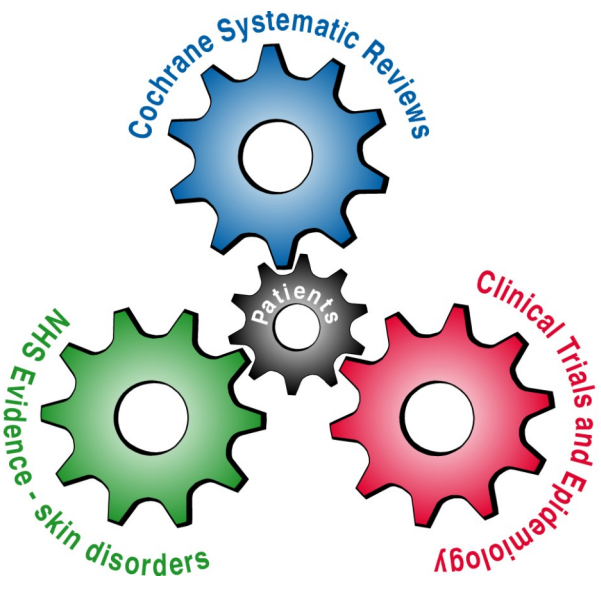
Annual Report 2009-2010











http://www.nottingham.ac.uk/dermatology

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Message from the Director

Welcome to our Annual Report, which covers the period from April 2009 to the end of March 2010. This report is all about the work that we do at the Centre of Evidence Based Dermatology, at the University of Nottingham. It is intended for anyone who is interested in our work, including health care professionals who use our research, and our funders, such as the National Institute for Health Research (NIHR). Patients and members of the public, who help us in our research both as collaborators and as study participants, might also find some bits interesting.

Our task is to prioritise and carry out clinically relevant research for informing day to day decisions in the management of people with skin problems. We do this in three stages, or through three interlinking 'cogs'. Cochrane Systematic Reviews provide the best evidence about the effects of interventions for skin diseases, which are then picked up and developed into fundable proposals by the UK Dermatology Clinical Trials Network and, finally, findings are disseminated to a community of users through the dermatology specialist electronic library (now called *NHS Evidence-skin disorders*). Our research strategy, spelled out in full on page 9 of this Report, is a very simple one: "do really good research", because good quality research prevails.

The last year has been a very productive one for our Centre team, and we have put effort into trying to find out more about the impact of our research. Cochrane Reviews continue to have a high impact, both for informing clinical guidelines and for helping to prioritise future research needs (pp 11-15, p30). Our NIHR programme grant, now in its second year, has bedded down well, with early publications already emerging. The work is on course as per the original plan, thanks to our excellent researchers and administrators. Two of our national clinical trials – water softeners for childhood eczema and another to see whether low dose antibiotics can prevent cellulitis, called PATCH – have successfully reached their target recruitment, and results are eagerly awaited. The PATCH study was the first UK Dermatology Clinical Trials Network study to be funded. It is especially pleasing to see that it is possible for a well organised and democratic national Network to conduct important work in the neglected field of cellulitis - a disease which does not seem to have a home in any specialty. Sadly, the lead clinician for PATCH, Dr. Neil Cox, died last year, but he knew we had achieved the target recruitment before he passed away. Our specialist collection of dermatology electronic resources continues to be one of the most widely accessed disease topics in *NHS Evidence*, now run by NICE. At a personal level, I have also had the honour of being appointed to Chair the NIHR Health Technology Assessment Commissioning Board for a 3 year period; an organisation that I have long admired for being able to address worthy questions that are important to the NHS.

So, we are going through a "purple patch" (no dermatological pun intended) at present, although, like any successful organisation, we could face some tough times ahead and we need to be flexible in order to adapt to the changing needs of society. As always, I would like to close by thanking all who support and use us. Most of all my thanks go to our most important resource – our dedicated staff, without whom none of this work would take place.

16 June 2010

About the Centre of Evidence Based Dermatology

The Centre of Evidence Based Dermatology (CEBD) has an international reputation for skin research and evidence based practice. It is the editorial base for the Cochrane Skin Group, the co-ordinating centre for the UK Dermatology Clinical Trials Network and the base for *NHS Evidence - skin disorders*

CEBD research strategy

"Do really good research"

by:

- Collaborating with the best people who bring different skills and perspectives, wherever they are
- Getting the right staff structures in place to support development and conduct of research
- Maintaining focus on being world leaders in just a few research areas (disease topics include eczema, vitiligo and non-melanoma skin cancer; methods include systematic reviews, clinical trials and outcome measures)
- Engaging with the community who use research to develop new ideas and to measure the impact of our research
- Taking advantage of the funding landscape: being in the right place with the right preliminary data at the right time
- Ensuring that research findings are disseminated credibly and accurately to funders, health care professionals and the wider community
- Do research that really matters to people - research that you would be proud of telling a member of the public about

Hywel Williams and Kim Thomas - on behalf of the CEBD team

January 2010

What is the Cochrane Skin Group?

The Cochrane Skin Group (www.csg.cochrane.org) is one of 52 Collaborative Review Groups that together make up the editorial bases of the international Cochrane Collaboration (www.cochrane.org).

What does the Cochrane Skin Group do?

The editorial base of the Cochrane Skin Group (CSG) is located at the CEBD in Nottingham, where its output regularly informs other strands of work such as the need for new trials. The Cochrane Skin Group has no financial links with any pharmaceutical companies. We receive infrastructure support from the National Institute of Health Research (NIHR).

The Cochrane Skin Group was established in 1997, and has an international board of editors. It currently has 849 members worldwide, of whom 102 are consumer referees and 570 are authors. All authors are volunteers, and one of its particular strengths is the involvement of consumers, who help the Group in many ways because skin disease impacts mainly on the quality of life of the individual. We define consumers as people who have a skin condition, and their close relatives/carers. Many members of the Cochrane Skin Group are also interested in evidence-based dermatology in general.

The CSG aims to provide the best evidence about the effects (beneficial and harmful) of interventions for skin diseases, in the form of Cochrane systematic reviews, so that health professionals and the public can make well-informed decisions about treatments and their uncertainties.

CSG members are invited to propose titles for systematic reviews within our scope, which are then displayed on our website. We operate a title prioritisation process, where we periodically ask the CSG membership to vote on the reviews they think should be done next. Those interested in leading a review team have their application assessed independently by a group of our editors. After title registration, the protocol is developed. This is a public statement by the authors of how they intend to systematically review the topic. The protocol and the subsequent review are peer reviewed before publication.

The finished reviews are published in *The Cochrane Library* which is the principal source of up-to-date high quality evidence on the effects of health care interventions. Access to the Cochrane Library is completely free in the UK, at www.thecochranelibrary.org.

If you are interested in finding out more about CSG, please visit the website www.csg.cochrane.org or e-mail csg@nottingham.ac.uk

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Prof. Dédée Murrell	Sydney, Australia
Dr Luigi Naldi	Bergamo, Italy

Reviews Published 2009-10

Issue April 2009	Topical treatments for chronic plaque psoriasis	Mason A R, Mason J, Cork M, Dooley G, Edwards G

Summary findings

One hundred and thirty one RCTs with 21,448 participants were included. Corticosteroids perform as well as vitamin D analogues and are associated with a lower incidence of local adverse events. However, treatment that combined vitamin D with a potent corticosteroid was more effective than either intervention alone. Further research is required to inform long-term maintenance treatment.

Issue April 2009	Interventions for American cutaneous and mucocutaneous leishmaniasis	González U, Pinart M, Rengifo-Pardo M, Mazaya A, Alvar J,

Summary findings:

Thirty eight trials involving 2,728 participants were included. Most trials within the review had been designed and reported so poorly that they were inconclusive. There is a need for large well-conducted studies that evaluate long-term effects of current therapies to improve quality and standardisation of methods.

Reviews Published 2009-10 cont.

Issue July 2009	Interventions for erythema nodosum leprosum	Van Veen N H J, Lockwood D N J, van Brakel W H,

Summary findings:

Thirteen trials with a total of 445 participants were included. There is some evidence of benefit for thalidomide and clofazimine, but generally the review did not find clear evidence of benefit for interventions in the management of erythema nodosum leprosum. However, this does not mean they do not work, because the studies were small and poorly reported.

Issue July 2009	Safety of topical corticosteroids in pregnancy	Chi C-C, Lee C-W, Wojnarowska F,

Summary findings:

Seven studies of 659,675 participants were included. The available data were limited, and most studies did not find statistically significant associations between topical corticosteroids and pregnancy outcomes. One study found a significant association between first trimester topical corticosteroid use and orofacial cleft, and another found a significant association between very potent topical corticosteroids and low birth weight. Nevertheless, all the studies had drawbacks, and the quality of evidence was low to very low.

Issue October 2009	Oral potassium iodide for Sporotrichosis	Xue S, Rui Gu, Wu T, Zhang M, Wang X

Summary findings:

In the absence of any suitable randomised placebo-controlled trials or comparisons with other treatments in this area, the team were unable to assess the effects of oral potassium iodide.

Issue October 2009	Surgical excision margins for primary melanoma	Sladden M J, Balch C, Brazilian D A, Berg D, Freiman A, Handiside T, Hollis S, Lens M B,

Summary findings:

Five trials (1,633 participants in the narrow excision margin group, and 1,664 in the wide excision margin group) were included. None of the published trials showed a statistically significant difference in overall survival between narrow or wide excision. The summary estimate for overall survival favoured wide excision by a small degree but the result was not significantly different. Therefore, a small (but potentially important) difference in overall survival between wide and narrow excision margins cannot be confidently ruled out.

Reviews Published 2009-10 cont.

Issue April 2010	Interventions for non-metastatic squamous cell carcinoma of the skin	Lansbury L, Leonardi-Bee J,

Summary findings:

One trial involving 65 people was included. This compared the time to recurrence in participants with aggressive skin squamous cell carcinoma who were randomised to receive either adjuvant 13-cis-retinoic acid and interferon alpha after surgery, with or without radiation treatment, or no adjuvant therapy after their initial treatment. There was no significant difference in time to recurrence of tumour between the two groups.

There is a clear need for well-designed randomised studies in order to improve the evidence base for the management of this condition.

Protocols Published 2009-10

Issue March 2010	House dust mite reduction and avoidance measures for treating eczema	Nankervis H, Smith E V, Boyle R J, Rushton L, Williams H C, Hewson D M, Platts-Mills T
Issue January 2010	Emollients for eczema	Oranje A P, de Waardvan der Spek F B, Ordonez C, De Raeve L, Spierings M, van der Wouden J C
Issue January 2010	Topical interventions for genital lichen sclerosus	Chi C-C, Baldo M, Kirtschig G, Brackenbury F, Lewis F, Wojnarowska F
Issue October 2009	Interventions for erosive lichen planus affecting mucosal sites	Cheng S, Kirtschig G, Cooper S, Silcocks P, Thornhill M, Murphy R
Issue October 2009	Interventions for seborrhoeic dermatitis	Okokon E O, Oyo-Ita A, Chosidow O
Issue October 2009	Systemic retinoids for ichthyosis in children	Stefano P, Ciapponi A, Giglio N, Deps P
Issue October 2009	Interventions for cutaneous lichen planus	Gorouhi F, Firooz An, Khatami A, Ladoyanni E, Bouzari N, Kamangar F, Gill J K
Issue July 2009	Interventions for non-metastatic squamous cell carcinoma of the skin	Lansbury L, Leonardi-Bee J, Perkins W, Goodacre T, Bath-Hextall F J Tweed J A
Issue July 2009	Light therapies for acne	Car J, Car M, Hamilton F, Layton A, Lyons C, Majeed A
Issue April 2009	H1 antihistamines for eczema	Apfelbacher C J, Ebert I, Scheidt R, Diepgen T L, Weisshaar E

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What is the UK Dermatology Clinical Trials Network?

The UK Dermatology Clinical Trials Network is a collaborative group spread across the UK and Eire of over 560 dermatologists, nurses, primary care staff, health care researchers and patients/carers. Membership of the UK DCTN is free and is open to anyone with an interest in applied dermatology research.

All members provide their time and expertise on a voluntary basis. The UK DCTN is a registered charity (charity number 1115745) and is an affiliate group of the British Association of Dermatologists (BAD).

What does the UK Dermatology Clinical Trials Network do?

The UK Dermatology Clinical Trials Network (UK DCTN) was established in February 2002 by Professor Hywel Williams and a group of colleagues, in order to provide much needed evidence for dermatology clinical practice.

The aim of the Network is simple - to develop and conduct independent, high quality randomised controlled clinical trials (RCTs) of interventions for the treatment or prevention of skin disease. Priority is given to trials that address questions of importance to clinicians, patients and the NHS. The Network is open to trial suggestions from any of its UK and Eire based members, and these are then developed using a rigorous and pre-defined trial development process, which includes an initial assessment by the UK DCTN Trial Generation and Prioritisation Panel. Funding for individual trials comes from external grant applications made to NIHR partners (eg the HTA, RfPB and charitable bodies such as Action Medical Research and the British Skin Foundation).

The Network is run by an Executive Group with an independent Chair (Gladys Edwards of the Psoriasis Association chaired up to February 2010, at which time Professor Andrew Finlay took over the role) and a Steering Group consisting of approximately 30 members. The Steering Group is responsible for evaluating trial proposals and deciding which ideas are developed further through the Network. The role of the Co-ordinating Centre, based within the Centre of Evidence Based Dermatology at Nottingham University, is to develop and manage the Network's portfolio of clinical trials and to develop the Network as an organisation. Specifically, with regard to trial development and support, we are able to:

- Facilitate and advise on trial development
- Co-ordinate study development teams
- Conduct membership surveys to assist with trial development
- Co-ordinate and write applications for funding
- Set up funded studies - gaining regulatory, ethical and host institution approvals
- Supervise trial managers employed on specific research grants
- Promote the benefits of collective effort within the Network
- Encourage and develop the involvement of service users/consumers

'I have witnessed the growth of the Network from concept to delivering world leading clinical trials that are on course and delivering the highest standard of clinical research in cellulitis, bullous pemphigoid and pyoderma gangrenosum. The hub of the Network in Nottingham has scaled up to embrace the activity of several studies and has engaged dermatologists throughout the UK who would not otherwise have had the opportunity to carry out trials that answer important questions independent[ly] of pharmaceutical companies.'

Dr Tony Ormerod, Clinical Reader in Dermatology, University of Aberdeen and
Clinical Lead for the STOP GAP study

On-going studies

PATCH

The end of 2009 saw a magnificent milestone for the UK DCTN, as the PATCH I study recruited to target. The PATCH I study is investigating whether the use of low dose penicillin can prevent the recurrence of cellulitis. The success of the study is a testament to the determination and hard work of the study team and the 29 recruiting centres involved. In total 274 patients were recruited, making it the largest study into the prevention of cellulitis ever conducted. The results of the study will be available in 2011 and further details can be found in the on-going research section of this report.

BLISTER

The BLISTER study is now recruiting at over 45 centres in the UK, with additional centres recruiting patients in Germany. The aim of this UK DCTN led study is to determine whether the antibiotic doxycycline is a useful alternative to prednisalone for treating bullous pemphigoid. It is investigating whether the benefits of less severe side effects outweigh any potential reduction in effectiveness of the treatment. To date, 38 patients have been recruited into the trial.

STOP GAP

The STOP GAP study is also now up and running, and is the first trial of its kind to formally evaluate the most commonly used systemic treatments for pyoderma gangrenosum (prednisolone and ciclosporin). Again, a large number of recruiting centres are involved, with over 30 patients recruited to date. The STOP GAP and BLISTER studies are an excellent demonstration of the Network in action; trials into such rare conditions would simply not be possible without such collaborative efforts.

LIMIT-1

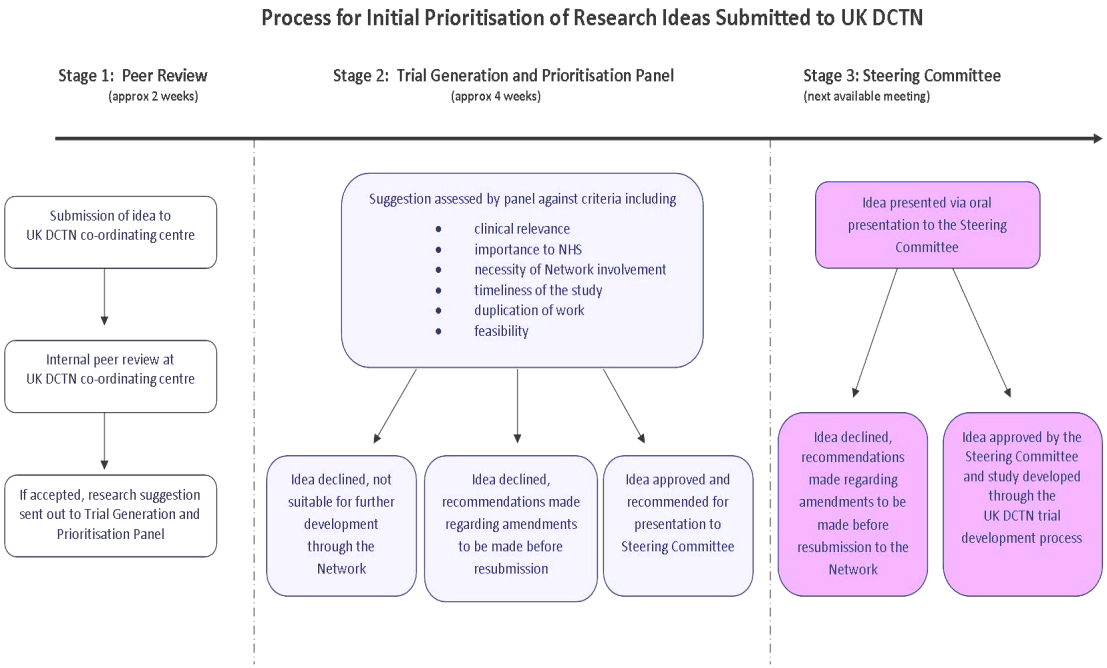
The LIMIT-1 study, a Phase II proof of principle study investigating whether imiquimod is a suitable treatment for lentigo maligna, is currently being set up at eight recruiting centres across the UK. Results of this small study will help to inform the design of a full-scale clinical trial in the future.

Full details of all studies can again be found in the ongoing research section of this report, pages 35 - 64.

Trials in development

The Network is open to trial suggestions from any of its members and these are developed using a rigorous and predefined trial development system. There has never been a better time to conduct clinical research in the NHS in terms of the available infrastructure (e.g. support available via the Comprehensive Local Research Networks) and funding opportunities (e.g. NIHR Health Technology Assessment Awards and Research for Patient Benefit Programmes) available. It is important that the UK DCTN takes full advantage of these opportunities while they are available and maintains a healthy pipeline of trials in development. There are currently seven studies at various stages of the trial development pathway, including potential studies on acne prevention, wound healing in epidermolysis bullosa, skin cancer prevention and the treatment of erosive lichen planus.

The trial development process used by the UK DCTN is shown in the figure below.



'Over the last two years I, and my colleagues working in the National Epidermolysis Bullosa (EB) Service in London and Birmingham, have received enormous assistance from the UK DCTN in devising and planning a clinical trial exploring the use of low dose antibiotics for EB. As a busy dermatologist with little hands-on experience of developing clinical trial protocols and applying for funding, the practical support I have received has enabled this work to proceed; without it, the project would possibly have foundered before getting off the ground'.

Dr Jemima Mellerio, Consultant Dermatologist, St Thomas's Hospital and Clinical Lead for the TREBL study on EB in development with the UK DCTN.

UK Dermatology Clinical Trials Network Awards

UK DCTN SpR Fellowships

The UK DCTN SpR Fellowships continue to go from strength to strength with three awards being made in 2009 due to the outstanding calibre of the applicants. The successful applicants (pictured below from left to right) are Abby Macbeth (Norwich), Kave Shams (Glasgow) and Roz Simpson (Leicester).



As part of the Fellowship programme they have joined the UK DCTN Steering Committee, attended the BEES dermato-epidemiology course and will develop critical appraisal skills further via a targeted reading curriculum.

'One of the best things about the UK DCTN fellowship is the chance to work on things like this with people like you ….. I have learnt a great deal from you and am continually grateful for the opportunities to be involved'.

Emma Smith SpR Fellow 2009-10

UK DCTN Nursing Prize Award

The 2009 Nursing Prize award winner was Gemma Minifie, who is based at the St John's Institute in London and was given the award in recognition of the commitment and enthusiasm shown while working as a research nurse on an acne genetics study. Gemma became the first ever nurse to attend the BEES dermato-epidemiology course and reported back to us that what she learned would be extremely useful in her new role as a nurse practitioner.

The UK DCTN SAS Award

Following consultation with key representatives from the Staff and Associate Specialist (SAS) community, early 2010 saw the launch of the UK DCTN SAS Award. The scheme has been developed to encourage more SAS staff to become actively involved in research. The winner of the first award was Dr Alison Devine, a specialty doctor in dermatology, based at the Glan Clwyd Hospital in North Wales.

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If you are interested in finding out more about the Network, please visit the website www.ukdctn.org

. . . . . remembering Dr Neil Cox

The Neil Cox UK DCTN SpR Fellowship Award

Many of you will already be aware of the tragic death of Dr. Neil Cox on 8th December 2009. Neil was lead clinician for the PATCH study and a long serving member of both the UK DCTN Steering and Executive Committees.

Based in Carlisle, it was Neil who suggested the idea to the UK DCTN for a study investigating the use of low dose penicillin to prevent recurrence of cellulitis of the leg. Neil took on a major role in working with the Network to develop the idea into successful funding applications. His knowledge of cellulitis was phenomenal, and he will be remembered for drawing attention to this common and often ignored debilitating condition, which does not seem to belong to any speciality. Neil recruited patients into the study himself and was always available during the study to deal with recruitment queries right up to the end of his life. He was aware that we had completed our recruitment target of 260 patients for the PATCH I study just before he died. We know he was very proud to have witnessed this, especially since PATCH was the first national study that the UK DCTN took on.

Neil was always a pleasure to work with and was more than a hard–working, knowledgeable, clever and thoroughly decent man. He was an exemplar of how a busy dermatologist working in a district general hospital could still participate in, and lead, clinically important research. We will all miss him very much in the PATCH study team and throughout the UK DCTN. We have lost a champion, a fountain of knowledge, but most of all a good friend.

After considering the best way in which to remember Neil and his wonderful contribution to the Network, the decision has been made to re-name one of the UK DCTN SpR Fellowships as The Neil Cox UK DCTN SpR Fellowship Award. The Neil Cox Award will be made to the Fellowship applicant with the highest overall score and has the full backing of Neil's family. We hope that this award will serve as a lasting and fitting tribute to the wonderful support and enthusiasm that Neil gave to the UK DCTN over the years.

What is NHS Evidence — skin disorders?

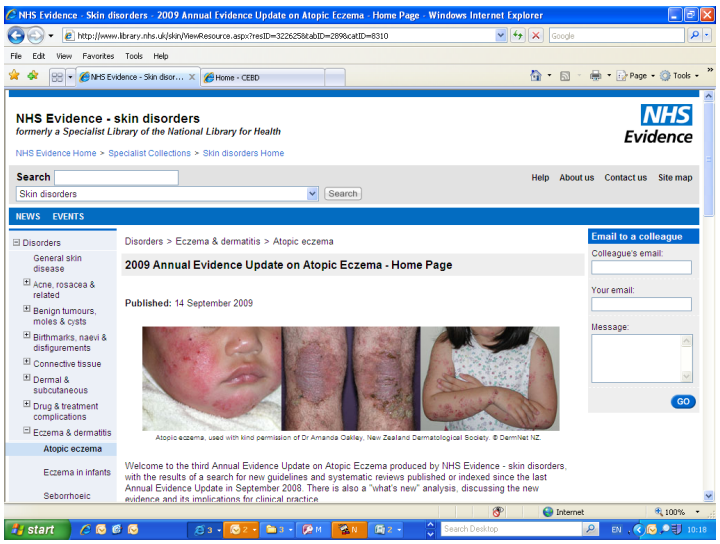
NHS Evidence—skin disorders, formerly known as the National Library for Health (NLH) Skin Disorders Specialist Library, is one of 30 specialist collections that are now provided as part of NHS Evidence. NHS Evidence allows everyone working in health and social care to access a wide range of health information to help them deliver quality patient care.

As well as the specialist collections, a key part of the service is the new NHS Evidence search engine, at www.evidence.nhs.uk.

What does NHS Evidence–skin disorders do?

NHS Evidence–skin disorders is intended as a 'one-stop shop'; a single site that can be used to find quality information on skin disorders and related topics that is relevant for UK health professionals (in particular dermatologists, dermatology nurses and general practitioners). NHS Evidence–skin disorders provides an organised, easily accessible and up-to-date electronic collection of relevant guidelines, policy documents, systematic reviews and other evidence-based resources, together with reference and educational materials and selected patient information.

NHS Evidence–skin disorders also produces monthly e-mail updates to alert subscribers to newly published resources added to the collection, as well as Annual Evidence Updates on acne vulgaris, atopic eczema, psoriasis and skin cancer, which each year search for newly published, high-level evidence.



Skin Cancer	11 May 2009 (20 systematic reviews and 6 invited clinical commentaries)
Atopic Eczema	14 September 2009 (11 systematic reviews)
Psoriasis	2 November 2009 (18 systematic reviews)
Acne Vulgaris	1 March 2010 (9 systematic reviews)

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If you are interested in finding out more about NHS Evidence—skin disorders, please visit the website www.library.nhs.uk/skin

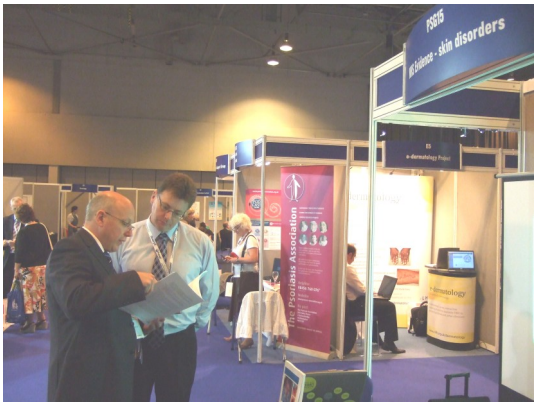
To sign up for the monthly e-mail updates, just follow the link on the right of the home pages at www.library.nhs.uk/skin or e-mail: douglas.grindlay@nottingham.ac.uk, with a request to be signed up

NHS Evidence–skin disorders, overview 2009-10

From April 2009, the operations of the old National Library for Health, including the former Specialist Libraries, were transferred to the new NHS Evidence service. As a result of the transfer a 'Lessons Learned' review has just been completed, the outcomes of which will shape the future role and contracting arrangements for the specialist collections. For much of the report period, NHS Evidence–skin disorders continued to have the most page views of all the NHS Evidence specialist collections, although recently NHS Evidence – mental health has caught us up. NHS Evidence–skin disorders consistently receives 32-35,000 page views per month.

The number of subscribers to our monthly e-mail updates goes on growing, up from 594 at the end of March 2009 to 705 at the end of March 2010. A December 2009 audit of recipients found that in England and Wales 185 dermatology consultants, 80 registrars and 45 SAS staff received the updates. We also have many subscribers amongst dermatology nurses and general practitioners and many recipients in Scotland, Northern Ireland, Eire and 30 other countries around the world.

We have continued our efforts to promote NHS Evidence–skin disorders to potential users. This has involved having stands at six national conferences and talks by Douglas Grindlay at the British Dermatology Nursing Group Annual Meeting, the University of Hertfordshire, and clinical meetings in Cambridge and Bristol. Hywel Williams and Douglas Grindlay also spoke about the work of the specialist collections at the NICE Annual Conference in December 2009.



Dr Douglas Grindlay at the BAD meeting in Glasgow, in 2009

"It is such a fantastic resource" - dermatology nurse specialist

"Thanks very much for your updates. They are superb and high quality, much appreciated" - dermatology registrar

"I will promote your service locally as it is excellent" - consultant dermatologist

The Annual Evidence Updates are now an established and central part of our work. Annual Evidence Updates present the results of a search for new evidence in the form of guidelines and systematic reviews published or indexed in the last year, accompanied by a 'what's new?' commentary on the significance of the new evidence for clinical practice.
In 2009 we published our third Annual Evidence Updates on acne vulgaris (2 March), atopic eczema (14 September) and psoriasis (2 November). On 11 May we produced our second Annual Evidence Update on Skin Cancer, which was once more a successful collaborative effort with the team from NHS Evidence–cancer.

A new innovation this year has been the involvement of UK DCTN SpR Fellows in writing the commentaries with Hywel Williams, which has proved very successful and educational while, for the psoriasis commentary, Dr Richard Warren in Manchester kindly took the lead.

Dr Jonathan Batchelor and Dr Emma Smith (Specialist Registrars and UK Dermatology Clinical Trials Network Fellows) - authors on recent Annual Evidence Updates

In 2009 we had four papers based on our Annual Evidence Updates commentaries published in the refereed journal *Clinical and Experimental Dermatology*. Feedback suggests these papers are popular for continuing professional development and journal clubs, and they help to spread the word about the Annual Evidence Updates and NHS Evidence–skin disorders to a wider, international audience.

We are continuing our co-ordinating role on the Skin Module of UK DUETs, the Database of Uncertainties about the Effects of Treatments (www.library.nhs.uk/DUETs). A comprehensive new module of uncertainties on vitiligo, derived from the Cochrane Review, was added to DUETs in April 2009. A module of uncertainties on acne vulgaris derived from clinician questions and all the relevant systematic reviews was also added to DUETs in July 2009. More recently, the DUETS modules on atopic eczema and acne have been reviewed and updated in the light of the new evidence found in the most recent Annual Evidence Updates. Douglas Grindlay has been a member of the steering group for our NIHR-funded project to gather patient and clinician questions on vitiligo, to feed in to the DUETs database and a James Lind Alliance research prioritisation exercise.

Health Care Needs Assessment

A major achievement this year for the NHS Evidence–skin disorders team has been the co-authoring with Dr Julia Schofield of *Skin conditions in the UK: a Health Care Needs Assessment*[1], which is a much-expanded update of the 1997 Dermatology Health Care Needs Assessment. This report was published in September 2009 as the first official publication of the Centre of Evidence Based Dermatology. NHS Evidence–skin disorders was a key source of information and evidence for this report, in particular the Annual Evidence Updates.

"[This document] is excellent, clearly written, and of immense importance and I congratulate the authors" *Sir Muir Gray, CBE, Consultant in Public Health*

The official launch of the Health Care Needs Assessment occurred on 22 October 2009, at the University of Hertfordshire. The programme linked the assessment of need relating to people with skin conditions to the commissioning of dermatology services.

Pictured at the launch, from left to right: Stephen Kownacki (Primary Care Dermatology Society), Julia Schofield (Lead author, Consultant Dermatologist, Lincoln, and Principal Lecturer, University of Hertfordshire), Douglas Grindlay (NHS Evidence-skin disorders) and Andrew Langford (Skin Care Campaign).

A second event held in London on the 17 November 2009, organised by The British Epidermo-Epidemiology Society (BEES) in conjunction with the Dowling Club, marked the launch of the Health Care Needs Assessment. A series of invited speakers gave different perspectives as to how UK dermatology services should be configured in the future.

Book Review

Skin conditions in the UK: a Health Care Needs Assessment Julia Schofield, Douglas Grindlay and Hywel Williams, Centre of Evidence Based Dermatology, University of Nottingham, 2009 - recently favourably reviewed in the *British Journal of Dermatology* 2010 **163,** 232-233 by Alex Anstey of the Department of Dermatology, Royal Gwent Hospital in Newport

Impact of the Centre's Research

We aim to do high quality research that changes practice or improves the lives of patients

Background

The Centre of Evidence Based Dermatology is proud of its reputation for conducting independent, patient-focused research, that is able to answer questions of importance to clinicians, patients and health providers. This reputation is evidenced by the range of randomised controlled trials currently being undertaken in the Centre. These are all studies that are unlikely to be funded through commercial sources, but which nevertheless address questions that are of importance to the health community.

Over the last 18 months, we have been fortunate to have received funding for a programme of research looking at setting priorities and reducing uncertainties for people with skin disease (SPRUSD - see page 37 for further details). This has meant that we are involved more than ever in all aspects of the research cycle; from working with patients and health professionals in order to prioritise research questions, through to engaging with policy makers and guideline writers to ensure that our findings are implemented into practice as quickly as possible. Some examples of the impact of our research are detailed on the following pages.

First Centre of Evidence Based
Dermatology patient panel meeting held at the Attenborough Nature
Reserve on 9th November 2009

National Institute for Health and Clinical Excellence (NICE) Technology Appraisals

The Centre of Evidence Based Dermatology and the Cochrane Skin Group are both stakeholders for NICE, and regularly contribute to the development and update of NICE clinical guidelines and technology appraisals. A summary of the protocols and guidance that members of the Centre have commented on during 2009/10 are summarised in the table below.

Summary of NICE reviews the Centre has commented on during 2009/10
Food allergy in children
Skin cancer guideline (update)
Alitretinoin for the treatment of chronic eczema of the hand refractory to steroids
Ustekinumab for the treatment of moderate to severe psoriasis
Etanercept, Infliximab and Adalimumab for the treatment of psoriatic arthritis
Provision of information for the general public on the prevention of skin cancer

NICE have also requested a copy of our recently published Health Care Needs Assessment (see pages 26 and 89), which is being used to inform guidelines for the treatment of low risk basal cell carcinoma in the community.

Other Clinical Guidelines

Systematic reviews that have been published by the Cochrane Skin Group are commonly used to inform national and international guidelines. Some recent examples include:

Cochrane Review	Guideline
Interventions for vitiligo (2010)	Clinical Knowledge Summaries (CKS) topic on vitiligo
Safety of topical corticosteroids in pregnancy (2009)	European Dermatology Forum's (EDF) guideline on the safe use of topical steroids in pregnancy
Interventions for rosacea (2009)	German and Dutch guidelines on the management of rosacea
Surgical excision margins for primary cutaneous melanoma (2009)	Cochrane Gem on the NHS Clinical Knowledge Summaries site
Probiotics for treating eczema (2008)	Clinical Knowledge Summaries (CKS) on atopic eczema
Interventions for basal cell carcinoma of the skin (2008)	College of Optometrist's guideline on BCC of the eyelid

In addition, Dr Sarah Gardner (Skin Group editor) has been awarded a Commonwealth Fund's Harkness Fellowship in Health Care Policy & Practice. This project will ensure that the results of Cochrane Reviews are fed into national policy making. A good example of this is the Cochrane Review of intervention to reduce staphylococcus aureus in the management of atopic eczema. This review resulted in a recent call from the NIHR Health Technology Assessment Board to fund a trial examining the use of topical and oral antibiotics for the treatment of infected eczema.

Commissioning

Professor Hywel Williams has recently been appointed as Chair of the NIHR Health Technology Assessment Commissioning Board and Deputy Director of the Health Technology Assessment (HTA) Programme. This is a three-year appointment, starting in 2010.

If you are interested in finding out more about the HTA, please visit the website:

http://www.hta.ac.uk

Prioritisation of Research

Over the last couple of years, we have been working with the James Lind Alliance (JLA) in order to establish research priorities relating to skin disease. This process brings together a working partnership of patients and health professionals, who are tasked with identifying, and prioritising, the most important research uncertainties in the field.

Two topics are being explored in this way - vitiligo (2009/10) and eczema (2010/11). The vitiligo prioritisation exercise is now complete and all of the 93 research uncertainties that were identified during the process have been included on the UK Database of Uncertainties about the Effects of Treatment (DUETs) (http://www.library.nhs.uk/duets).

Anyone who is interested in contributing to the eczema prioritisation exercise, please contact Helen.nankervis@nottingham.ac.uk

A list of the TOP 10 most important research questions for vitiligo was finalised at a meeting in London in March 2010. The day was attended by 43 delegates (including broadly equal numbers of patients and health professionals). The results of this meeting will be published shortly.

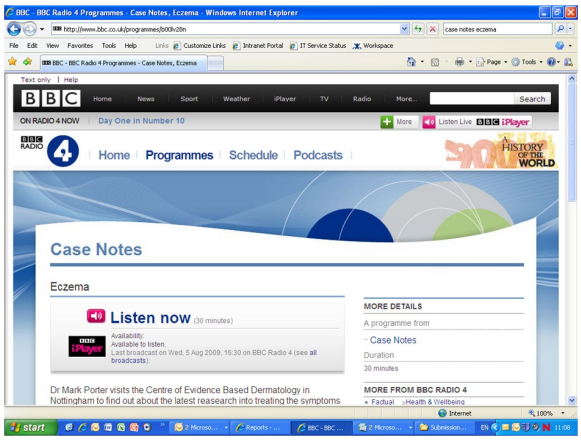
Feedback from delegates at the meeting:

"Format allowed for varied expertise and sharing of views and opinions"
"Excellent exchange of views"
"People were listened to"
"Very interesting experience and process"

In addition to the above JLA prioritisation exercises, the Centre of Evidence Based Dermatology contributes to the prioritisation of skin research in several ways. Through its work for NHS Evidence-skin disorders, uncertainties identified in relevant systematic reviews are entered onto the UK Database of Uncertainties about the Effects of Treatments (DUETs). In addition, the UK Dermatology Clinical Trials Network has its own Prioritisation and Generation Panel, which assesses all trial suggestions submitted to the Network against set criteria, in order to determine relevance to the NHS, feasibility, and clinical importance. We have also been approached for advice by a group in Pennsylvania, who are looking at the prioritisation of research in psoriasis.

Dissemination of Research

We are keen to support initiatives that ensure up-to-date research evidence is available for those who need it most. We work with patient support groups and the media whenever possible to disseminate our research findings, and have now established a CEBD Patient Panel in order to help with this process. Over the last year our work has been highlighted on Radio 4 (an interview on Dr Mark Porter's Case Notes programme); BBC Radio Nottingham; BBC Radio Suffolk and on the BBC Local TV News. The Case Notes broadcast can be found at http://www.bbc.co.uk/programmes/b001v28n



Our Annual Evidence Updates, published through *NHS Evidence - skin disorders*, continue to be a popular resource. These updates search for and summarise new evidence that has been published over the last year. They include expert commentaries on the significance of this evidence for clinical practice, and are summarised and disseminated as abridged peer reviewed publications in *Clinical and Experimental Dermatology* in addition to the NHS Evidence website. The recent acne update was highlighted by MDLinx at http://mdlinx.com and was identified as the "top read" for that issue.

Full details of the Evidence Based Updates are available at www.library/nhs.uk/skin

We also hold an Annual Evidence Based Update Conference in May each year. This popular meeting tackles a specific topic each year chosen by the past year's audience. The topic for May 2009 was urticaria and the topic for 2010 is eczema. Further details of the day can be found in the training section of this report.

Publications related to our Annual Evidence Updates

Brown BC, Warren RB, Grindlay DJ, Griffiths CE.
What's new in psoriasis? Analysis of the clinical significance of systematic reviews on psoriasis published in 2007 and 2008. *Clin Exp Dermatol.* 2009;34(6):664-7.

Ingram JR, Grindlay DJ, Williams HC.
Management of acne vulgaris: an evidence-based update. *Clin Exp Dermatol.* 2009 Oct 23. [Epub ahead of print]

Williams HC, Grindlay DJ.
What's new in atopic eczema? An analysis of systematic reviews published in 2007 and 2008. Part 1. Definitions, causes and consequences of eczema. *Clin Exp Dermatol.* 2010;35(1):12-5.

Williams HC, Grindlay DJ.
What's new in atopic eczema? An analysis of systematic reviews published in 2007 and 2008. Part 2. Disease prevention and treatment. *Clin Exp Dermatol.* 2010;35(3):223-227.

Quality of Research

Quality of Reporting (EQUATOR)

Hywel Williams continues to contribute to, and is a keen supporter of, the EQUATOR Network. This is an international initiative that seeks to improve the reliability of medical research literature by promoting transparent and accurate reporting of research studies. Full details of all reporting guidelines (eg CONSORT, QUOROM, STROBE, SQUIRE), plus a wealth of other resources, are available at www.equator-network.org

The newly issued CONSORT 2010 statement was accompanied by a highly cited, invited editorial by Hywel Williams, outlining the importance of the revised guidelines (Williams H C. Cars, CONSORT 2010, and Clinical Practice. *Trials* 2010, 11:33).

> Response to editorial from an author of CONSORT 2010
>
> "I would like to extend my thanks and to compliment you on a brilliant piece. I think it is the best editorial / comment on CONSORT thus far, with insightful observations on how CONSORT helps trial conduct in the future"
>
> *Kenneth F Schulz PhD, MBA*

Development of Core Outcome Measures (COMET)

Hywel Williams and Kim Thomas are assisting with the Core Outcomes Measures in Effectiveness Trials (COMET) initiative: (http://blogs.bmj.2010/03/08/the-comet-initiative). This project builds on the successful work of the OMERACT group (in rheumatology), and aims to identify a core set of outcome measures for use in future clinical trials. A workshop, called 'HOME 1' (Harmonising Outcome Measures in Eczema), will be held at the International Symposium of Atopic Dermatitis in Munich in July 2010, at which development of a set of eczema core outcome measures will be discussed, and work is underway at the Centre of Evidence Based Dermatology to establish the most important outcome measures to use in vitiligo trials.

Evidence based medicine in general

Members of the Centre of Evidence Based Dermatology are active supporters of evidence-based medicine. We continue to work in collaboration with ebDerm.org to provide information and training support for dermatologists wishing to develop their skills in evidence-based medicine.

ebDerm.org is an organisation which places a high value on complete editorial independence and remains independent from commercial interests. ebDerm.org promotes the teaching and practice of evidence based medicine in dermatology, providing a guide to web-based resources, a digital library of materials and tools for learning and practising evidence-based dermatology, and an online forum for bringing together teachers, students and practitioners of evidence-based dermatology for academic dialogue and exchange (www.ebderm.org)

A podcast interview of Hywel Williams talking to Professor Paul Glasziou at the Centre of Evidence Based Medicine in Oxford entitled "Applying evidence in a hectic outpatient clinic: an interview with Hywel Williams", is available to download from www.cebm.net/index.aspx?o=4648

Evidence Based Veterinary Medicine

A new Centre for Evidence Based Veterinary Medicine has recently been established in Nottingham, an idea that was initially suggested by Hywel Williams when he was a member of the Nottingham Veterinary School Development Group. The Centre is now led by Dr Rachel Dean with generous support from Novartis and continued mentorship from Hywel Williams and his staff at the Centre of Evidence Based Dermatology.

We are pleased to say that the first systematic review in veterinary dermatology has now been published[1], along with a commentary from Hywel Williams[2] .

Publications:

[1] Olivry T, Foster A P, Mueller R S, McEwen N A, Chesney C. Williams F C Interventions for atopic dermatitis in dogs: a systematic review of randomised ontrolled trials. *Veterinary Dermatology.* 2010;21(1):4-22)

[2] Williams H C Evidence-based veterinary dermatology - better to light a candle than curse the darkness. *Veterinary Dermatology.* 2010;21(1):1-3

Ongoing Research

Our research strategy is a simple one, based on the concept of three overlapping, but closely related, methodological disciplines: systematic reviews, clinical trials and epidemiology.

Atopic eczema is our main disease interest because it is so common, the prevalence is rising, it causes a lot of suffering, and we understand little about its causes, treatment and prevention.

SPRUSD
Setting Priorities & Reducing Uncertainties for people with Skin Disease

NIHR Programme Grant Award

This Programme Grant award takes the theme of 'Setting Priorities and Reducing Uncertainties for the prevention and treatment of Skin Disease' (SPRUSD)

The work is being conducted in collaboration with a wide range of researchers, doctors and patients. It covers five disease areas:

- Eczema treatment
- Eczema prevention
- Skin cancer
- Vitiligo
- Pyoderma gangrenosum

SPRUSD programme

The research is taking place over five years and is built around the concept of a 'Research Cycle'. This starts by looking at existing research evidence, identifying gaps in our knowledge and then starting to design future research that can answer these questions.

What we are doing

A range of research methods is being used to provide answers to the NHS about uncertainties in the treatment and prevention of four skin diseases. We are starting by reviewing the work that has already been done. These reviews will show up a number of important research gaps for clinical trials. We then plan to work with patients and healthcare professionals to prioritise the most important questions for future research. In order to do this, we are working closely with colleagues from the James Lind Alliance (www.lindalliance.org)

The next stage will be to conduct some feasibility studies to sort out the practical problems of running the trials, and to see if we can recruit enough patients. One feasibility study looking at the use of moisturisers to prevent the development of eczema in new-born babies is already underway (see www.beepstudy.org). Funding applications will then be prepared for large-scale randomised controlled trials in the areas that have been prioritised for research.

We have already done the preparatory work to run a national trial on treatments for pyoderma gangrenosum, so we will complete this trial during the 5 year project. Further details about the STOP GAP trial are available on pages 47 and 48 and at www.stopgaptrial.co.uk

Impact of this research

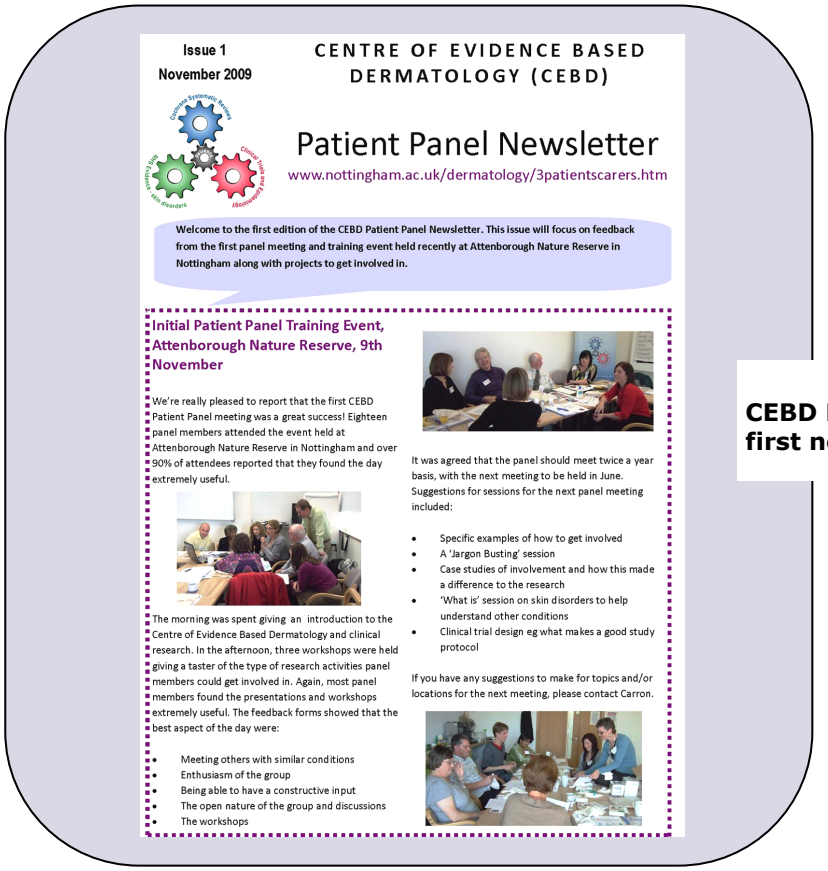
The following pages describe the progress that has been made in each of the work streams of the SPRUSD programme over the last 18 months. We are delighted that two Cochrane systematic reviews have been completed (vitiligo and squamous cell carcinoma) and that two multi-centre randomised controlled trials are now underway. The Global Resource of Eczema Trials (GREAT database) is due to be launched in July 2010, and this will provide a unique resource for researchers and guideline writers throughout the world. We have links with the National Institute for Clinical Excellence (NICE), the British Association of Dermatologist's Guideline Committee, the Scottish Intercollegiate Guidelines Network (SIGN), NHS Evidence, NHS Choices and the Royal College of Paediatrics and Child Health (RCPCH). These groups are all aware of our work, and will make use of the resources that we provide. For example, the updated vitiligo systematic review has been used to inform the development of a Clinical Knowledge Summary (CKS) on vitiligo. This is extremely important, as the majority of vitiligo patients are treated in primary care and, up until now, there has been very little guidance for GPs on how best to treat these patients. Similarly, the review of eczema treatments and the GREAT database will be key resources for the development and update of eczema guidelines. We have made contact with all relevant groups to ensure that they are aware of the likely timing and content of our reviews.

Start date:	September 2008
Finish date:	August 2013
Funded by:	Programme Grant from the National Institute for Health Research

Centre of Evidence Based Dermatology Patient Panel

As part of the SPRUSD programme, we are proud to be leading the way in working with patients and carers in all aspects of our research. In particular, we have received great support from both the National Eczema Society and the Vitiligo Society.

We have also established the Centre of Evidence Based Dermatology's Patient Panel. The panel has over 25 members affected by a range of skin disorders, many of whom are now contributing to our work in a variety of ways (eg joining research committees, commenting on surveys, grant applications and patient resources and joining systematic review teams). We communicate with the panel using e-mail updates and a bi-monthly CEBD Patient Panel Newsletter. One of the aims of the panel is to provide training so that those involved get the support they need to take part effectively in CEBD research. Details of the training events held can be found in the training section of this annual report.



Issue 1
November 2009

CENTRE OF EVIDENCE BASED DERMATOLOGY (CEBD)

Patient Panel Newsletter

www.nottingham.ac.uk/dermatology/3patientscarers.htm

Welcome to the first edition of the CEBD Patient Panel Newsletter. This issue will focus on feedback from the first panel meeting and training event held recently at Attenborough Nature Reserve in Nottingham along with projects to get involved in.

Initial Patient Panel Training Event, Attenborough Nature Reserve, 9th November

We're really pleased to report that the first CEBD Patient Panel meeting was a great success! Eighteen panel members attended the event held at Attenborough Nature Reserve in Nottingham and over 90% of attendees reported that they found the day extremely useful.

The morning was spent giving an introduction to the Centre of Evidence Based Dermatology and clinical research. In the afternoon, three workshops were held giving a taster of the type of research activities panel members could get involved in. Again, most panel members found the presentations and workshops extremely useful. The feedback forms showed that the best aspect of the day were:

- Meeting others with similar conditions
- Enthusiasm of the group
- Being able to have a constructive input
- The open nature of the group and discussions
- The workshops

It was agreed that the panel should meet twice a year basis, with the next meeting to be held in June. Suggestions for sessions for the next panel meeting included:

- Specific examples of how to get involved
- A 'Jargon Busting' session
- Case studies of involvement and how this made a difference to the research
- 'What is' session on skin disorders to help understand other conditions
- Clinical trial design eg what makes a good study protocol

If you have any suggestions to make for topics and/or locations for the next meeting, please contact Carron.

CEBD Patient Panel - first newsletter

For further information about any aspect of this research, please contact:

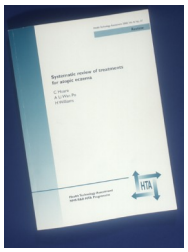
Dr Kim Thomas
SPRUSD Programme Manager
Centre of Evidence Based Dermatology
University of Nottingham, King's Meadow Campus
Lenton Lane
Nottingham
NG7 2NR

E-mail: cebd@nottingham.ac.uk

Eczema Treatment Work Package

Outline/Background

This workstream is being coordinated by Helen Nankervis, currently studying for a PhD, and includes the following projects:



Systematic review: An overarching systematic review of all treatments for atopic eczema. This review was first published nearly 10 years ago, by the Health Technology Assessment Programme, www.hta.ac.uk. We are now in the process of updating the review in order to bring together all the up-to-date, good quality evidence about the different treatments for eczema. This will help to identify areas where future research could be directed, and will be a vital resource for those developing clinical guidelines.

Global Resource of Eczema Trials: Alongside the review, a database of randomised clinical trials for eczema treatment is being created (www.greatdatabase.org.uk) with the aim of helping researchers trying to answer specific questions about eczema treatment in the future.

Prioritisation exercise: The James Lind Alliance prioritisation exercise for eczema treatment aims to collect as many of the unanswered questions about the treatment of eczema as possible from patients and carers, clinicians, other health professionals and patient support groups. The questions will be prioritised by representatives from all the interested parties to produce a list of the top 10 unanswered questions about eczema treatment.

Decision aid: A decision aid for treatments for severe eczema including UV phototherapy, azathioprine, methotrexate and cyclosporine will be developed. This shared decision making tool aims to improve patient and clinician satisfaction with the treatment choice and improve patient's knowledge and perception of treatment risk.

Contact details:

Helen Nankervis
+44 (0)115 846 8634 e-mail: Helen.nankervis@nottingham.ac.uk

Output for 2009-10

Publications

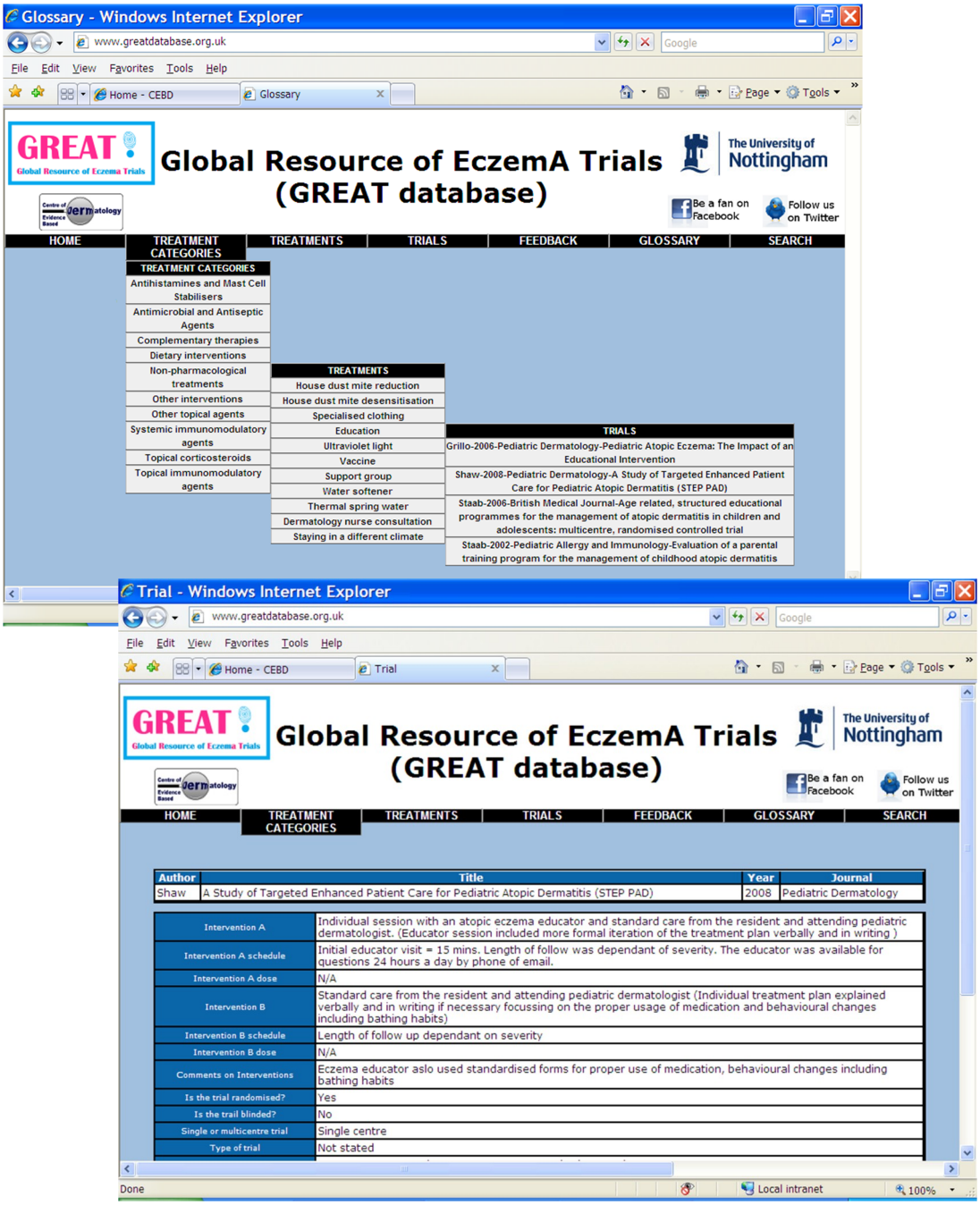
Nankervis H, Smith E V, Boule R J, Rushton L, Williams H C, Hewson D M, Platts-Mills T. *House dust mite reduction and avoidance measures for treating eczema* (Protocol). Cochrane Database of Systematic Reviews, 2010, Issue 3. Art. No.: CD008426. DOI: 10.1002/14651858. CD008426

Conference presentations/posters

Nankervis H, Delamere F, Thomas K and Williams H C *Introducing the Global Resource of EczemA Trials (GREAT Database).* Abstract P1.18 New Trends in Allergy VII and 6th Georg Royka Symposium Munich 22-24 July 2010 *Allergo Journal* 5(5.283-358):324

Newsletters/Magazines

Thomas K S and Williams H C *A new programme of independent eczema research* Exchange, Number 132, March 2009



Collaborative Links

Nottingham Support Group for Carers of Children with Eczema Report (NSGCCE)
Visit www.nottinghameczema.org.uk for further details

National Eczema Society (NES)
Helpline: 0800 089 1122 Mon-Fri 8am to 8pm

Eczema Prevention - BEEP feasibility study

Barrier Enhancement for Eczema Prevention: The BEEP Feasibility Study

The hypothesis for this study, being co-ordinated by Dr Joanne Chalmers, is that enhancing the skin barrier from birth by using emollients will prevent or delay the onset of eczema in high-risk infants.

Outline / Background

There are three main outputs of this workstream:

Feasibility study: To establish the feasibility of conducting a large scale definitive RCT to determine whether applying emollients from birth can prevent, or delay, the onset of eczema. A feasibility study (BEEP) is currently underway which will give us valuable information with regard to running this RCT, including willingness to participate, dropout rates and adherence, and will allow us to test and refine the proposed diagnostic criteria. An application for funds for the main RCT will then be developed.

Systematic review: A systematic review that summarises the result of existing randomised controlled trials looking at the prevention of eczema. The purpose of this is to ensure that patients and clinicians have access to the most up-to-date information about the prevention of eczema and to identify possible research gaps for future research.

Patient information: Summarising the best evidence available about the prevention of eczema and distribution of this information widely and freely.

Contact details:

Trial Manager, Joanne Chalmers:
+44 (0)115 832 email: joanne.chalmers@nottingham.ac.uk

This feasibility study will NOT answer the question of whether emollient use will prevent or delay the onset of eczema - this will be the purpose of a subsequent definitive RCT. But, prior to undertaking such a large and expensive trial, information regarding the feasibility of this strategy is needed, which this study will provide.

The study is a single (assessor) blind, parallel group, randomised controlled trial. Willingness to participate is the main outcome measure. Families will be randomly allocated, within three weeks of birth, to either the intervention (emollient) group or the non-intervention (control) group. Families in both groups will be given advice on best practice skin care and avoidance of soap.

Approximately 100 families will be invited to take part through primary and secondary care, in four recruiting centres: Nottinghamshire, Derbyshire, Lincolnshire and Portland, Oregon, USA.

The study is funded in the UK by the NIHR as part of SPRUSD Programme grant award, and in the US by the National Institute of Health.

The first centre opened for recruitment in February 2010 and screening of families should be completed by September 2010.

Investigators: Hywel Williams[1], Joanne Chalmers[1], Sue Davies-Jones[1], Jane Ravenscroft[2], Sandra Lawton[2], Ruth Murphy[2], Adam Ferguson[3], Coral Smith[3], Vanessa Unsworth[3], Ruth Ballington[3], Krisztina Scharrer[4], Amanda Roper[4], Eric Simpson[5]

[1]University of Nottingham, [2]Nottingham University Hospital NHS Trust, [3]Derby Hospitals NHS Foundation Trust, [4]United Lincolnshire Hospitals NHS Trust, [5]Oregon Health and Science University

Planned Activities for 2010-11

The main focus for 2010-11 will be to recruit the families to the BEEP feasibility study and refine the study as it progresses. We will also look to start the application process for funds for the main RCT. The systematic review will be planned and started.

Choice of emollients:

Sunflower seed oil

Doublebase

White soft paraffin / liquid paraffin (50:50)

Start date:	July 2009
Finish date:	August 2013
Funded by:	NIHR (as part of the SPRUSD programme grant award)
Website:	http://www.beepstudy.org

Output for 2009-2010

Conference Presentations/Posters

Simpson E, Chalmers J R, Irvine A D, Cork M J, McLean W H I, Williams H C
Barrier enhancement for Eczema Prevention: The BEEP Feasibility Study.
International Symposium of Atopic Dermatitis in Munich, July 2010.

Simpson E L, Keck L, Chalmers J, Williams H C
How do you define an incident case of atopic dermatitis? - A Systematic Review of Primary Prevention Studies. International Symposium of Atopic Dermatitis Munich, July 2010.

Newsletters / Magazines

Chalmers J R and Williams H C Introducing the BEEP Study (Barrier Enhancement for Eczema Prevention) *Exchange,* Number 135, December 2009

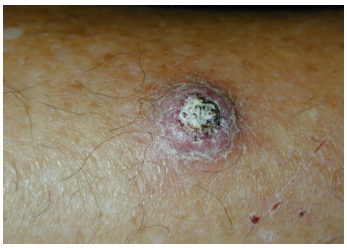
Collaborative links

BEEP feasibility study adopted by the Comprehensive Clinical Research Network, the Medicines for Children Network and the Primary Care Research Network.

The study is being developed and carried out in collaboration with Dr Eric Simpson in Portland, USA.

Squamous Cell Carcinoma

Outline / Background



Squamous cell carcinoma of the skin (SCC) is the second most common cancer in humans and has been increasing in incidence worldwide. The initial part of this project involves assessing the current evidence on the effectiveness of treatments for SCC. This workstream is being developed by Louise Lansbury, currently studying for a PhD.

A Cochrane systematic review of the evidence from randomised controlled trials (RCTs) will be published imminently, but as this has shown that very little good quality evidence exists from this kind of trial, a separate analysis of case series will also be done. Clinicians involved in the management are being invited to submit research questions they feel need to be answered about the management of SCC of the skin and these, together with gaps in the evidence base identified from the reviews, will be used to prioritise a research topic in the area.

A feasibility study will be developed based on the identified research topic, the aim of which will be to test the willingness of clinicians to recruit into a trial, and to assess the suitability and timing of outcome measures and the impact of exclusion criteria. The input of patients who have been treated for SCC of the skin will be sought, in order to help with the design of the study and with the development of patient information resources. The findings of the feasibility study will guide the development of a proposal and funding application for a full-scale clinical trial, in an area where there is a clear need for well-designed prospective studies.

Contact details:

Louise Lansbury
+44 (0)115 846 8721 e-mail: Louise.Lansbury@nottingham.ac.uk

Output for 2009-10

Publication

Lansbury L, Leonardi-Bee J, Perkins W, Goodacre T, Bath-Hextall F J, Tweed J A Interventions for non-metastatic squamous cell carcinoma of the skin (Protocol). *Cochrane Database of Systematic Reviews* 2009, Issue 3. Art. No.: CD007869. DOI: 10.1002/14651858.CD007869

Conference Presentation / Poster

Lansbury L, Leonardi-Bee J, Perkins W, Goodacre T, Bath-Hextall F J, Tweed J A Interventions for Non-Metastatic Squamous Cell Carinoma of the Skin - a Cochrane Systematic Review. *13th World Congress on Cancers of the Skin,* April 2010

Collaborative links

British Society for Dermatological Surgery
British Association of Plastic, Reconstructive and Aesthetic Surgeons

Vitiligo

Outline/Background

This project is being co-ordinated by Viktoria Eleftheriadou, currently studying for a PhD, and is in collaboration with various organisations such as BAD, UK DCTN, Cochrane skin group and patients' support group (Vitiligo Society). We believe that it is crucial we involve patients, their families, patients' support groups and clinicians in all aspects of the research.

Project overview:

- The Cochrane Review has now been updated (38 new trials identified) and published in the Cochrane Library January (2010)
- The prioritisation exercise was conducted in collaboration with the James Lind Alliance and Vitiligo Society (March 2010)
- One of the identified research topics will be developed into a feasibility trial, which is a small pilot trial to inform a large randomised multi-centre trial
- A full protocol for a large multi-centre trial on treatment of vitiligo will be designed, and a funding application will be prepared for submission to the relevant funding body
- We will also be producing decision aids to help patients and clinicians make informed choices about treatment

Contact details:

Viktoria Eleftheriadou
+44 (0)115 846 8633 e-mail: Viktoria.eleftheriadou@nottingham.ac.uk

www.vitiligostudy.org.uk

Output for 2009-10

Publication

Whitton M E, Pinart M, Batchelor J, Lushey C, Leonardi-Bee J, González U *Interventions for vitiligo.* Cochrane Database of Systematic Reviews 2010, Issue 1. Art. No.: CD003263. DOI: 10.1002/14651858.CD003263.pub4.

Newsletters/Magazines

Eleftheriadou V, Thomas K. Have your say in research in to vitiligo *Dermatological Nursing* 2009; 8 (4), 56-57

Eleftheriadou V. SPRUSD UPDATE: A big thank you to all those who completed the survey. *Dispatches,* Number 52, Nov 2009

Whitton M. The Cochrane systematic review of interventions for vitiligo: why it is important. *Dispatches*, Number 52, Nov 2009

Crowe S. Research priorities for vitiligo - an opportunity in 2009. How can you be involved? *Dispatches*, Number 49, November 2008

Lushey C. Setting priorities and reducing uncertainties for people with skin disease (SPRUSD) *Dispatches*, Number 50, March 2009

Viles J. BAD guidelines published. *Dispatches*, Number 50, March 2010

Collaborative links

British Association of Dermatologists	www.bad.org.uk
James Lind Alliance	www.lindalliance.org
Vitiligo Society	www.vitiligosociety.org.uk

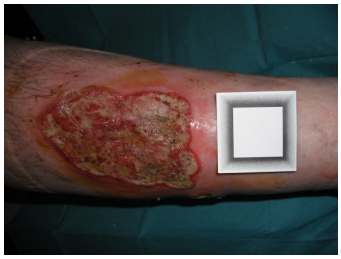
"The James Lind Alliance considers ourselves to be extremely privileged to be working with such an esteemed and enthusiastic group"

Sally Crowe, Director Crowe Associates

Study of Treatments for Pyoderma Gangrenosum Patients

This is a randomised controlled trial being conducted as part of the SPRUSD Programme Grant award, to compare the two most commonly used treatments for pyoderma gangrenosum - oral steroids or ciclosporin.

Pyoderma gangrenosum (PG) is a mutilating, very painful skin disease that often affects people with an underlying internal disease (such as inflammatory bowel disease, monoclonal gammopathy and rheumatoid arthritis). It starts as a reddish purple bump in the skin that develops into a large, deep, spreading ulcer in a matter of days. People with pyoderma gangrenosum are often misdiagnosed, and spend a long time in hospital waiting for the affected areas to heal. Ulcers can last for a variable length of time, healing, on average, after three to four months. Patients are not able to work, require daily dressings, have a high need for health care resources and have very poor quality of life. Patients often have repeat episodes of PG and may have multiple areas of the body affected.



In this study, we are comparing head-to-head the two most commonly used systemic treatments for pyoderma gangrenosum. Participants are being randomised to receive either prednisalone (0.75 mg/kg/day) or ciclosporin (4 mg/kg/day) for a period of up to six months. A parallel observational study is also being conducted in order to capture prospective outcomes for participants treated with topical therapies such as corticosteroids or calcineurin inhibitors.

Start date:	April 2009
End date:	August 2013
Funded by:	National Institute for Health Research - Programme Grant Award
Website:	www.stopgaptrial.co.uk

Contact details:

Trial Manager: Eleanor Mitchell
+44 (0)115 823 0489 e-mail: Eleanor.mitchell@nottingham.ac.uk

Investigators: Anthony Ormerod[1], Kim Thomas[2], Fiona Craig[1], John Norrie[3], James Mason[4], Eleanor Mitchell[2], Hywel Williams[2]

[1]Aberdeen Royal Infirmary, [2]University of Nottingham, [3]University of Glasgow,[4]University of Durham

Primary outcome:

- Speed of response to treatment (rate of healing) - assessed by digital images at six weeks

Secondary outcomes:

- Time to complete healing
- Safety and tolerability of the compared treatments
- Cost-effectiveness of the compared treatments

This trial is being run through the UK Dermatology Clinical Trials Network. We aim to recruit 140 patients into this trial and currently have 45 hospitals around the UK open to recruitment, with several others going through the approval process. It is anticipated that each centre will recruit one to two patients with pyoderma gangrenosum each year.

Currently, 32 patients have been enrolled into the trial. We are still looking for additional recruiting centres.

Output for 2009-10

Newsletters / Magazines

Mitchell E STOP GAP trial. National Association of Crohn's & Colitis newsletter, December 2009

Mitchell E Dermatology trials is the first to test CSP waters. *Trent Comprehensive Local Research Network newsletter*, February 2009.

STOP GAP study was featured in the Skin Voice newsletter, produced by the Dermatology Continuing Professional
Development Society. Summer 2009

Clinical Trials

Softened Water Eczema Trial (SWET)

This is a single-blind, randomised controlled trial looking at the effect of softened water on childhood eczema. A total of 336 families were randomised into the trial in eight recruiting centres: Nottingham, Leicester, Cambridge, Boston/Lincoln, North London, East London, Isle of Wight and Portsmouth.

The study is funded by the NIHR HTA Programme, with contributions from a consortium of water softening companies, who designed and tested the water softening units, funded salt supplies, and tested the water samples. The industry contribution is being co-ordinated by the Trade body - the UK Water Treatment Association (UK WTA), with expert advice from Ian Pallet from British Water.

Recruitment started in April 2007 and was completed in September 2009.

Results will be available in the Autumn of 2010

Comments from children on the SWET trial:

"I am so glad that I saw it on the news and I really liked our study nurse. I think I was so lucky to be chosen. Thank you!"

"I loved doing the eczema trial … and I always use the SWET cup"

"Thank you for my cup and thank you for making my body more comfortable"

"Brilliant … very, very, very good

Contact details:

SWET Trial Manager: Dr Karin Koller
+44 (0)115 846 8623 email: CEBD@nottingham.ac.uk

Investigators: Hywel Williams[1], Kim Thomas[1], Andrew Nunn[2], Sarah Meredith[2], Tracey Sach[1], Ian Pallett[3], Ian Pollock[4], Nigel Burrows[5], Tara Dean[6], David Potter[7], David Paige[8], Nerys Roberts[9], Karin Koller[1], Sue Davies-Jones[1], Rhiannon Medhurst[10], Rosalind Simmonds[11], Jane Grundy[12],Tony Frost[13], Mansoor Dilnawaz[14], Amanda Ropert[14], Edel O'Toole[15], Alison Allen[15], Denise McClure[4], Caroline Gilbert[2]

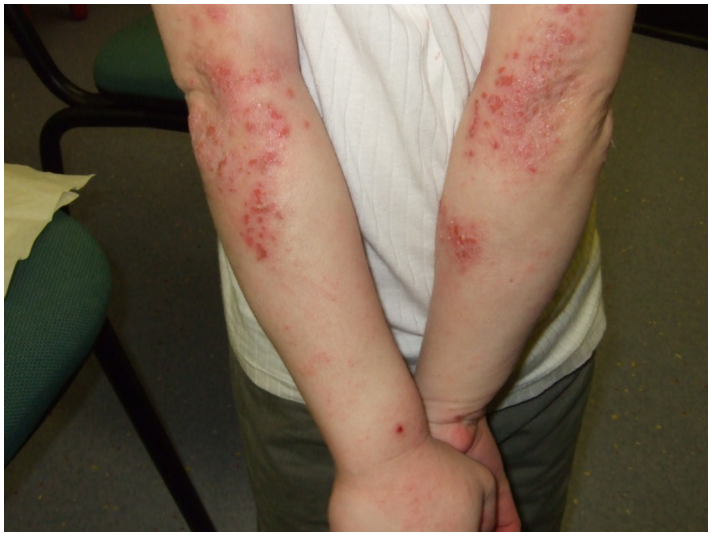
[1]University of Nottingham, [2]MRC Clinical Trials Unit, [3]British Water, [4]Barnet & Chase Farm Hospital, [5]Addenbrooks Hospital, [6]David Hyde Allergy Centre, [7]Service user, [8]The Royal London Hospital, [9]Chelsea & Westminster Hospital, [10]Barnett & Chase Farm Hospital, [11] Addenbrooks Hospital, Cambridge, [12]St Mary's Hospital, Newport, Isle of Wight, [13]UK Water Treatment Association, [14]Pilgrim Hospital, Boston, [15]The Royal London Hospital

Start date: 1 September 2006
Finish date: 14 May 2010
Funded by: NIHR HTA programme, with softeners, salt and water testing supplied by UK WTA
Website: www.swet-trial.co.uk

Comments from carers of children on the SWET trial:

"The process was excellent. The communication was very good and timely; the appointments were child-friendly, my son looked forward to going along … the nurse was lovely. Thank you for the opportunity of being involved in the trial"

"Our experience was very positive, everything was very organised so it was easy to follow and there wasn't any disruption in our everyday routines. We felt that our participation was appreciated and we were well looked after"



Publications arising from this study:

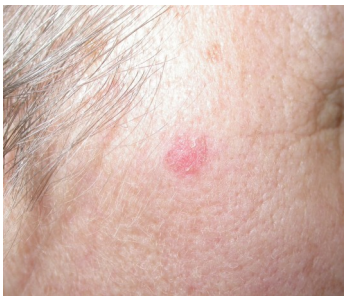
Thomas K S & Sach T H on behalf of the SWET Trial Investigators
A multi-centre randomised controlled trial of ion-exchange water softeners for the treatment of eczema in children - protocol for the Softened Water Eczema Trial (SWET) 2008. *British Journal of Dermatology.* 2008;159(3):1152-1159

CANCER RESEARCH UK

Clinical Trials

Surgery vs imiquimod for nodular and superficial basal cell carcinoma (SINS)

This is a randomised controlled trial of excisional surgery versus imiquimod 5% cream (Aldara) for nodular and superficial basal cell carcinoma, funded by Cancer Research UK. The study aims to assess cure rates for tumours at low risk sites, cost-effectiveness and cosmetic result. Recurrence at intervals up to five years will also be assessed, the primary assessment point being three years. Genetic markers are also being investigated.



The study was originally conducted in three centres: Queen's Medical Centre, Nottingham; Solihull Hospital and Chesterfield Royal Hospital. To improve the recruitment rate, nine additional centres joined: King's Mill Hospital, Sutton-in-Ashfield; Dorset County Hospital, Dorchester; Inverclyde Royal Hospital, Glasgow; Victoria Infirmary and Southern General Hospital, South Glasgow; Lincoln County and Boston Pilgrim Hospitals, Lincoln; Monklands, Hairmyres and Wishaw Hospitals in Lanarkshire; St. Barts and The London; Broadgreen Hospital, Liverpool; and Birmingham City Hospital.

Start date:	16 September 2002
End date:	31 August 2012
Funded by:	Cancer Research UK (imiquimod and funding for genetic markers addendum provided by 3M) + small R&D grant

Recruitment (501 participants) was completed in February 2007. The three year visits (primary endpoint) are now nearly complete, with the last visit due in April 2010, and at least 74% of participants (database status February 2010) reaching the three year visit. We will continue to capture five year outcomes from patient notes until 2012. As well as completion of participant visits, main activities over the last year have included data entry, comparison of double data entry and data cleaning. A summary of the protocol has recently been published, and we hope to publish the conjoint data analysis soon. Later this year, once the database is complete up to the three year visit, we can start the main analysis.

Contact details:

Trial Manager: Mara Ozolins
+44 (0)115 846 8624 e-mail: mara.ozolins@nottingham.ac.uk

Publications:

The SINS trial: a randomised controlled trial of excisional surgery versus imiquimod 5% cream for nodular and superficial basal cell carcinoma Ozolins M, Williams H C, Armstrong S J, Bath-Hextall F J. *Trials.* 2010; Apr 21;11:44

Investigators: Fiona Bath-Hextall[1], Hywel Williams[2], William Perkins[3], Jan Bong[3], Irshad Zaki[4], Graham Colver[5], Paul Miller[2], Sarah Armstrong[2], Graeme Perks[3], Mara Ozolins[2]

Clinical Research Nurses: Joanne Llewellyn[2], Beryl Cunningham[4], Sam Annasamy[5]

[1]School of Nursing, University of Nottingham, [2]Departments of Dermatology and Trent RDS, University of Nottingham, [3]Department of Dermatology, NUH, Nottingham, [4]Department of Dermatology, Solihull Hospital, [5]Department of Dermatology, Chesterfield Royal Hospital.

Data monitoring committee: Nick Telfer (Hope Hospital, Manchester), Stephen Walters (School of Health Related Research, Sheffield), Carol Jagger (Newcastle University).

A randomised controlled trial to compare the safety and effectiveness of doxycycline (200 mg/day) with prednisolone (0.5 mg/kg/day) for initial treatment of bullous pemphigoid (BLISTER)

This is a randomised controlled trial to compare the safety and effectiveness of doxycycline (200 mg/day) with prednisolone (0.5 mg/kg/day) for the initial treatment of bullous pemphigoid. Bullous pemphigoid is a skin condition mainly affecting the elderly, which causes tense, itchy blisters and painful skin erosions that can affect the whole body. It is a severe autoimmune blistering disease associated with significant morbidity and mortality, which cannot be left untreated. Bullous pemphigoid is usually treated with long-term oral prednisolone, which can cause many unwanted long-term side effects such as high blood pressure, osteoporosis, infections and diabetes. A safer alternative treatment is sought for this condition. This study will determine whether doxycycline (an antibiotic) would be a useful alternative to prednisolone for treating bullous pemphigoid. It will assess whether the benefits of less severe side effects outweigh any potential reduction in effectiveness.

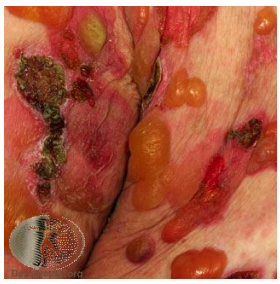


Image used with permission of Dr Amanda Oakley, New Zealand Dermatological Society ©DermNet NZ)

Start date: March 2008
End date: February 2013
Funded by: NIHR Health Technology Assessment programme
Website: www.blistertrial.co.uk

In this study, patients will be randomised to receive either prednisolone or doxycycline. To help prevent bias, the investigator will not know which treatment the patient has been given until after assessment of the main outcome at week six (a count of the number of remaining blisters). Once this measure has been taken, the investigator will be un-blinded and able to amend the medication dose in line with the patient's clinical condition. To assess safety, all adverse events will be recorded for a year after starting the study.

Outcome measures:

- Proportion of patients who have three, or fewer than three, significant blisters at six weeks
- Proportion of patients with moderate or severe side effects (including mortality) at one year

Adults with bullous pemphigoid who have received no treatment for this condition in the past year will be enrolled into the study. We have approximately 45 active recruiting centres in the UK and Germany and aim to recruit a total of 256 patients over a three year period. The study has currently recruited 38 patients and has just opened to recruitment in Germany.

Contact details:

Trial Manager: Caroline Onions
+44 (0)115 823 0510 email: blister@nottingham.ac.uk

Investigators: Fenella Wojnarowska[1], Hywel Williams[2], Gudula Kirtsh[3], James Mason[4], Andrew Nunn[5], Joanne Chalmers[5]

[1]Churchill Hospital, [2]University of Nottingham, [3]Vrje Universiteit Medical Centre Netherlands, [4]University of Durham, [5]MRC Clinical Trials Unit

Randomised controlled trials to investigate whether prophylactic antibiotics can prevent further episodes of cellulitis (erysipelas) of the leg. (PATCH I & PATCH II)

PATCH I and PATCH II are two closely related trials looking at the impact of prophylactic antibiotics on subsequent episodes of cellulitis of the leg. PATCH I is funded by Action Medical Research and PATCH II is funded by the BUPA Foundation.

These two studies will establish whether low dose penicillin given after an attack of cellulitis can prevent further attacks and complications, such as swelling and ulceration. People with cellulitis of the leg are randomly allocated to receive either penicillin or a placebo tablet for 12 months (PATCH I) or six months (PATCH II). We will continue to monitor patients for up to two and a half years, to see whether penicillin reduces the frequency of attacks of cellulitis compared to placebo. If it does, then it means that this cheap and simple treatment can make a big impact on the quality of life of the thousands of people in the UK who suffer from repeat attacks of cellulitis. Preventing further attacks will also save money for the NHS, by reducing hospital admissions.

PATCH I	**Start date:**	01 July 2006
	End date:	31 December 2010
	Funded by:	Action Medical Research
PATCH II	**Start date**:	01 July 2006
	End date:	31 December 2010
	Funded by:	BUPA Foundation
	Website:	**www.patchtrial.co.uk**

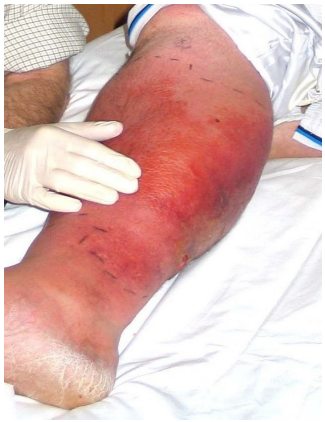
The PATCH I and PATCH II studies are both now closed to recruitment

Cellulitis can have a hugely negative impact - one lady told us that having an attack of cellulitis is like "walking through nettles or having boiling water poured over you" while another participant has said that he lost his job three years ago, because of the number of days he had had to take off work due to repeat episodes of cellulitis

Participants also tell us of the positive effect of taking part in the PATCH study…..

"When I'm feeling a bit despondent about my leg, when it's bothering me, I know I can call and ask the PATCH team anything and they are always so happy and helpful"

"This has been a well managed study; I've been kept well informed and thoroughly instructed. I appreciated the birthday card!"



When recruitment for PATCH I closed in December 2009, the 29 recruiting centres had enrolled a fantastic 274 participants (exceeding the 260 target). Participant follow up for PATCH I will continue until December 2010, after which the final data collection and study write-up will take place.

123 participants were recruited in to PATCH II and are now in final follow up. Data analysis and write up for PATCH II will take place towards the end of 2010.

The study results will be submitted for publication in Spring 2011.

Contact details:

Trial Manager: Katharine Foster
+44 (0)115 846 8626 email: kath.foster@nottingham.ac.uk

Publications arising from this study:

Thomas K S & UK Dermatology Clinical Trials Network's PATCH Study Group. Studying a disease with no home - lessons in trial recruitment from the PATCH II study. *Trials* 2010, 11:22

UK Dermatology Clinical Trials Network's PATCH Study Group. Prophylactic antibiotics for the prevention of cellulitis (protocol). *Journal of Lymphoedema.* 2007;2(1):34-37

Thomas K S, Cox N H, Savelyich B S P, Shipley D, Meredith S, Nunn A, et al. Feasibility study to inform the design of a UK multi-centre randomised controlled trial of prophylactic antibiotics for the prevention of recurrent cellulitis of the leg. *Trials.* 2007;8

Trial Steering Committee: Peter Featherstone[1] (Independent Chair), Hywel Williams[2], Nick Reynolds[4], Angela Crook[6], Ingrid Salvary[5], Andrew Nunn[6], Peter Mortimer[7], Kim Thomas[2], Katharine Foster[2]

Data Monitoring Committee: Robert Hills[8], Beverly Adriaans[9], Jane Daniels[10]

[1]Queen Alexandra Hospital Portsmouth, [2]University of Nottingham, [4] University of Newcastle, [5]James Paget Hospital, Great Yarmouth, [6]MRC, [7]St Georges Hospital Medical School, [8]Cardiff University, [9]Formerly of Gloucestershire Hospitals NHS Trust, [10]Birmingham Clinical Trials Unit.

Clinical Trials

Effect of topical imiquimod on lentigo maligna (LIMIT-1 trial)

This is a multi-centre, open label, non-randomised, single-stage trial to establish the pathological complete regression (CR) rate for lentigo maligna, following topical treatment with imiquimod.

The purpose of this study is to see whether imiquimod is an effective alternative therapy to surgery. Patients will undergo 12 weeks of treatment with topical imiquimod. All patients will progress to re-mapping, biopsy and complete surgical excision.

Primary outcome:

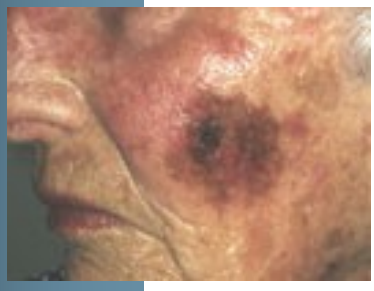
To establish the pathological complete regression (CR) rate for lentigo maligna following topical treatment with imiquimod.

Secondary outcomes:

- to define the accuracy of the clinical assessment of response after imiquimod treatment using visual assessment and biopsy
- to investigate the tolerability of imiquimod treatment
- to investigate the NHS resource associated with imiquimod treatment
- to determine whether imiquimod therapy might vaccinate against melanoma
- to establish patient treatment preferences for future trial design

This trial is being run through the UK Dermatology Clinical Trials Network. We aim to recruit 40 patients from 13 treatment centres. It is anticipated that each centre will recruit 3 to 4 patients with lentigo maligna in an 8 month recruitment period.
We hope to have most of the centres approved and open to recruitment by April 2010.

Start date:	April 2010
End date:	September 2011
Funded by:	NIHR Research for Patient Benefit Programme,



Lentigo Maligna (LM) is an early form of cancer which usually appears as a dark patch of skin on the face and neck. The current treatment is surgery to remove all the cancerous cells.

(Image used with permission of Dr Amanda Oakley, New Zealand Dermatological Society ©DermNet NZ)

Contact details:

Trial Manager: Nazia Boota
+44 (0)115 823 0579 e-mail: nazia.boota@nottingham.ac.uk

Lead Investigator: Dr Jerry Marsden, University Hospitals of Birmingham

Cryotherapy versus salicylic acid for the treatment of verrucae: a randomised controlled trial (EVERT)

This trial includes patients with verrucae, aged 12 years and over. Participants were randomised to receive either:

- Daily self-treatment with 50% salicylic acid (for a maximum of eight weeks)
  or
- Cryotherapy, using liquid nitrogen delivered by a health care professional (repeated up to a maximum of four treatments)

The main outcome was complete clearance of all verrucae, as observed on digital photographs taken at twelve weeks. Data on side effects of treatment, pain intensity after treatment, use of painkillers, restrictions to lifestyle due to having verrucae, treatment details and patient satisfaction with treatment have also been collected. Economic costs are presented from the perspective of the NHS and the patient.

Recruitment into this study ended on the 7 January 2010, having recruited 242 participants (91% of target). Results of the trial will be available towards the end of 2010.

Start date:	October 2006
End date:	November 2008 (30 June 2010 with extension)
Funded by:	NIHR Health Technology Assessment Programme
Website:	www.verrucatrial.co.uk

Contact details:

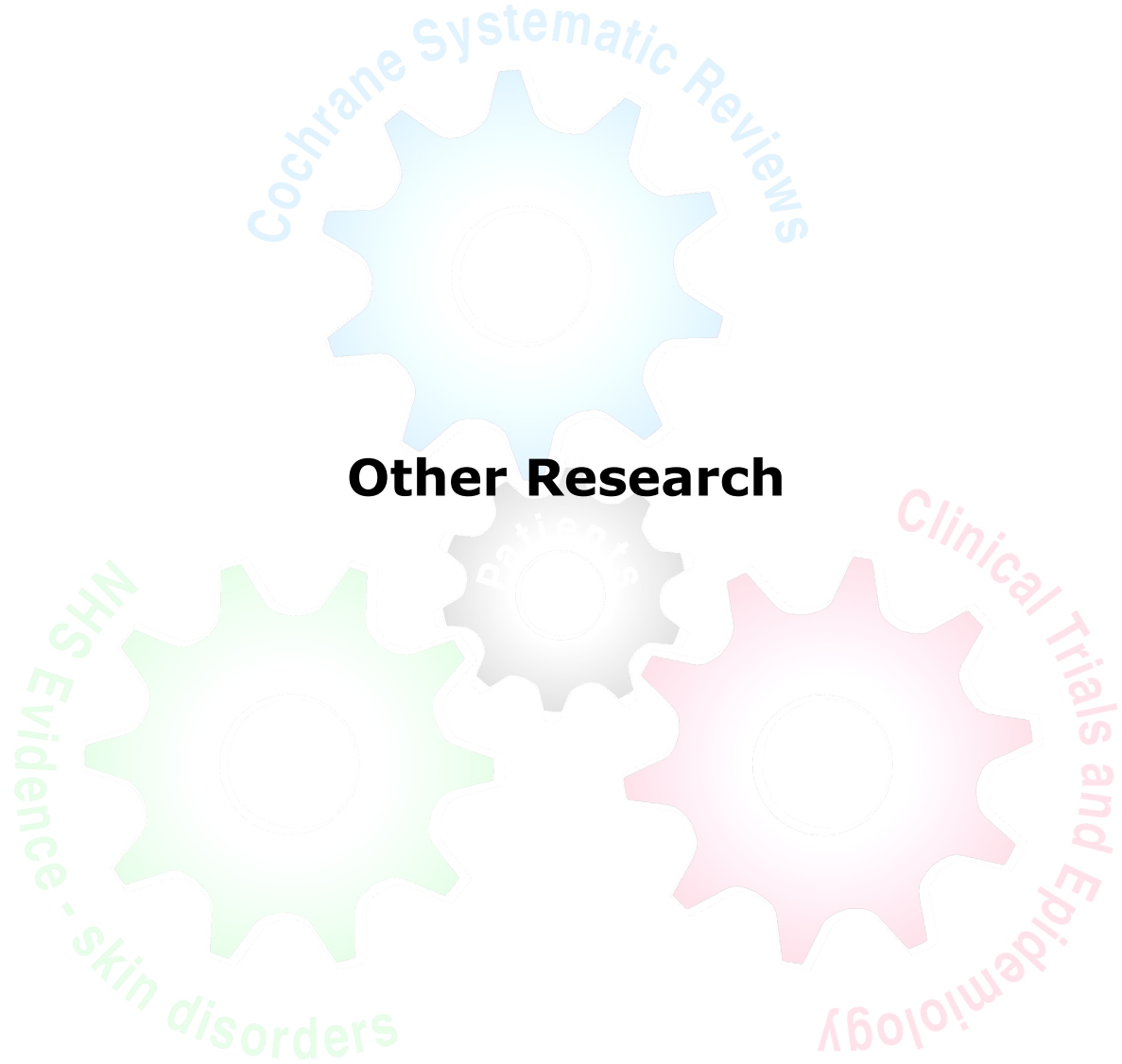
Trial Manager: Sarah Cockayne (Health Services Researcher at York University) e-mail: esc5@york.ac.uk

Recent publication:

Cockayne E, Sarah and EVerT Trial Team, 2010
The EVerT (effective verruca treatments) trial protocol: a randomised controlled trial to evaluate cryotherapy versus salicylic acid for the treatment of verrucae. *Trials, 11, 12*

Investigators: Cockayne, E S[1], Torgerson D J[1], Curran M[2], Thomas K S[3], Hashmi F[4], McLarnon N A[5]

[1]University of York, [2]University of Northampton, [3]University of Nottingham, [4]University of Brighton, [5]Glasgow Caledonian University

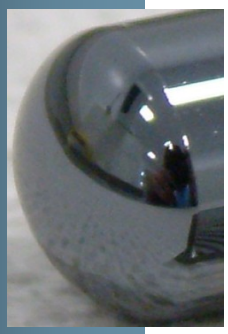


Other Research

Development of infrared optical fibre devices and systems for applications in medical diagnosis

We aim to develop a mid-infrared fibreoptic device for use in surface tissue evaluation to help medical diagnosis and possible early detection of skin cancer. Skin cancers are the most common of all human cancers and their number is increasing annually. For skin diagnostics, the reference standard at present is visual inspection by an experienced dermatologist, but this is both time-consuming and dependent on human judgement. Mid-infrared light (invisible to the naked eye) potentially provides a clinically important diagnostic capability. The mid-infrared light reflected from tissue like skin is rich in characteristic tissue signatures. The light is amenable to the technique of spectroscopy *i.e.* monitoring of light intensity after interaction with the tissue. There are examples in the recent literature of spectroscopic differences between malignant and normal tissue in surgically removed tissue.

Our challenge is to develop a device for carrying out tissue spectroscopy on skin *in vivo.* Such a device could lead to easier, faster, more accurate diagnoses and perhaps screening for skin cancer. Key enabling technologies for practical deployment of this device are compact discrete and broadband, bright infrared light sources and the means of efficiently routing the light to where it is needed. We are engineers working on practical solutions of a device based on mid-infrared-transmitting optical fibres both to produce and carry the light.



Figures show examples of mid-infrared transmitting glasses being developed into fibre optic systems for medical applications

Start date: October 2008
End date: September 2009
Funded by: The Royal Academy of Engineering / Leverhulme Trust Senior Research Fellowship to ABS, Medical Research Council, NEAT

Contact details for Angela Seddon:

+44 (0)115 8466755
email: angela.seddon@nottingham.ac.uk

Progress to date

The design of the mid-infrared fibre optic sensor device has been informed by attending skin cancer clinics, laser skin surgery and by following in detail the course of Mohs' Surgery, including the pathological preparation of tissue sections and their scrutiny for cancer tissue boundaries. Mid-infrared devices have been tested in the Optical Laboratories at Nottingham University's Faculty of Engineering and also at the Synchroton source Infrared Beamline at Diamond Light, Oxford.

Initial results appear promising and work continues.

Investigators: Professor Angela B Seddon[1], Dr David Furniss[1], Dr Sandeep Varma[2] Professor Hywel Williams[2]

[1]Faculty of Engineering, University of Nottingham, [2]Queen's Medical Centre, Nottingham

Raman spectral imaging for automated Mohs' micrographic surgery of high-risk basal cell carcinoma

Basal cell carcinoma (BCC) is the commonest cancer in humans. Although Mohs' micrographic surgery is the treatment of choice for high risk basal cell carcinomas, its availability in the UK is limited due to costly and time-consuming procedures.

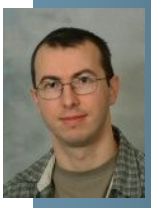
Raman spectroscopy is an established analytical technique and has been extensively used in medicine to study individual cells and complex tissues, including skin and BCC. This technique is based on inelastic scattering of laser light following its interaction with vibrating molecules of biological samples; therefore, a Raman spectrum represents a 'chemical fingerprint' of the sample. Recently, we demonstrated that Raman micro-spectroscopy (RMS) is able to discriminate between healthy and tumour derived bone cells and to determine the effect of cancer drugs and chemical and biological warfare on lung tumour cells.

The aim of this project is to develop an automated, quick and reliable method for evaluation of tissue blocks by imaging residual basal cell carcinoma during Mohs' micrographic surgery, without the need for frozen sections and subsequent reading by the Mohs' surgeon. The technique is based on Raman spectroscopy to produce 2-D biochemical images to separate the spectral signal of BCC areas from surrounding normal tissue. Tissue sections containing healthy and basal cell carcinoma regions obtained during surgery have been analysed to determine the ability of Raman spectroscopy to discriminate the BCC.

Basal cell carcinoma was discriminated from healthy tissue with 90±9% sensitivity and 85±9% specificity in a 70%-30% split cross-validation algorithm. This multivariate model was then applied on tissue sections from new patients to image tumour regions. The RMS images showed excellent correlation with the gold standard of histopathology sections, BCC being detected in all positive sections.

New funding has been obtained from NIHR (i4i FPD2, £696,143) to develop the technology. The main aims are to expand the database of tissue to include more types of basal cell carcinomas and healthy conditions which can be confused with basal cell carcinoma and to improve the speed of data acquisition and image analysis to levels acceptable to surgeons — a few minutes.

Start date: 1 May 2010
End date: 30 April 2013
Funded by: National Institute for Health Research and Nottingham University Hospital Charity



Contact details for Ioan Notingher:
+44 (0)115 951 5172 e-mail: ioan.notingher@nottingham.ac.uk

Publications arising from this study:

Marta Larraona-Puy, Adrian Ghita, Alina Zoladek, William Perkins, Sandeep Varma, Iain H Leach, Alexey A Koloydenko, Hywel Williams, Ioan Notingher. Development of Raman micro-spectroscopy for automated detection and imaging of Basal Cell Carcinoma. *J Biomed Opt.* 2009;14,054031

Ioan Notingher, William Perkins, Sandeep Varma, Hywel Williams Development of Raman micro-spectroscopy for automated detection and imaging of Basal Cell Carcinoma, Patent Application. Filing Date: 13/05/2009 Application number: 0908204.1

Investigators: Ioan Notingher[1], Hywel Williams[2], William Perkins[3], Sandeep Varma[3], Sarah Armstrong[2], Tracey Sach[2]

[1]University of Nottingham, School of Physics and Astronomy, [2] University of Nottingham, [3]Queen's Medical Centre, Nottingham

International Study of Asthma and Allergies in Childhood (ISAAC)

Both Hywel Williams and Carsten Flohr (former research fellow at our Centre and now NIHR Clinician Scientist in London) are Steering Group members of the ISAAC study - the largest epidemiological study of allergic diseases in the world. The idea behind ISAAC is to conduct large surveys of children to determine how common allergic problems such as eczema, asthma and hay fever are, using simple standardised tools that allow participation of all countries.

Until ISAAC's inception in 1991, little was known about the burden of asthma, hay fever, and eczema in developing nations.

ISAAC Phase One (fieldwork 1994-1996) addressed this gap in a standardised questionnaire-based survey in 156 study centres from 56 countries, which produced the first world map of asthma and allergy. Large differences in disease prevalence were found, even among ethnically similar populations, highlighting the important role environmental factors must play in disease aetiology.

ISAAC Phase Two (fieldwork 1998-2006) then explored potential risk factors, including allergic sensitisation, in 30 diverse centres from 22 countries. One of the key findings of Phase Two was that the association between allergic sensitisation and clinical diseases such as eczema was much weaker than previously thought and was positively linked to economic development. Thus, contrary to conventional wisdom, allergic mechanisms are unlikely to be the main cause of symptoms of asthma, hay fever (rhinoconjunctivitis) and eczema, especially in developing country settings.

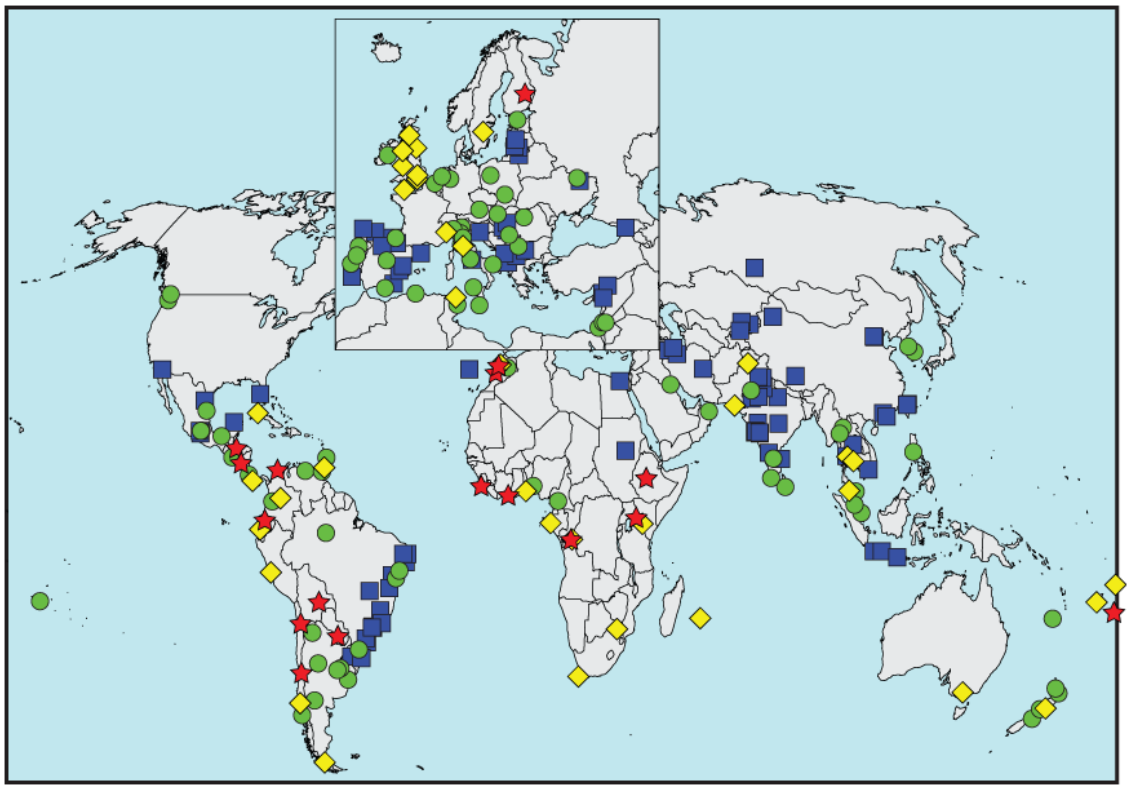
ISAAC Phase Three (fieldwork 2001-2006) studied time trends in asthma and allergy prevalence through comparison with Phase One in 110 centres in 58 countries. Where populations have undergone rapid demographic change, marked by urbanisation and adoption of a western lifestyle, such as in cities in Africa, Latin America and parts of Asia, eczema and asthma has continued to be on the rise, whereas there has been little change in disease burden where prevalence was already high in Phase One. Phase Three included an environmental questionnaire which revealed positive associations between allergy symptoms and paracetamol as well as antibiotic consumption in early life, and an increase in risk with exposure to truck traffic.

ISAAC Phase Four involved the development of the ISAAC website and the online publication of management guidelines for asthma, hay fever, and eczema. Our current list of 409 ISAAC publications includes 99 original papers in journals with impact factors (for 2008) of 5.0 or more.

http://www.isaac.auckland.ac.nz/publications/journalSummary.php))

The last year has been a significant period for the eczema aspects of ISAAC.

The first was the publication of the new world map for eczema symptoms which shows that eczema is now quite common in many cities in developing countries, especially in South America and Africa. The map below shows prevalence of current symptoms of eczema for the age group 13 to 14 years. Each symbol represents a centre. Blue squares indicate prevalence of less than 5%, green circles indicate prevalence of 5% to less than 10%, yellow diamonds indicate prevalence of 10% to less than 15%, and red stars indicate prevalence of 15% or more. Europe is shown in greater detail in the inset section.



The second important publication, led by Carsten Flohr, showed that questions used to elicit symptoms of eczema for prevalence surveys, corresponded reasonably well to eczema when confirmed by physical examination:

Flohr C, Weinmayr G, Weiland SK (deceased), Addo-Yobo E, Annesi-Maesano I, Björkstén B, Bråbäck L, Büchele G, Chico M, Cooper P, Clausen M, El-Sharif N, Martínez Gimeno A, Mathur RS, von Mutius E, Morales Suárez-Varela MM, Pearce N, Svabe V, Wong GWK, Yu M, Zhong NS, Williams HC and the ISAAC Phase Two Study Group. How well do questionnaires perform compared with physical examination in detecting flexural eczema? Findings from the International Study of Asthma and Allergies in Childhood (ISAAC) Phase Two. *Br J Dermatol*. 2009;161(4):846-853.

A final paper illustrated the difficulties in translating the ISAAC questionnaires about

Ellwood P, Williams H, Aït-Khaled N, Björkstén B, Robertson C; ISAAC Phase III Study Group. Translation of questions: the International Study of Asthma and Allergies in Childhood (ISAAC) experience. *Int J Tuberc Lung Dis*. 2009;13:1174-82.

Both Hywel (front row right) and Carsten (next but one to Hywel in the front) attended the Steering Group meeting in Merida, Mexico, on 27 - 28 November 2009 where key discussions took place to plan on a fifth and final phase of ISAAC, although funding is yet to be secured.

For more information about the ISAAC study and publications, please look at the ISAAC website at:

http://isaac.auckland.ac.nz/

Publications

Odhiambo J, Williams H, Clayton T, Robertson C, Asher MI, and the ISAAC Phase Three Study group. Global variations in prevalence of eczema symptoms in children from ISAAC Phase Three. *J Allergy Clin Immunol*. 2009;124:1251-8.

Flohr C, Weinmayr G, Weiland SK (deceased), Addo-Yobo E, Annesi-Maesano I, Björkstén B, Bråbäck L, Büchele G, Chico M, Cooper P, Clausen M, El-Sharif N, Martínez Gimeno A, Mathur RS, von Mutius E, Morales Suárez-Varela MM, Pearce N, Svabe V, Wong GWK, Yu M, Zhong NS, Williams HC and the ISAAC Phase Two Study Group. How well do questionnaires perform compared with physical examination in detecting flexural eczema? Findings from the International Study of Asthma and Allergies in Childhood (ISAAC) Phase Two. *Br J Dermatol.* 2009;161(4):846-853.

Ellwood P, Williams H, Aït-Khaled N, Björkstén B, Robertson C; ISAAC Phase III Study Group. Translation of questions: the International Study of Asthma and Allergies in Childhood (ISAAC) experience. *Int J Tuberc Lung Dis*. 2009,13:1174-82

Collaborative Links

The Centre continues to work closely with many partners and stakeholders throughout the UK. These include links with NHS partners, other academic departments, charitable bodies, patient groups and industry.

National Institute of Health Research (NIHR) Clinical Research Networks

Comprehensive Local Research Networks (CLRNs)

Professor Hywel Williams is Chair of the NIHR Specialty Group for Dermatology, and was a Board member for the Trent Comprehensive Research Network until the end of March 2010.

All trials run through the Centre of Evidence Based Dermatology are registered on the NIHR portfolio of trials http://www.crncc.nihr.ac.uk/index/clinical/portfolio and, as such, are eligible for support from the Comprehensive Local Research Networks (CLRNs). We have been extremely grateful to have received support from the Trent CLRN in the form of research nurse time, clinical trials administrators and PA sessions for clinicians based locally. Support in the form of nursing time and/or PA sessions has also been made available to some investigators across England involved in our multi-centre trials from their respective CLRNs. Such additional support has made an enormous difference in our ability to successfully recruit into our multi-centre trials.

Medicines for Children Research Network (MCRN)

Dr Kim Thomas represents dermatology on the Medicines for Children's Clinical Studies Group for general paediatrics.

The MCRN has been very supportive of the Softened Water Eczema Trial by providing additional nurse time in Nottingham, London and Lincoln. They have also provided assistance for the Barrier Enhancement for Eczema Prevention study (BEEP), co-adopting the study and providing nurse support in Lincoln.

Primary Care Research Network (PCRN)

The majority of dermatology consultations take place in primary care, and we have established close links with the Primary Care Research Networks (PCRNs) to help deliver dermatology research in this setting. We have worked with the PCRN to help successfully deliver both the Softened Water Eczema Trial (SWET) and the study of prophylactic antibiotics for the prevention of cellullitis (PATCH). Our local PCRN, East Midlands and South Yorkshire (PCRN EMSYNET), are being particularly helpful in helping to identify primary care practices to become involved in recruiting participants into the Barrier Enhancement for Eczema Prevention study (BEEP).

Health Technology Assessment Programme

Hywel Williams, Director of CEBD, was appointed as Chair of the NIHR Health Technology Assessment (HTA) commissioning board on the 1 January 2010. The HTA commissioning board considers the scientific merit of research applications to promote health, prevent and treat disease and improve rehabilitation and long-term care. He will also serve as Deputy Director of the entire HTA programme, which is the largest independent funding source of clinical trials in the UK.

The Nottingham Clinical Trials Unit (CTU)

Hywel Williams was the Director of the Nottingham Clinical Trials Unit at the University of Nottingham from its inception in 2005 until the end of 2008. He continued to support the unit as deputy director until the end of 2009. Trials developed by CEBD are increasingly using the services of the Nottingham Clinical Trials Unit and we are working on a collaborative basis on several trials.

MRC Clinical Trials Unit, London

Collaborative links with colleagues at the MRC Clinical Trials Unit were first established in 2002. Dr Sarah Meredith and Professor Andrew Nunn are members of the UK Dermatology Clinical Trials Network Steering Committee and provide invaluable methodological and statistical advice to the group.

Birmingham Clinical Trials Unit

A study looking at the use of imiquimod for the treatment of lentigo maligna has been developed in collaboration with the Birmingham Clinical Trials Unit and the UK Dermatology Clinical Trials Network (UK DCTN). This study has been funded by the Research for Patient Benefit funding scheme and is due to start recruiting in 2010. The unit is also assisting the UK DCTN with the development of a study investigating skin cancer prevention in organ transplant recipients.

East Midlands Research Design Service (RDS)

The Centre works with the East Midlands Research Design Service (previously the Trent Research & Development Support Unit) on grant applications submitted to the local Research for Patient Benefit funding scheme.

Higher Education Institutions

We have a history of successful collaborative links with other Higher Education Institutions. These currently include:

- University of East Anglia - SWET
- Brunel University - MATCH
- University of York - EVerT
- University of Aberdeen - STOP GAP
- University of Oxford - BLISTER
- University of Glasgow & University of Durham - SPRUSD NIHR Programme Grant
- Universities of Portsmouth, Southampton and Bristol - joint applications for an outline proposal to the HTA for a commissioned study on the treatment of infected eczema in young children

Patient Support Groups

The Centre of Evidence Based Dermatology has a long history of involving service users in research. This has traditionally included activities such as:

- Leading and commenting on Cochrane systematic reviews
- Participating in trial development and steering group
- Commenting on trial design, and patient information sheets
- Participating in focus group discussions to help inform trial design

In order to help formalise this, and to provide patients and carers with the training and support they may need to become effectively involved in our research, we have recently established the CEBD Patient Panel. Funding for the panel is provided by the NIHR Programme Grant and further details can be found under this section of the report. We should particularly like to thank the following patient support groups and charities for their help in disseminating information about the panel and helping us to identify potential panel members:

- The National Eczems Society www.eczema.org
- The Psoriasis Association www.psoriasis-association.org.uk
- The Vitiligo Society www.vitiligosociety.org.uk
- The Lymphoedema Support Network www.lymphoedema.org
- Skcin www.skcin.org

In addition, we should like to recognise the contribution of the Vitiligo Society, as they have played a central role over the past year as a member of the 'Working Partnership' for the vitiligo workstream of the NIHR Programme Grant Award.

As part of our longstanding interest in atopic eczema, some of us (Sandra Lawton, Jane Ravenscroft, Ruth Murphy and Hywel Williams) have worked closely with volunteers who run the Nottingham Eczema Support Group (Colin Gibb and Amanda Roberts). They have done a fantastic job in setting up a useful resource that now gets hits from all over the world. We are proud to include this short report of this work in our annual report, since it is such an important channel for disseminating results from our studies.

NOTTINGHAM SUPPORT GROUP FOR CARERS OF CHILDREN WITH ECZEMA

Nottingham Support Group for Carers of Children with Eczema Report (NSGCCE)

NSGCCE is made up of carers of children with eczema and healthcare professionals and was set up over 15 years ago to offer support and information on an informal basis. The group meets infrequently, responding to need in the East Midlands as appropriate. Much of the information we provide is available through our website www.nottinghameczema.org.uk

The highlights of the year were:

- An Eczema Awareness Day for both professionals and carers
- 1000th follower of our Twitter feed
- 100th visitor nation to our website
- A new regular blogger for the website
- Two new patient information leaflets - "Winter and eczema" and "What to expect for children newly diagnosed with eczema"
- Central TV news broadcast and participation in the CEBD Radio 4 Case Notes programme (available as podcasts on our website)

Ask the experts topics have included: bamboo clothing, weaning, prebiotics and probiotics, flare treatment, bleach baths, eye eczema, sun protection, unresponsive eczema, immunomodulators, ADHD, swine flu, pollen avoidance and winter strategies.

Looking to the future, planning has begun for an event to coincide with National Eczema Week in September, participating in a training day for health care professionals in November and the imminent launch of our redesigned website.

British Association of Dermatologists (BAD)

Both the UK dermatology Clinical Trials Network (UK DCTN) and the British Epidermo-Epidemiology Society (BEES) are Special Interest Groups of the BAD.

The UK DCTN acts as an affiliate group for the British Association of Dermatologists for topic prioritisation through the HTA programme.

Nottingham University Hospitals NHS Trust

The NUH NHS Trust has identified dermatology as one of its priority research topics. We are grateful to Dr Brian Thomson (R & D Director) for his leadership, and to him and his staff for their continuing support.

NHS Trusts

All CEBD led trials are multi-centre studies requiring collaboration with many NHS Trusts throughout the UK. This is particularly well demonstrated by the study investigating treatments for pyoderma gangrenosum (STOP GAP) as approximately 50 centres across the UK are involved in recruiting patients into this trial.

James Lind Alliance

NHS Evidence-skin disorders - the UK Dermatology Clinical Trials Network and the Cochrane Skin Group are all members of the James Lind Alliance. The James Lind Alliance aims to identify the most important gaps in knowledge about the effects of treatments, and has been established in order to bring patiejnts and clinicians together in 'Working Partnerships' to identify and prioritise the unanswered questions that they agree are most important. More information can be found on their website www.lindalliance.org

This partnership has been greatly enhanced during 2009-10 by the vitiligo workstream of the NIHR Programme Grant Award. This project involved the first ever on-line prioritisation exercise for research uncertainties which saw 718 questions reduced down to 93. The top ten research uncertainties for vitiligo were then identified from this list at a final priority workshop, run in collaboration with the James Lind Alliance. Further details of this project can be found in the Programme Grant Section of the Report, starting on page 37.

All research questions that are identified through this process will be submitted into the Database of Uncertainties about the Effects of Treatment (DUETs) www.duets.nhs.uk

It is now possible to submit suggestions for inclusion on the DUETs database by lodging your ideas on the NHS Evidence-skin disorders website www.library.nhs.uk/skin/DuetsSubmissionForm.aspx

Training Events

CEBD is proud to be involved in a wide variety of training programmes, courses and clinical meetings focussing on our strengths of epidemiology and evidence based practice.

Annual Evidence Based Update Meetings

Each Spring the Centre of Evidence Based Dermatology holds an Annual Evidence Based Update Meeting, which is Chaired by CEBD Director Hywel Williams. The day is aimed mainly at dermatologists and specialist dermatology nurses, although anyone with an interest in the topic is welcome. Subject topics are chosen following suggestions given by the previous year's delegates. This popular annual meeting focuses on a different topic each year, and seeks to summarise the most recent evidence in the form of systematic reviews and recently completed trials for the treatment and management of skin diseases. The programme also includes a popular Q&A session, where delegates submit clinical questions to an expert panel composed of the speakers from the day.

We seek to include presentations from European experts in the field, as feedback indicates that gaining a European perspective on a subject is extremely useful for clinical practice. The meeting is written up for the Conference Reports Section of the *British Journal of Dermatology* (BJD) and the write up of the 2008 meeting (Alexandrov A, Harman K Blistering Skin disorders: An Evidence Based Update Conference Report, *British Journal Dermatol* 160(3): 502-504) was the ninth most popular downloaded paper from BJD on-line in 2009.

Topics have included bullous diseases (in 2008), urticaria (in 2009) and we plan to cover eczema in 2010. At the 2009 meeting, presentations included Management of the Difficult Case by Malcolm Greaves, Evidence for Doing Diagnostic Tests for Urticaria by Clive Grattan and a summary of evidence from a Cochrane Systematic Review on Antihistamines for Chronic Ordinary Urticaria by Stuart Cohen. A European perspective was provided by colleagues from Germany including Marcus Maurer giving an update on Recently Completed RCTs in Cold Urticaria and a talk from Bettina Wedi on the Management of Acute Urticaria. Presentations from the 2009 event (and also from previous years meetings) can be found at www.ukdctn.org

A particular strength of the meetings is the involvement of service users from relevant patient support groups. These organisations typically assist by eliciting questions from their membership to be addressed by the 'expert panel'. We also aim to have formal presentations from service users on the day or have service user representation on the expert panel for the Q&A session.

All proceeds from the day are donated to the UK DCTN pump priming funds which are used to support the UK DCTN SpR Fellowship and Nursing Prize awards along with providing monies to support small pilot studies for trials in development through the Network.

Comments from delegates:

"Excellent talks on a very difficult topic"

"I have taken several nuggets away which will change my clinical practice in this area"

"Q & A session was very useful for everyday clinical practice"

British Epidermo-Epidemiology Society (BEES) Annual Course

Getting to Grips with Evidence Based Dermatology

The annual BEES Getting to Grips with Evidence Based Dermatology hosted twenty two participants in total, which included UK Specialist Registrars, the UK DCTN Nursing Prize winner and a colleague from Australia.

This three-day course is taught by staff from the Centre of Evidence Based Dermatology along with colleagues from the Primary Care and Rheumatology departments. It covers areas such as study design, statistics, clinical trials, and writing scientific papers.

Following on from the success of the 2008 BEES Summer School, a one day training event which focussed on writing and publishing in papers, the decision was taken to hold a one day course every two years. The next BEES Summer School will take place in Nottingham in association with the EQUATOR group from The Centre of Statistics and Medicine based at Oxford University.

Comments from delegates:

"Length of the course is perfect, as is the order and length of the talks"

"Very nice course, probably one of the best I have ever been on"

For further details of the next course (23rd—25th February 2011), contact Margaret Whittingham:

margaret.whittingham@nottingham.ac.uk
or visit the BEES website at www.bees.org.uk

Places are limited to 24 in order to retain small teaching groups

CEBD Patient Panel Training Event

The first training event for the newly formed CEBD Patient Panel took place at Attenborough Nature Reserve in Nottingham on 9th November 2009. The day included presentations on CEBD and an introduction to clinical research and workshops illustrating specific examples of how patients and carers can get involved in the research development process. Eighteen of the panel members attended on the day and we had some fantastic feedback about the event. The next training day is being held in June 2010 and will include a jargon busting session and a workshop on prioritising research topics for eczema prevention.

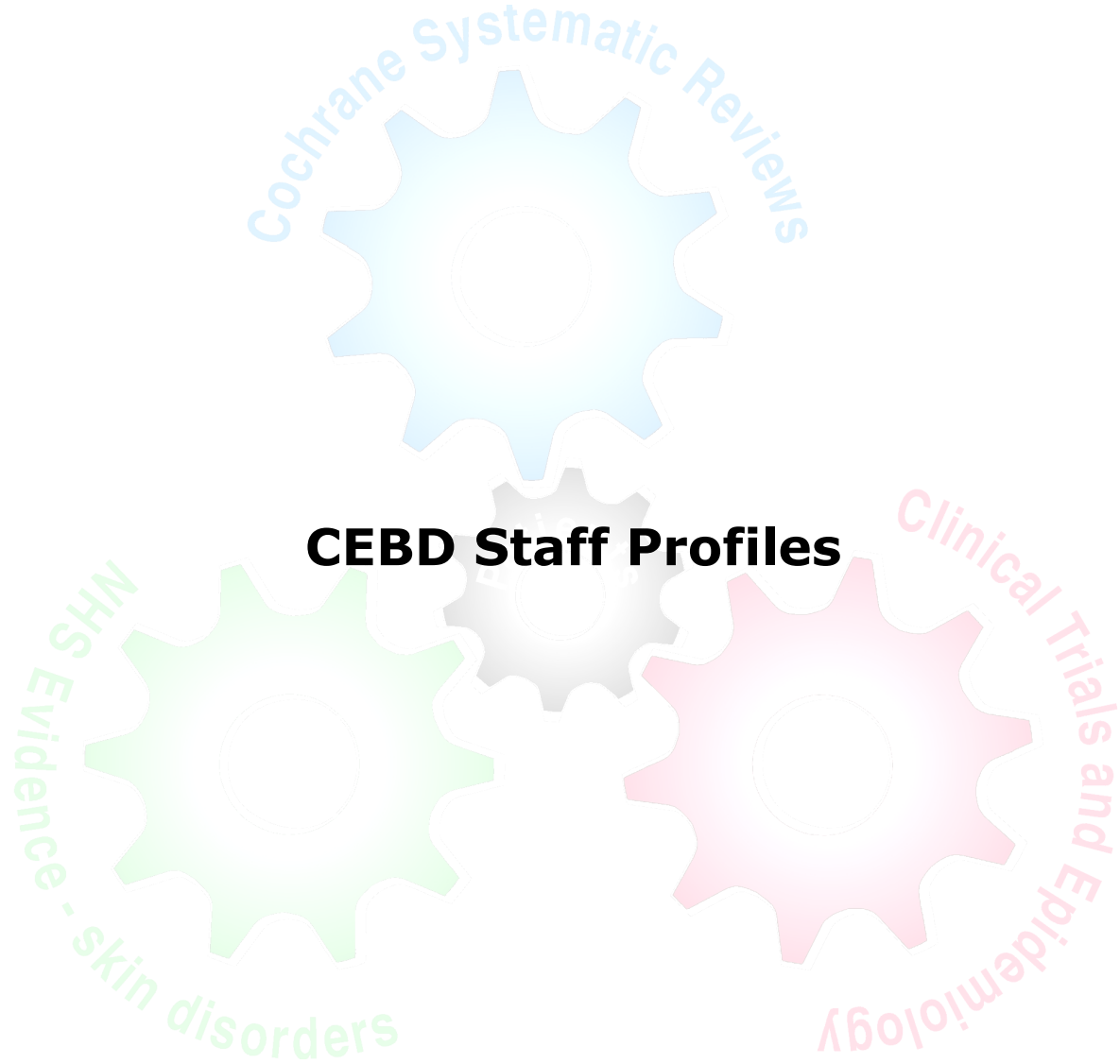
British Contact Dermatitis Course

The British Contact Dermatitis Society holds the Contact Dermatitis Course every two years and the 2009 event was held in Nottingham at the end of April. This course is run by Dr John English, Consultant Dermatologist and aims to improve the dermatologist's diagnostic management of patients with suspected contact dermatitis. The three day programme included a series of lectures and patch testing in the dermatology clinic.

National Skin Surgery Course

Each year the clinical Dermatology Department runs a two day National Skin Surgery Course organised by Skin Cancer Nurse Specialist Gill Godsell, OBE. The next course takes place on 9 and 10 September 2010 and focuses on the practical skills required to undertake skin surgery.

For further details please contact
Gill Godsell on gill.godsell@nuh.uk



CEBD Staff Profiles

Professor Hywel Williams
Director of the Centre of Evidence Based Dermatology

Hywel Williams was brought up in the hillside village of Cymmer Afan in South Wales, where he attended the local comprehensive schools. He trained in medicine at Charing Cross Hospital, London. After qualifying, Hywel did further medical and dermatology training in London at the Hammersmith Hospital, Charing Cross Hospital, Kingston Hospital and King's College Hospital. In 1994, he won a Wellcome Trust clinical epidemiology training fellowship and did an MSc in Clinical Epidemiology at the London School of Hygiene and Tropical Medicine. This led to a PhD in developing diagnostic criteria for atopic eczema in 1994 when he worked at St John's Dermatology Centre, London. That year, Hywel was appointed as Senior Lecturer in Dermatology to the clinical dermatology department at Nottingham, and became Foundation Professor of Dermato-Epidemiology in April 1998.

Outside of dermatology, Hywel was Director of Research and Development at Queen's Medical Centre NHS Trust from 1998 to 2001, and then became Director of the Nottingham unit of the Trent Institute for Health Services Research (TIHSR) from 2000 to 2004. Hywel chaired the National Research Development Support Unit network from 2004 to 2006. He founded and then directed the University of Nottingham Clinical Trials Support Unit which has recently won 5 major new NIHR trials and registration from the UKCRC. Hywel also undertakes research commissioning and chaired the Research for Patient Benefit Programme for East Midlands from 2006 to 2009. Hywel was appointed Chair of the HTA Commissioning Board and Deputy Director of the HTA Programme in January 2010.

Hywel's main interests are evidence-based dermatology and the epidemiology and treatment of childhood eczema. Hywel has published over 270 peer-reviewed articles, including papers in Nature, the NEJM, Lancet and BMJ, and three books. He has raised over £8m in non-commercial externally funded research into health technology assessment in relation to skin disease. Hywel was awarded a silver merit award from the NHS in 2007 for his work into supporting NHS-related research, and in 2008, he was awarded an NIHR senior investigator award in the first competition round.

Dr Kim Thomas
Associate Professor (non-clinical)
& Deputy Director of the Centre of Evidence Based Dermatology

Kim was appointed Associate Professor in April 2005, having worked in the Centre as a Senior Trial Manager for the previous six years. She is Deputy Director of the Centre of Evidence Based Dermatology and is responsible for the conduct and supervision of clinical trials in the Centre. She has a particular interest in clinical trial methodology and is a founder member of the UK Dermatology Clinical Trials Network.

Kim is currently acting as Programme Manager for the recently funded NIHR programme grant award - Setting Priorities and Reducing Uncertainties for the prevention and treatment of Skin Disease (SPRUSD).

She is an advisor to the National Institute for Clinical Excellence (NICE), is a member of the Medicines for Children Research Network (MCRN) clinical studies group for general paediatrics, and is an affiliate member of the Health Technology Assessment (HTA) Commissioning Board.

Dr Fiona Bath Hextall
Associate Professor

Fiona is an Associate Professor and Reader in Evidence-Based Health Care in the School of Nursing, Midwifery and Physiotherapy and Honorary Associate Professor in the Centre of Evidence Based Dermatology. She has been involved with the Cochrane Collaboration since 1995. For the last 6 years her main research area has been non-melanoma skin cancer (NMSC). Fiona is leading the squamous cell carcinoma stream of work for the recently funded NIHR grant. She is the grant holder for the SINS study, funded by Cancer Research UK. She has also been involved in using primary care databases (THIN database) to look at the incidence of basal cell carcinoma (BCC) in primary care and to investigate the relationship of smoking with BCC.

Nazia Boota
Clinical Trial Manager

Having completed a degree in Biological Sciences, Nazia spent three years working for the Oncology & Haematology Trials Unit (UHL NHS Trust) as a Clinical Research Assistant. She then went on coordinate paediatric leukaemia and brain tumour trials for the Children's Cancer and Leukaemia Group (CCLG). Nazia joined the UK DCTN in 2009 to manage the LIMIT-1 study. Nazia is also studying part-time for an MSc in Oncology.

Dr Joanne Chalmers
Research Fellow

Following an undergraduate degree and a PhD in Biochemistry from the University of Sheffield, Joanne spent five years in clinical research in the pharmaceutical industry. She joined the Centre of Evidence Based Dermatology in 2003, and since then has been involved in the design and implementation of several studies including a study of cost-effectiveness of treatments for cutaneous warts, an RCT to determine whether prophylactic antibiotics can prevent cellulitis, an RCT to compare doxycycline and prednisolone for bullous pemphigoid, a proof of principle trial to establish whether imiquimod is suitable for treating lentigo maligna and a study of antibiotics for wound healing in epidermolysis bullosa. Joanne is currently working on the eczema prevention workstream of the SPRUSD programme grant.

Dr Ling Chua
Specialist Registrar, Queen's Medical Centre

Ser Ling graduated from Guy's, King's and St Thomas' School of Medicine and Dentistry in 2000. She joined the Department of Dermatology, Queen's Medical Centre in December 2004 as a specialist registrar. She has spent a year in Mbarara, Uganda studying skin disease in HIV-infected patients on anti-retroviral therapy. Dr Kim Thomas is her academic supervisor for her research degree based at the University of Nottingham.

Susan Davies-Jones
Research Nurse

Since qualifying as a Staff Nurse in 1995, Sue has worked in a variety of adult nursing specialities, including Endoscopy, Theatre Recovery, Rheumatology and Dermatology. Sue joined the CEBD in March 2007 as a research nurse, working initially on the SWET trial. Since SWET completed recruitment, Sue has been working on various other trials within the department, including PATCH, STOPGAP and BLISTER.

Dr Finola Delamere
Managing Editor of the Cochrane Skin Group

Finola's biochemistry-based PhD involved investigating the forensic identification of human seminal plasma. She then worked for the Forensic Science Service. In Nottingham she undertook laboratory-based research in cystic fibrosis and asthma. As Managing Editor of the Cochrane Skin Group, Finola works closely with Cochrane Review author teams to help them produce protocols and reviews and guides them through the editorial process. Finola is the lead author on the Cochrane systematic review 'Interventions for alopecia areata' and co-author on 'Dietary exclusions for established atopic eczema', the updated systematic review 'Drugs for discoid lupus erythematosus' and the protocol 'Dietary supplements for established atopic eczema'.

Dr Viktoria Eleftheriadou
Research Associate

After completing her Medical degree and pre-registration jobs in Greece, Viktoria decided to continue her medical career in the UK. She worked for the NHS in various hospitals for 2 years, mainly in Medicine and A&E. Always aspiring to a career as a Consultant Dermatologist and having a great interest in Evidence-based Medicine, Viktoria joined the Centre of Evidence Based Dermatology as a Research Associate in August 2009, and is working on the Vitiligo workstream of the NIHR funded programme, 'Setting Priorities and Reducing Uncertainties in People with Skin Disease'. She is also studying for a PhD in Dermatology at the University of Nottingham.

Dr Katharine Foster
Clinical Trials Manager

Kath worked as a research scientist in Atlanta, Georgia (USA) and then the Institute for Animal Health, Berkshire following her PhD in Salmonella pathogenesis. She then moved into clinical trials in 2001, initially in oncology (colorectal cancer) for an academic trials unit in Oxford. After a brief spell in industry in the field of medical devices (orthopaedics), she moved back to academic trials in stroke medicine. Kath joined the Centre for Evidence Based Dermatology in January 2007 as the PATCH Trial Manager.

Dr Karin Koller
Clinical Trial Manager

Karin joined the Centre in September 2006 as Trial Manager for the Softened Water Eczema Trial (SWET) Karin originally qualified as a pharmacologist (University College London), and spent two years as a post-doctoral research scientist before becoming a freelance medical and scientific book indexer. For a number of years she combined freelance indexing with bringing up a family. Before taking up her current post Karin was Clinical Trial Manager at the UK Children's Cancer Study Group (2001-2003), Toxicologist at the MRC Institute for Environment & Health (2003-2005) and Research Fellow at the Children's Brain Tumour Research Centre, University of Nottingham (2005-2006).

Louise Lansbury
Research Associate

Louise studied Medicine and after graduating and completing pre-registration jobs she spent several years working as a clinical microbiologist in hospitals around the UK. During this time she also undertook laboratory-based research, working on projects ranging from virus survival in glycerol preserved cadaveric skin, to the relationship between pathogenicity and the flagellar proteins of *Helicobacter pylori.* She was the UK study co-ordinator for a pan-European project investigating the impact of antibiotic-resistant *S.aureus* and *E.coli* bloodstream infections. Louise joined the Centre of Evidence Based Dermatology as a Research Associate in November 2008, and is working on the Squamous Cell Carcinoma workstream of the NIHR funded programme, SPRUSD. She is also studying for a PhD.

Joanne Llewellyn
Research Nurse

Joanne joined the Centre of Evidence Based Dermatology in January 2003 and was employed as a Research Nurse on the SINS trial comparing surgery v imiquimod in the treatment of basal cell carcinomas. Recruitment has now finished and she is continuing to follow up her patients at the Queen's Medical Centre (Nottingham) and King's Mill Hospital (Sutton-in-Ashfield). In 2006, Joanne received her MSc in Science (distinction) from the Open University. From April 2008, Joanne has also been involved in recruiting patients onto the PATCH.

Eleanor Mitchell
Clinical Trial Manager

Eleanor is the Trial Manager for the STOP GAP Trial. She joined the Centre of Evidence Based Dermatology in 2008 having previously worked in clinical research for 8 years as a Project Co-ordinator and Research Manager for Academic Rheumatology at the University of Nottingham. During this time she managed a large gene-environmental interaction study for patients with osteoarthritis, and oversaw a variety of epidemiological studies and trials.

Helen Nankervis
Research Associate

Helen studied at Leeds University for a Degree in Medical Microbiology. After graduating, she spent a year designing A-level Microbiology practical experiments for the Society for General Microbiology. Helen has also worked on clinical trial data before joining the Centre of Evidence Based Dermatology in 2005 as the editorial assistant for the Cochrane Skin Group. She is currently working as a research associate on the eczema treatments workstream of the SPRUSD programme grant. She is also studying for a PhD.

Caroline Onions
Clinical Trial Manager

After completing her degree in Medical Science incorporating a year working in drug discovery for AstraZeneca, Caroline worked as a hospital service manager in the NHS for 5 years and in the health service in New Zealand. She then moved into clinical trials, setting up and managing a large 2x2 multi-centre trial looking at treating moderate to severe Alzheimer's Disease with either donepezil or memantine. Caroline joined the UK DCTN in October 2008 as the trial manager for the BLISTER trial.

Mara Ozolins
Clinical Trials Co-ordinator

Mara worked for 12 years as a statistician in the pharmaceutical industry. In 1997 she changed direction and became a clinical trial co-ordinator with the University of Nottingham, working on a large multi-centre, community-based study of antimicrobial treatments for mild to moderate acne. This trial completed in 2002, and was published in the *Lancet* (Dec 2004) and as an HTA monograph (Jan 2005), generating a lot of interest. Alongside her trial management Mara has delivered occasional lectures in trial management and statistical topics and in 2007 achieved associate teacher status. In 2002 Mara took over responsibility for the SINS trial.

Karen Attreed
Research Administrator

Karen joined the Centre in April 2006 and is responsible for providing administration support to Dr Kim Thomas. Her role also involves providing core support to the Centre, purchasing, general business management and maintaining the Centre's website.

Julie Barnes
Clinical Trial Administrator

Julie joined the Centre of Evidence Based Dermatology in October 2008. Her role is to provide administrative support to the STOP GAP trial and the BLISTER trial, and the trial managers - Eleanor Mitchell and Caroline Onions.

Lisa Charlesworth
Clinical Trial Administrator

After working as an administrator at the Clinical Trials Unit, University of Nottingham, for three years, Lisa joined the CEBD in September 09 to work as a trials administrator on projects funded by the UK DCTN. Having a BA (Hons) Degree in Communication Studies, prior to joining the University she worked for a number of years in marketing and for a graphic design agency.

Bryony Elliott
Research Administrator

Bryony joined the centre in August 2009 and is responsible for providing administration support for the programme grant. Her role also involves monitoring finances for the programme grant and other grants within the office, arranging meetings and conferences, and the use of digital imagery software for the STOP GAP Trial.

Douglas Grindlay
Information Specialist, NHS Evidence - skin disorders

Douglas has been Information Specialist for NHS Evidence – skin disorders (formerly the National Library for Health Skin Disorders Specialist Library) since 2004. He set up the specialist collection from scratch and has since been responsible for its maintenance and development. Douglas is also co-ordinating the Skin Disease module in the UK Database of Uncertainties about the Effects of Treatments (DUETs). Douglas made a late change in career when he took an MA in Information and Library Studies at Loughborough University. Previously he worked in crop science research and as a scientific officer and administrator in the Civil Service. Douglas is a Chartered Member of CILIP, the Chartered Institute of Library and Information Professionals.

Dr Carron Layfield
UK Dermatology Clinical Trials Network Manager

Following a degree and a PhD in Biochemistry, Carron spent three years in academic scientific research here at Nottingham University. She then undertook a career in life science sales and marketing for seven years, working for a variety of companies, before returning to the University in November 2006. Carron is now Network Manager for the UK Dermatology Clinical Trials Network (UK DCTN) and as such is responsible for developing and promoting the UK DCTN. She also has a number of general departmental duties including being the lead for the recently formed Centre of Evidence Based Dermatology Patient Panel, organising the Annual Evidence Based Update Meeting and co-ordinating CEBD publicity.

Alan Maplethorpe
IT Programmer

Alan has been employed to help in the IT side of clinical trials for the CEBD. This involves the design and development of databases and websites. This role covers the key aspects of data capture and data presentation. He has worked on database design and websites for the following studies: Blister, STOPGAP, Vitiligo Study and the Programme Grant.

Margaret McPhee
UK DCTN Administrator

Margaret joined the centre in January 2007. She provides administrative support to both the senior clinical trials manager and the UK DCTN manager. Her role involves managing the membership database and the UK DCTN website, producing publicity material, monitoring finances, arranging meetings and conferences.

Laura Prescott
Editorial Assistant

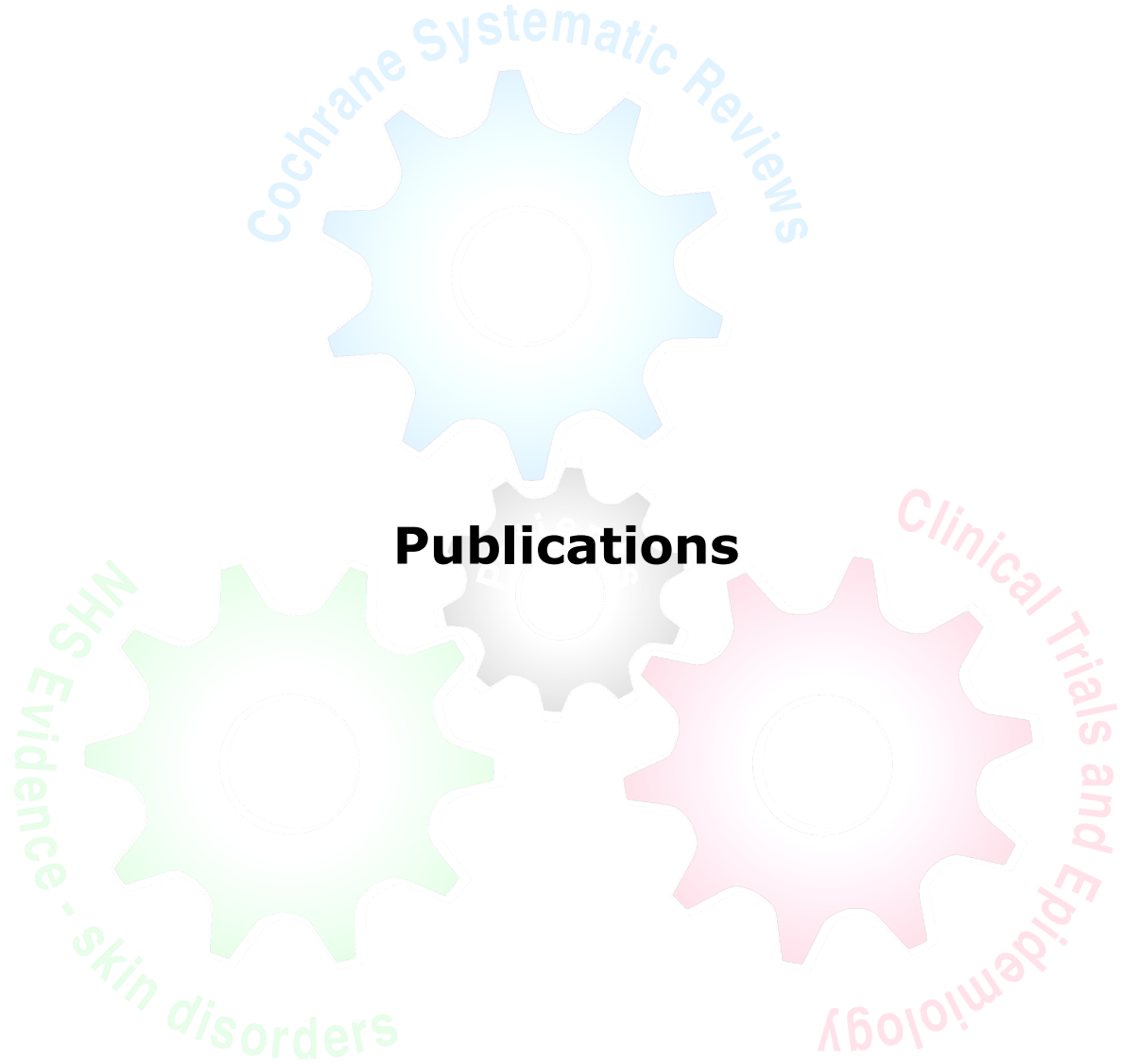
Laura works as the Editorial Assistant for the Cochrane Skin Group (CSG), providing support to the Managing Editor, Finola Delamere. She assists in all aspects of the editorial process, including communicating with authors and other contributors, copy-editing, and the management of channels of dialogue throughout production. She also undertakes a number of administrative tasks. These include the management and continued organisation of the folders within the electronic and paper systems and maintaining up-to-date records of the Group membership's contact details. She also maintains the CSG website, and helps organise the annual Skin Group meeting.

Johanna Perdue
Clinical Trial Administrator

Jo joined the CEBD in March 2009, initially in a temporary capacity assisting the Trial Manager, Kath Foster, on the PATCH study, before beginning a fixed, two year contract as Clinical Trial Administrator in the Department, funded by the CLRN. Prior to joining the CEBD, Jo had worked for over 20 years in the upholstery textile trade (marketing, design and customer care). Whilst working full time she achieved a long held ambition to return to study, graduating from the Open University in 2006 with a first-class honours degree in Literature.

Margaret Whittingham
Administrator to Professor Williams & Academic Secretary in Dermatology

Margaret provides administrative and secretarial support to Professor Williams and is the departmental administrator for research, teaching and general business management. Her role also involves the organisation of undergraduate and postgraduate teaching activities in the dermatology department. She is responsible for helping to organise the BEES course and annual meeting, as well as other national and international meetings held in the Department.



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Larraona-Puy M, Ghita A, Zoladek A, Perkins W, Varma S, Leach IH, Koloydenko AA, Williams H, Notingher I. Development of Raman micro-spectroscopy for automated detection and imaging of Basal Cell Carcinoma. *J Biomed Opt.* 2009;14(5):054031

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Additional key abstracts

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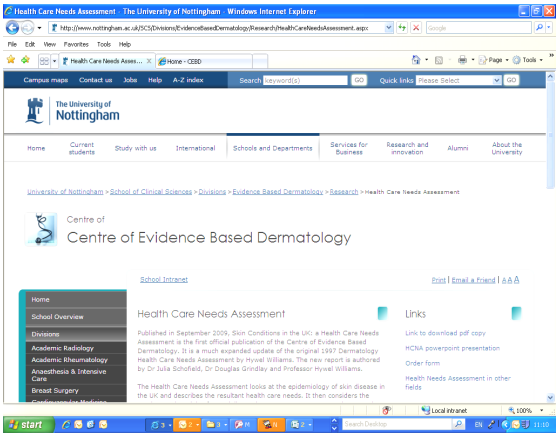
Simpson EL, Keck L, Chalmers J, Williams H. How do you define an incident case of atopic dermatitis? - A Systematic Review of Primary Prevention Studies. Abstract submitted to New Trends in Allergy & 6th George Raijka Symposium, Munich, July 2010.

Health Care Needs Assessment



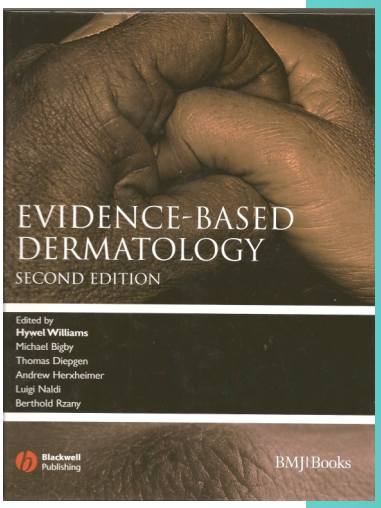
Published in September 2009, Skin Conditions in the UK: a Health Care Needs Assessment is the first official publication of the Centre of Evidence Based Dermatology. It is a much expanded update of the original 1997 Dermatology Health Care Needs Assessment by Hywel Williams. The new report is authored by Dr Julia Schofield, Dr Douglas Grindlay and Professor Hywel Williams.

The Health Care Needs Assessment looks at the epidemiology of skin disease in the UK and describes the resultant health care needs. It then considers the services and models of care delivery that are necessary to meet these needs against the background of central government policy, and makes specific recommendations. The report will be of interest to commissioners, policy makers and all who are involved in the delivery of care for skin conditions. It also provides useful summaries of the epidemiology and impact of the major skin diseases.

To download a pdf copy or to order a hard copy, please go to the Centre of Evidence Based Dermatology website at:

http://www.nottingham.ac.uk/SCS/Divisions/EvidenceBasedDermatology/ResearchHealthCareNeedsAssessmetn.aspx

Evidence-Based Dermatology



The second edition of the textbook on Evidence-Based Dermatology was published in 2008. This book is a Centre of Evidence-Based Dermatology project since Hywel Williams is the lead editor, with contributions to chapters from other colleagues including Kim Thomas, Fiona Bath-Hextall, Jane Ravenscroft, Carolyn Charman, Finola Delamere, Sinead Langan, Tina Leonard and William Perkins.

The book has already received rave reviews. The first edition was a world first and highly acclaimed by a number of leading general and specialist journals. The second edition is published by BMJ Books with Blackwell Publishing and contains 68 chapters, and with further new chapters and additional information published on the book's accompanying website.

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