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

The Centre of Evidence Based Dermatology

Annual Report 2007—2008

UK Dermatology Clinical Trials Network

Cochrane Skin Group "The truth is out there"

NHS National Library for Health

CONTENTS

Welcome from the Director

Honestly, I think I am in a dream sometimes. I arrive at the Centre of Evidence Based Dermatology office and see around 18 colleagues and visitors all busy working on a range of really interesting applied dermatology research projects. I just wonder where has it all come from, and will it all come to an end? "I don't think so" is the answer. Skin diseases are incredibly common, and we seem to be doing exactly the sort of work that the UK National Health Service needs; summarising current evidence and identifying research gaps through Cochrane systematic reviews, addressing those gaps through the UK Dermatology Clinical Trials Network, and then disseminating new knowledge to a community of users through the Skin Disorders National Electronic Library. It is a simple idea, but it all works beautifully.

Please take a moment to flick through this report – it describes the work that we do and the wonderful team of people and collaborators doing it. There must be something there that interests you. Funding is at an all-time high (over £6 million over the last 5 years) and crowned by our recent NIHR Applied Programme grant award for "Setting priorities and reducing uncertainties in the prevention and treatment of people with skin diseases". Research output always exceeds 20 peer-reviewed papers per year, including at least two in the top general journals.

Although it is good to take stock and reflect on our shared achievements to date, please be reassured we will not rest on our laurels. The future challenges include: (i) delivery of our funded work on time and to a uniformly high standard; (ii) working closely with the evolving NIHR structures such as the Comprehensive Clinical Research Network and Dermatology Specialty Interest Group; (iii) finding ways of working with industry in an explicit and unbiased way; (iv) developing international partners for our clinical trial programme; (v) doing better at applying research into clinical practice and most important of all, not losing our core values of doing clinically relevant research that involves users of health care, so that we reach the problems that are important to them. A lot still to do then. It has been a very good dream so far. Long may it continue.

Hywel Williams 30th June 2008

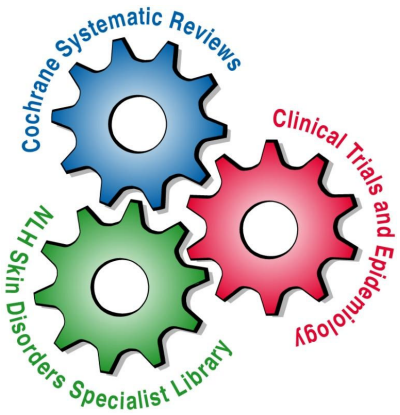
RESEARCH

Research Strategy

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 the National Library for Health Skin Disorders Specialist Library.

The research strategy of the CEBD is based on the concept of three interdependent research cogs. Systematic reviews are used to review the existing evidence and to generate research questions; these are then picked up and developed into clinical trials through the UK Dermatology Clinical Trials Network. The resulting guidance and evidence base is then disseminated to a community of users through the National Library for Health Skin Disorders Specialist Library.

The Model of Three Research Cogs



The department's websites include:

The Centre of Evidence Based Dermatology
www.nottingham.ac.uk/dermatology
UK Dermatology Clinical Trials Unit
www.ukdctn.org
NLH Skin Disorders Specialist Library
www.library.nhs.uk/skin
Cochrane Skin Group
www.nottingham.ac.uk/~muzd

''The confluence of your Centre of Evidence Based Dermatology, the Cochrane Skin Group and the NELH specialist library really all build on everything together and is most impressive'
Professor Sally Davies, Director General of Research & Development Department of Health

RESEARCH

Cochrane Skin Group

The Cochrane Skin Group (CSG) (www.csg.cochrane.org) is one of 52 Collaborative Review Groups that together make up the Cochrane Collaboration (www.cochrane.org). This international organisation was developed in response to a challenge, issued by the late Archie Cochrane, a British epidemiologist, who pointed out the deficiencies of reviews of the medical literature and the lack of access to up-to-date evidence about health care.

The CSG aims to provide the best evidence about the effects (beneficial and harmful) of interventions for skin diseases, so that health professionals and the public can make well-informed decisions about treatments and their uncertainties. The scope of the Skin Group is wide and includes any skin problem that leads an individual to seek help from a healthcare provider. The Group also considers evidence about skin treatments that are sold over-the-counter or are widely available. Many members of the CSG are also interested in evidence-based dermatology in general, and we regularly publish interesting methodological articles on understanding and promoting the principles of evidence-based dermatology.

The CSG was established in 1997, and has an international board of editors. One of the particular strengths of the CSG has been the involvement of consumers, who help it in many ways. We define consumers as people who have a skin condition and their close relatives/carers. The impact of skin disease is mainly on the quality of life of the individual. Many trials in the past have been done to answer questions that are important to the pharmaceutical industry, with little emphasis on non-pharmacological interventions. Consumer involvement in the Skin Group helps us to redress this imbalance.

The Group currently has about 690 members worldwide, of whom about 100 are consumers and 481 are authors. All authors are volunteers and the CSG has no financial links with any pharmaceutical companies. The editorial base of the CSG is located at the Centre of Evidence Based Dermatology at Nottingham where its output regularly informs other strands of work such as the need for new trials and the best design of new trials. Hywel Williams serves as the co-ordinating editor, Finola Delamere

as acting review group co-ordinator, Helen Nankervis as editorial assistant, with Diane Horsley providing further administrative help. Tina Leonard, who has worked with the group for several years, has just retired after a long illness, and we thank her for her many contributions to the Group. We receive infrastructure support from the NHS Research and Development Programme.

Topics for review have traditionally been suggested by potential authors who have then gone on to write the reviews. From April 2007 the editorial group were unable to take on new review topics due to a backlog at the editorial base because of staff shortages. Since April 2008, having succeeded in working through the backlog, we have been able to welcome new review titles again. Whilst we were closed to new review topics we accepted suggestions for 21 titles proposed by the membership. In order to prioritise our future workload we have asked the whole of the CSG membership to vote on their six preferred topics for systematic reviews. Those interested in leading a review team on one of these titles are required to submit an application in which they have to satisfy several criteria. Their applications are then assessed independently by a group of our editors, who decide which review teams are most likely to be able to complete the review.

After title registration is completed the protocol is developed, peer reviewed and published. Writing a review is a two-stage process: the protocol is a public statement by the authors of how they intend to systematically review the topic, this is then developed into a full systematic review, which is also peer reviewed. After publication of the protocol, the authors search for all the relevant published and unpublished clinical trial information, critically appraise it, and summarise the information in such a way that it can be understood not only by clinicians but also by healthcare practitioners, consumers and managers.

The finished reviews are published in *The Cochrane Library* on www.thecochranelibrary.org. The Cochrane Library is the principle source of up-to-date high quality evidence on the effects of health care interventions.

RESEARCH

Cochrane Skin Group

Recent Publications in the Cochrane Library

Published Reviews

Issue 3, 2007	Psychological and educational interventions for atopic eczema in children	Ersser SJ, Latter S, Sibley A, Satherley PA, Welbourne S
Issue 4,2007	Interventions for preventing non-melanoma skin cancers in high-risk groups.	Bath-Hextall F, Leonardi-Bee J, Somchand N, Webster A, Delitt J, Perkins W
	Systemic antifungal therapy for tinea capitis in children	González U, Seaton T, Bergus G, Jacobson J, Martínez-Monzón C
	Topical pimecrolimus for eczema	Ashcroft DM, Garside R, Stein K, Williams HC
Issue 1,2008	Dietary exclusions for atopic eczema	Bath-Hextall F, Delamere FM, Williams HC
Issue 2,2008	Interventions for alopecia areata	Delamere FM, Dobbins HM, Sladden MJ, Sinclair R

Published Updates

Issue 3, 2007	Topical treatments for fungal infections of the skin and nails of the foot	Crawford F, Hart R, Hollis S

Published Protocols

Issue 1, 2008	Interventions for erythema nodosum leprosum	van Veen N, Lockwood D, van Brakel WH, Ramirez jr J, Richardus JH
Issue 2,2008	Lasers and light sources for port-wine stains	Faurschou A, Olesen AB, Gotzsche PC, Haedersdal M

Examples of Cochrane systematic reviews that have impacted on primary research activity in the Centre of Evidence Based Dermatology

Focus of systematic review	Subsequent research project	Funded by
Acne	An RCT for the identification of the most cost-effective microbiologically safe antimicrobial treatments for acne	NIHR HTA
Basal Cell Carcinoma	An RCT of excisional surgery versus imiquimod 5% cream for nodular and superficial basal cell carcinoma	Cancer Research UK
Bullous Pemphigoid	An RCT to compare doxycycline (200 mg/day) with prednisolone (0.5 mg/kg/day) for initial treatment of bullous pemphigoid	NIHR HTA
Warts	What is the effectiveness and cost-effectiveness of topical salicylic acid and cryotherapy for cutaneous warts? An economic decision model. An RCT of cryotherapy versus salicylic acid for the treatment of verrucae.	NIHR HTA
Vitiligo	Vitiligo is being used to develop a work stream as part of the NIHR programme grant	NIHR programme grant
Non-melanoma skin cancer (SCC)	SCC is being used to develop a work stream as part of the NIHR programme grant	NIHR programme grant
Eczema	Eczema is being used to develop a work stream as part of the NIHR programme grant	NIHR programme grant
Alopecia	Alopecia study is in development through the UK DCTN .	

RESEARCH

Cochrane Skin Group

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RESEARCH

UK Dermatology Research Network

An Introduction to the Network

The UK Dermatology Clinical Trials Network (UK DCTN) was formed in February 2002. Its aim is to develop and conduct high quality randomised controlled clinical trials (RCTs) of interventions for the treatment, or prevention, of skin diseases. Members of the UK DCTN are mainly dermatologists with an interest in finding out answers to questions about the treatment of skin disease. In addition to dermatologists, our members include statisticians, health economists, epidemiologists, research nurses, primary care staff and patient representatives. Network membership has now grown to over 330 members across the UK and Eire, an increase of over 50% in the past eighteen months.

The UK DCTN was initially funded by the National Co-ordinating Centre for Research Capacity Development (NCC RCD), and we have just been successful in securing further funding for the Network's infrastructure from the Department of Health until March 2009. This interim funding will allow us to see how we can best align ourselves with the new comprehensive clinical research network within the National Institute for Health Research (NIHR)

Role of the Network Co-ordinating Centre

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 portfolio of clinical trials and to developing the Network as an organisation. Trial suggestions relating to less common skin diseases are particularly welcome as such research is unlikely to succeed without the aid of a national research network. Specifically, we are able to:

- Facilitate and advise on trial development and 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

RESEARCH

UK Dermatology Research Network

What has the Network Achieved?

Funding for individual trials comes from external grant applications made to NIHR partners (NIHR HTA and charitable bodies). These funds typically include an allocation to support data management services run through the Nottingham Clinical Trials Support Unit (CTSU), or other Clinical Trial Units in the UK.

To date, the Network has been awarded the following grants:

Study title	Funding Body	Amount
Setting priorities and reducing uncertainties in the prevention and treatment of people with skin diseases.	NIHR Programme grant	£1,930,186
Effect of topical imiquimod on lentigo maligna; a phase II study	NIHR Research for Patient Benefit	£250,000
RCT to compare the safety and effectiveness of doxycycline (200 mg/day) with prednisolone (0.5 mg/kg/day) for initial treatment of bullous pemphigoid.	NIHR HTA – open call for pragmatic clinical trials (May 2007)	£829,590
Pilot studies for a multi-centre clinical trial studying topical and oral treatments for pyoderma gangrenosum patients (STOP-GAP)	British Skin Foundation (May 2007)	£9,710
Project to improve links between the UK DCTN and Primary Care	Trent RDSU Research Capacity Development Award (Dec 2007)	£3,226
RCT to investigate whether prophylactic antibiotics can prevent further episodes of cellulitis (erysipelas) of the leg – PATCH I	Action Medical Research (July 2005)	£116,175
RCT to investigate whether prophylactic antibiotics can prevent further episodes of cellulitis (erysipelas) of the leg – PATCH II	BUPA Foundation (July 2005)	£191,654
Pilot studies to inform the design of a UK multi-centre randomised controlled trial of prophylactic antibiotics for the prevention	British Skin Foundation (March 2004)	£9,920

We also have studies at various stages of development in a variety of other dermatological conditions including infantile haemangioma, vitiligo and alopecia.

UK DCTN Pump Priming Funds

Rapid deployment, pump-priming funds are provided by donations from a consortium of pharmaceutical partner organisations and from the proceeds of the annual Evidence Based Update meeting run by the Centre of Evidence Based Dermatology (CEBD). These funds are allocated on a case-by-case basis following formal application to the UK DCTN Awards Committee.

Awards given by the UK DCTN 2007-2008

- £16,000 given to the PATCH study team. This pilot study was to assess whether providing dedicated administrative/nursing support staff to identify patients with cellulitis would increase recruitment rates into the PATCH studies.
- £10,000 given to the STOP GAP pilot study team. This was to provide a dedicated trial manager for the pilot trial.

UK Dermatology Clinical Trials Network wins award in NHS Network of the Year competition'

We are delighted to be one of only three Networks to have been awarded Highly Commended status in the 2007 NHS Networks Award Network of the Year Award.

Network Infrastructure Developments

The past year has seen a number of exciting developments within the UKDCTN which include:

- The establishment of a Research Prioritisation Committee. This is in order to maintain a degree of focus and momentum to our work and to ensure that the Network focuses on the most important questions in dermatology.
- The development of a trial adoption procedure for non-commercial dermatology trials that have been developed by other groups. Two studies have been adopted

so far; i) Softened Water Eczema Trial (SWET), a HTA funded trial to evaluate whether ion-exchange water softeners help children with eczema, and ii) an RCT of excisional surgery vs imiquimod 5% cream (Aldara) for nodular and superficial basal cell carcinoma (SINS), funded by CRC UK.

- The implementation of a UK DCTN SpR fellowship programme and nursing prize.
- Increasing our links with the Primary Care community via the Trent RDSU award and other links including the Primary Care Research Network (PCRN) and Primary Care Dermatology Society.
- Representation on the Medicines for Children Research Network (MCRN) General Paediatric Clinical Studies Group.

"....by joining the UK DCTN I managed to add clinical research to my daily activities and get credit for it. "
Quote from a Consultant involved in the UK DCTN who had previously been struggling to become actively involved in research.

Network Contact Details

If you are interested in finding out more about the Network, please contact us. Membership of the Network is free and open to anyone with an interest in dermatological research.

Network Manager:	Dr Carron Layfield	carron.layfield@nottingham.ac.uk 0115 8468625
Senior Trials Manager:	Dr Joanne Chalmers	joanne.chalmers@nottingham.ac.uk 0115 8468622
Network Administrator:	Maggie McPhee	margaret.mcphee@nottingham.ac.uk 0115 8468621

"I have learned a huge amount from involvement with the UK DCTN which has exposed me to the processes involved in developing research ideas and allowed me to participate in a relevant clinical trial. I hope it will provide other trainees with the opportunity to fulfil their training requirements in such a productive manner. "
Quote from an SpR involved in the UK DCTN.

National Library for Health

RESEARCH

NLH National Skin Disorders Specialist Library

The Centre of Evidence Based Dermatology has been the home of the National Library for Health (NLH) Skin Disorders Specialist Library, www.library.nhs.uk/skin, since the project began over four years ago. The Skin Disorders Specialist Library is one of 29 Specialist Libraries now available online in the National Library for Health (NLH), which provides an integrated physical and electronic library service across the National Health Service in England and Wales.

'The site is an invaluable resource I promote it wherever I go!'

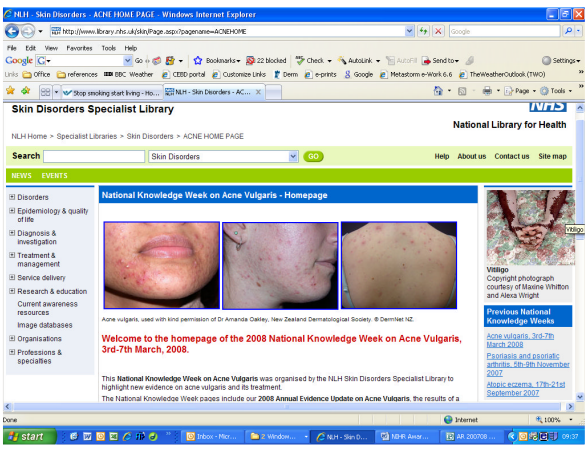
'Fantastic! Great Resource'

The Skin Disorders Specialist Library is intended to be a "one-stop shop", a single site that can be used as a portal to find information on skin disorders and related topics that is relevant for UK health professionals, in particular dermatologists, dermatology nurses and general practitioners. The Library is an organised, easily accessible and up-to-date electronic collection of relevant guidelines, policy documents, systematic reviews and other reviewed evidence, together with reference material and selected patient information resources.

During 2007, site visits to the Skin Disorders Specialist Library have continued to increase, after more than doubling in 2006. Monthly site visits were 10,773 in January 2007 but had reached 20,767 by March 2008 , representing an increase of 93% over the year. The Skin Disorders Specialist Library is now consistently the most visited NLH Specialist Library, with more visits than even the National Library of Guidelines or the Health Management Specialist Library, and it regularly receives 11-12% of total Specialist Library site visits each month.

The year 2007 also saw our first National Knowledge Weeks and Annual Evidence Updates on:

- acne vulgaris (5th-9th March),
- atopic eczema (17th-21st September)
- psoriasis and psoriatic arthritis (5th-9th November).



RESEARCH

National Library for Health

NLH National Skin Disorders Specialist Library

In this first year, the Annual Evidence Updates presented the results of searches for systematic reviews dating back to a chosen reference document for each disease topic. The National Knowledge Week pages also include links to evaluated information resources and commentaries from a range of invited experts on current issues and the clinical significance of recent research evidence, which have been very favourably received. These three National Knowledge Weeks will be run again in 2008, with the addition of a new National Knowledge Week on skin cancer during Sun Awareness Week, from 5th-9th May. This National Knowledge Week was run jointly with the NLH Cancer Specialist Library and in co-operation the Communications Officer of the British Association of Dermatologists (BAD), Nina Goad, who organises Sun Awareness Week.

I get my regular updates from Douglas and always have a quick look, but I did not appreciate the wealth of information in this section.
I found it incredibly useful, both for study and every day practice.
Your summary is definitely the highlight thank you.

The National Knowledge Weeks and Annual Evidence Updates are one aspect of the Skin Disorders Specialist Library's role in Continuing Professional Development and current awareness for NHS health professionals. Another important aspect is our free monthly e-mail updates, which provide a summary of new guidelines, official documents, systematic reviews and other important information resources in our topic area. These e-mail updates are also an effective way to promote the Skin Disorders Specialist Library to our main target users and to encourage repeat visits to the site. The number of subscribers to the e-mail updates has continued to increase, from 435 at the end of March 2007, to 512 at the end of January 2008. This includes a large proportion of the dermatologists in England and Wales, as well as many dermatologists in Scotland, Ireland and elsewhere in the world, and also dermatology nurses and GPs.

Much effort is still being put into promoting the Skin Disorders Specialist Library in other ways, which must undoubtedly contribute to the continued increase in site visits. Douglas Grindlay has been continuing his programme of visits to dermatology departments around the country to talk about and demonstrate the Library, with visits to Glasgow and Merseyside, and as usual he attended the BAD Annual Meeting and selected other conferences with a promotional stand.

Finally, the NLH Skin Disorders Specialist Library continues its involvement in the pilot exercise to collate uncertainties about the effects of treatments for skin disorders and enter them into DUETs (the Database of Uncertainties about the Effects of Treatments) (www.duets.nhs.uk). DUETs has been established in order to bring to together uncertainties that cannot be answered reliably by up-to-date systematic reviews of existing research evidence, in order to inform future research. A comprehensive DUETs module on atopic eczema has now been compiled and was officially launched during the eczema National Knowledge Week in September 2007, and work continues on modules on acne and psoriasis and other skin disorders. So far uncertainties are being harvested from systematic reviews and from patient questions submitted by patient support groups, but it is hoped that uncertainties submitted by professional groups will be added in the future.

In September 2007, Hywel Williams and Douglas Grindlay were invited to give a presentation to the Board of the James Lind Alliance (JLA). The JLA seeks to identify the most important gaps in knowledge about the effects of treaments. We described our activities and explained how the NLH Specialist Libraries are in a strong position to harvest uncertainties for DUETs and to link with their wide community of users. The response was very enthusiastic from both the clinicians and patient representatives who were present.

NLH National Skin Disorders Specialist Library promotional stand at the Annual Evidence Based Update Meeting

RESEARCH

NIHR Applied Programme of Research

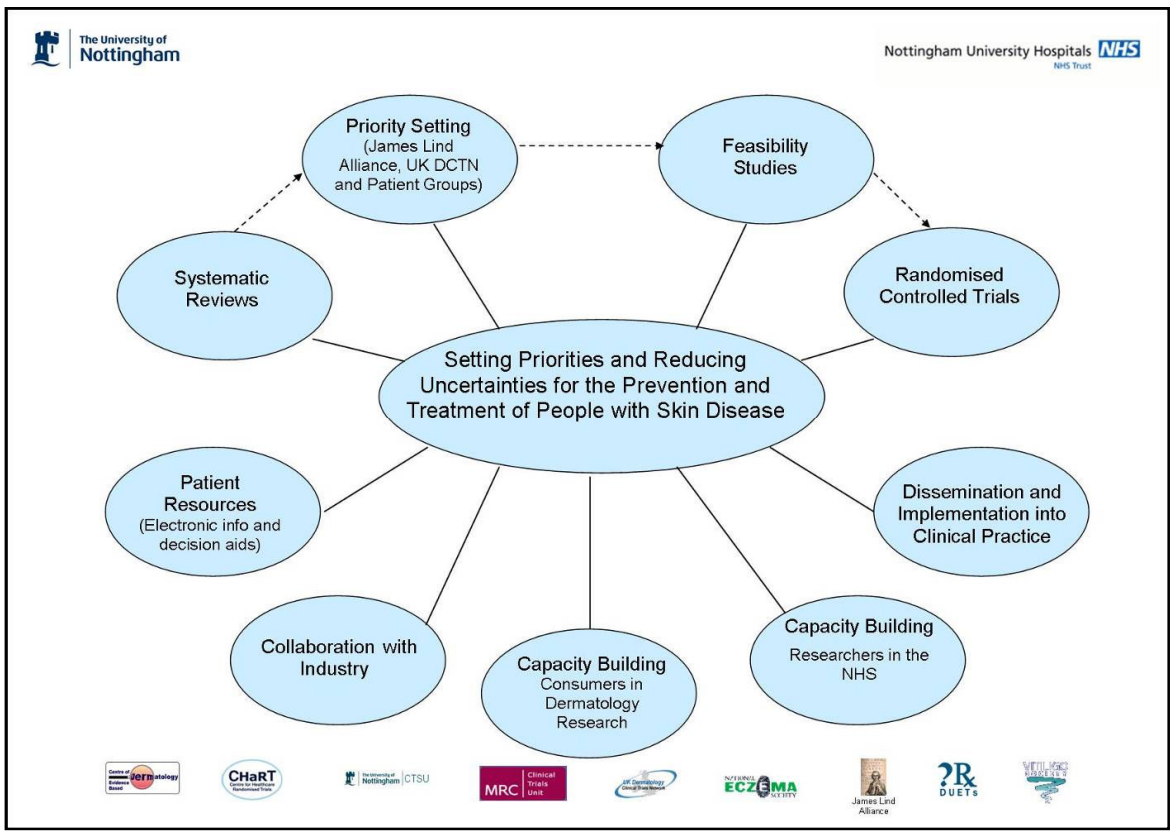
Setting Research Priorities and Reducing Uncertainties in the Prevention & Treatment of Patients with Skin Diseases

Much of 2007/8 has been spent on developing an ambitious programme of research with other key collaborators from throughout the UK and Europe. The work is being funded by the Department of Health's National Institute for Health Resaerch (NIHR). Key collaborators include colleagues from the James Lind Alliance, Clinical Trials Units, the UK Dermatology Clinical Trials Network, the Cochrane Skin Group, the National Eczema Society and the Viltiligo Society.

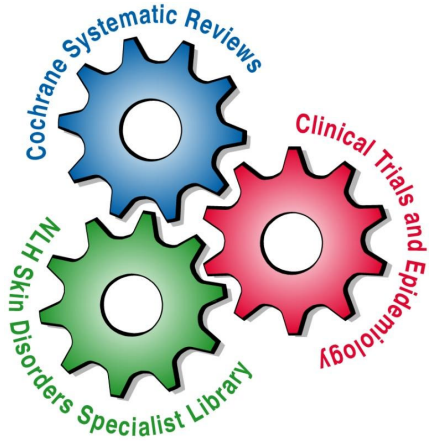
The programme covers five disease areas:

- Eczema prevention
- Eczema treatment
- Non-melanoma skin cancer
- Vitiligo
- Pyoderma gangrenosum

Main components of the programme are shown below



The Centre of Evidence Based Dermatology Ongoing Research Projects in 2007-2008



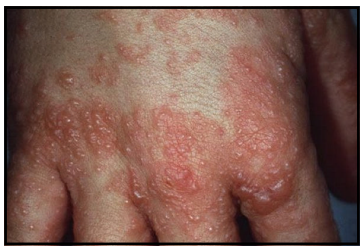
RESEARCH

Clinical Trials

Softened Water Eczema Trial (SWET)

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]*

[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 Marys Hospital, Newport, Isle of Wight, [13] UK Water Treatment Association



This is a single-blind, randomised controlled trial looking at the effect of softened water on childhood eczema. A total of 310 families will be randomised into the trial in four recruiting centres: Nottingham /Leicester; Cambridge; North London; Isle of Wight/ Portsmouth.

The study has been funded by the NIHR HTA Programme, with contributions from a consortium of water softening companies, who are providing the water softening units, salt, and testing of 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 is expected to continue for 24 months.
For further information see the study's website:
www.swet-trial.co.uk

Start date: 1st September 2006
Finish date: 31st August 2009
Funded by: NIHR HTA programme, with softeners, salt and water testing supplied by UK WTA.

Publications arising from this study:

Thomas KS & Sach TH 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 (in press)*

RESEARCH

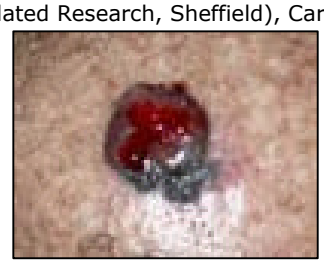
Clinical Trials

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

Investigators: *Fiona Bath-Hextall, Hywel Williams, William Perkins[2], Jan Bong[2], Irshad Zaki[3], Graham Colver[4], Paul Miller[1], Sarah Armstrong[1], Graeme Perks[2], Mara Ozolins[1]* Clinical Research Nurses*: Joanne Llewellyn[1], Beryl Cunningham[3], Sam Annasamy[4]*

[1]Departments of Dermatology and Trent RDSU, University of Nottingham, [2]Department of Dermatology, QMC, Nottingham, [3]Department of Dermatology, Solihull Hospital, [4]Department of Dermatology, Chesterfield Royal Hospital,.

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



Basal Cell Carcinoma
©Dermatlas; http://www.dermatlas.org

This is a randomised controlled trial of excisional surgery v's 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, Birmingham; 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.
The study reached its revised recruitment target of 500 patients in February of 2007. The group received an extension with extra funding from Cancer Research UK to complete the three year follow-ups (last visit due March 2010) and also to capture five year outcomes from patient notes.

Start date: 16th September 2002
End date: 31st August 2012
Funded by: Cancer Research UK (imiquimod and funding for genetic markers addendum provided by 3M) + small R&D grant (2002-2007).

Publications arising from this study:
None to date

RESEARCH

Clinical Trials

Does the eradication of endoparasites promote allergic disease?

Investigators: *Carsten Flohr[1], Hywel Williams[1], John Britton[1], David Pritchard[1], Sarah Lewis[1], Jeremy Farrar[2,4], Rupert Quinnell[3], Tran Tinh Hien[4], Truong Tan Minh[5] , Luc Nguyen Tuyen[5]*

[1]University of Nottingham, [2]University of Oxford, [3]University of Leeds, [4]Hospital for Tropical Diseases, Ho Chi Minh City, Vietnam, [5]Khanh Hoa Provincial Health Service, Vietnam

Dr Carsten Flohr has recently returned from his field research at the Oxford University Clinical Research Unit in Vietnam, where he studied the links between intestinal parasites and allergic diseases, including eczema.

Allergic diseases are rare in developing nations, such as Vietnam, but are commoner in more affluent settings and in urbanised populations. Many cross-sectional studies from developing countries suggest that this urban-rural gradient for allergic disease can partly be explained by a higher prevalence of geohelminth infection in rural areas.

Dr Flohr examined the links between gut worms and allergic diseases in 1,600 rural Vietnamese children and found in cross-sectional analysis that those with the highest level of hookworm infestation were the least likely to have an allergic response to house dust mites. Treating these 1,600 hookworm-infected children with de-worming tablets in a randomised, double-blind, placebo-controlled trial over a 12-month period significantly increased their allergen skin reactivity. While there was no increase in clinical allergic disease, such as eczema, at the end of the trial period, the results suggest a direct immuno-modulatory effect of geohelminth infection on skin prick test responses. Geohelminth-induced IL-10 was inversely related to skin prick test positivity at baseline and also reduced after antihelminthic treatment, albeit non-significantly, suggesting that IL-10 might be involved in the downregulation of skin prick test responses, but other so far unknown immunological mechanisms must be at play as well.

Start date: May, 2004
End date: June, 2006 (end of fieldwork)
Funded by: Radcliffe Research Fellowship from the University of Oxford, a grant from Asthma UK, and the Bastow research grant from the Special Trustees for Nottingham University Hospital. salary support from the Wellcome Trust UK between April 2006 and February 2007.

RESEARCH

Clinical Trials

Publications arising from this study:

Flohr C, et al Effect of anti-helminthic treatment on exercise-induced bronchospasm, allergen skin sensitisation, and immunological responses: A randomised, double blind, placebo-controlled trial in Vietnam. [submitted to *the Lancet*]

Flohr C, et al. Low efficacy of mebendazole against hookworm in Vietnam: two randomised controlled trials. *American Journal of Tropical Medicine & Hygiene* 2007;76 732-736

Flohr C, et al Poor sanitation and helminth infection protect against skin sensitization in Vietnamese children: A cross-sectional study. *Journal of Allergy and Clinical Immunology* 2006; 118: 1305-11.

Carsten and Vietnamese field workers at a training workshop

Going to Vietnam was a great challenge personally and culturally, a unique opportunity to lead a large team of fieldworkers and laboratory assistants. Doing research in a developing country setting is far from easy, and I was very pleased to bring the project to a successful end and for my work to be recognized through the Barry Kay award 2007 for the best scientific research from the British Society for Allergy and Clinical Immunology
Carsten Flohr

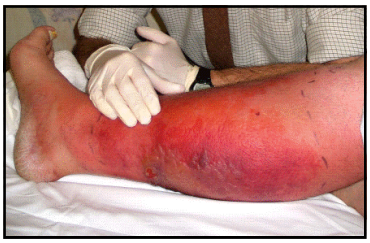
RESEARCH

Clinical Trials

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

Investigators: *Peter Featherstone[1] (Independent Chair), Hywel Williams[2], Neil Cox[3], Nick Reynolds[4], David de Berker[5], Andrew Nunn[6], Peter Mortimer[7], Kim Thomas[2], Joanne Chalmers[2], Katharine Foster[2]*
Independent Chair: *Robert Hills[8], Beverly Adriaans[9], Jane Daniels[10]*

[1]Queen Alexandra Hospital Portsmouth [2]University of Nottingham, [3]Cumberland Infirmary, , [4]University of Newcastle, [5]Bristol Royal Infirmary, [6]MRC, [7]St Georges Hospital Medical School, [8]Cardiff University, [9]Gloucestershire Hospitals NHS Trust, [10]Birmingham Clinical Trials Unit,



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.
The study is actively recruiting participants and will continue to do so until December 2009 (PATCH I) and July 2008 (PATCH II).

The study now has 24 recruiting centres and had enrolled 139 patients as of the end of April, 2008.
For further information see the study's website: www.patchtrial.co.uk

RESEARCH

Clinical Trials

PATCH I:

Start date: 01 July 2006
End date: 30 June 2009
Funded by: Action Medical Research

PATCH II

Start date: 01 Jan 2007
End date: 31 Dec 2010
Funded by: BUPA Foundation

Publications arising from this study:

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

Thomas KS, Cox NH, Savelyich BSP, 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 Jan 26; 8:Art. No. 3.

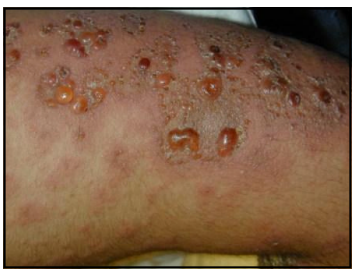
RESEARCH

Clinical Trials

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)

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

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



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 affecting mainly 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, i.e. do the benefits of less severe side effects outweigh any potential reduction in effectiveness.

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. After six weeks, the investigator will count the number of blisters that remain. The medication dose will then be assessed every few weeks and reduced if appropriate until the blisters have virtually all cleared. To assess safety, all adverse events will be recorded for a year after starting the study.

Outcome measures:

1. Proportion of patients who have five or less significant blisters at six weeks.

2. Proportion of patients with grade 3 or above side effects (inc. 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 will have approximately 40 active recruiting centres in the UK, Germany and the Netherlands and aim to recruit a total of 256 patients over a three year period. If you are interested in this study, please contact the Senior Clinical Trials Manager, Joanne Chalmers (joanne.chalmers@nottingham.ac.uk)

Start date: September 2008
End date: September 2013
Funded by: NIHR Health Technology Assessment programme

RESEARCH

Clinical Trials

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

Investigators: *Cockayne, ES[1]; Torgerson, DJ[1]; Curran, M[2]; Thomas, KS[3]; Hashmi, F[4]; McLarnon, NA[5]*

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

Approximately 270 patients with verrucae aged 12 years and over, are being recruited into the trial.

Patients will receive one of:

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

The main outcome is complete clearance of all verrucae as observed on digital photographs taken at 12 weeks.

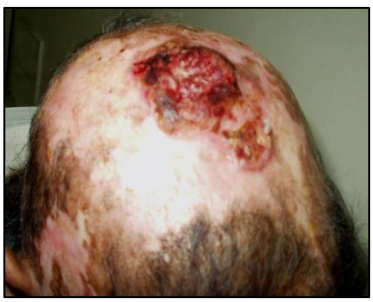
Data on side effects of treatment, pain intensity after treatment, use of painkillers, restrictions to lifestyle due to having verrucae, treatment details and patient satisfaction with treatment are also being collected. Economic costs will be presented from the perspective of the NHS and the patient.

Start date: October 2006
End date: November 2008
Funded by: NIHR Health Technology Assessment programme

Non-Melanoma Skin Cancer: Pilot study to examine patterns of incidence, risk factors and treatments in primary care using the THIN database

Investigators: *Fiona Bath-Hextall, Jo Leonardi-Bee, Andy Meal, Richard Hubbard*
University of Nottingham

The principal research questions for this study are the following:



1) Is there a time trend in the incidence of non-melanoma skin cancer and does this vary with age?

2) What are the potential risk factors for non-melanoma skin cancer, e.g. smoking and immunocompromised patients?

A case control study of smoking and basal cell carcinoma (BCC) has been completed.

The THIN database has been validated for BCC and a paper has been submitted for publication.

Start date: 1 December 2004
End date: December 2007

Funded by: University of Nottingham and NHS R&D Support Funding

Publications arising from this study:

Fiona Bath-Hextall, Jo Leonardi-Bee, Andy Meal, Richard Hubbard. Trends in incidence of basal cell carcinoma: A primary care population based study. *International Journal of Cancer* (In press)

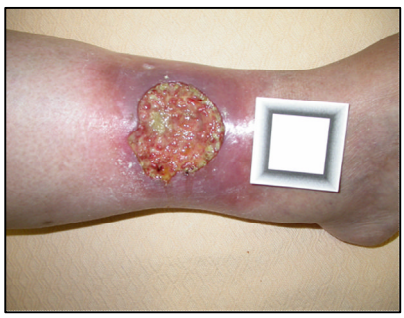
RESEARCH

Pilot Studies

Pyoderma gangrenosum feasibility study (Pilot STOP GAP)

Investigators: *Anthony Ormerod[1], Kim Thomas[2] and John Norrie[1]*

University of Aberdeen[1], University of Nottingham[2]



The UK Dermatology Clinical Trials Network (UK DCTN), in collaboration with The Centre for Healthcare Randomised Trials (ChaRT) (Health Services Research Unit at the University of Aberdeen) has developed a protocol for the first randomised controlled trial (RCT) to compare commonly used treatments for pyoderma gangrenosum. Pyoderma gangrenosum is relatively rare, but has severe consequences for patients, and represents a relatively large drain on NHS resources as patients require daily dressing changes and are often hospitalised for long periods of time.

This study is designed to assess the feasibility of conducting the future RCT. In particular, it will inform the design of the RCT; assess the viability of using digital images taken by the participants to capture time to healing for the study; assess the willingness of clinicians to randomise patients into the study; and involve patients and their carers in the research process at an early stage.

This feasibility work comprises three separate studies:

The first is a retrospective case note review that will be used to assess incidence, therapy, morbidity, co-morbidity and time to healing. This aspect of the study will be used to inform the recruitment strategy by assessing the suitability of eligibility criteria and providing data to inform sample size calculations.

The second study will assess the use of digital photography to capture the primary outcomes of time to healing and velocity of healing. Importantly, the study will explore the novel use of digital images as taken by participants themselves.

The third study will employ qualitative techniques (focus groups, structured interviews, research meetings and surveys) to capture the opinions of patients with pyoderma gangrenosum and clinicians, in order to ensure that the trial addresses their concerns and to get advice on design, focus and ethics of the RCT. This aspect of the study includes a survey of the membership of the UK Dermatology Clinical Trials Network and a survey of members of the European Dermato-Epidemiology Network (EDEN).

Funded by: British Skin Foundation
Start date: Dec 2007
End date: Dec 2008

Publications arising from this study:
None to date

RESEARCH

Cochrane Systematic Reviews

Anti staphylococcal agents in the treatment of atopic eczema

Investigators: *Andrew Birnie[1], Jane Ravenscroft[1], Fiona Bath-Hextall[2], Hywel Williams[2]*

[1]Queens Medical Centre, Nottingham, [2]University of Nottingham

This review was initiated by Dr Jane Ravenscroft who published the protocol. Dr Andrew Birnie, a dermatology specialist registrar, then took on the role of lead reviewer at this stage and has now prepared and published the review.

Expected date of publication within Cochrane library: Summer 2007

Publications arising from this study:

Ravenscroft JC, Williams HC, Weston V, Page J, Williams R. Interventions to reduce Staphylococcus aureus for atopic eczema. (Protocol) *Cochrane Database of Systematic Reviews* 2002, Issue 1. Art. No.: CD003871

Birnie AJ, Bath-Hextall F, Ravenscroft JC, Williams HC. Interventions to reduce Staphylococcus aureus for atopic eczema. British *Journal of Dermatology*. 2007;156(5):1114.

Interventions for alopecia areata

Investigators: *Finola Delamere[1], Mike Sladden[2], H Dobbins[1], Jo Leonardi-Bee[1]*

[1]University of Nottingham, [2]University of Tasmania Launceston General Hospital

This systematic review summarises the results of 16 RCTs covering a range of interventions, including topical minoxidil, topical and systemic steroids, PUVA, cyclosporin and dinitrochlorobenzene.

This systematic review summarised the results of 17 RCTs covering 540 participants, covering a range of treatments. Overall none of the interventions showed significant treatment benefit in terms of hair growth when compared to placebo. Also none of the studies addressed the participants assessment of their hair growth or quality of life.

This review has now been submitted.

Publications arising from this study:

Delamere FM, Sladden MM, Dobbins HM, Leonardi-Bee J. Interventions for alopecia areata. *Cochrane Database of Systematic Reviews* 2008, Issue 2. Art. No.: CD004413. DOI: 10.1002/14651858.CD004413.pub2.

RESEARCH

Cochrane Systematic Reviews

Dietary supplements for established atopic eczema

Investigators:*Fiona Bath-Hextall[1], Finola Delamere[1], R Humphreys[2], Hywel Williams[1], W Zhang[1]*

[1]University of Nottingham, [2]Consumer

This review explores the possible benefits of dietary supplements, such as zinc and pro-biotics for people with eczema.

Publications arising from this study:

Bath-Hextall F, Delamere F, Humphreys R, Williams HC, Zhang W. Dietary supplements for established atopic eczema. *Cochrane Database of Systematic Reviews* 2008, Issue 4. Art. No.: CD005205.

RESEARCH

Other Related Research

International Study of Asthma and Allergies in Childhood (ISSAC)

Hywel remains as the eczema representative on the ISAAC Steering Committee – the largest epidemiological study on the distribution and causes of eczema, asthma and hay fever worldwide. ISAAC is unique in the way it has involved over 100 countries, including many developing countries.
One of the most commonly asked questions from people with eczema is whether or not allergies such as eczema are really on the increase, or whether they are just reported more frequently in recent years. This year, the ISAAC study was able to directly address this question by seeing how the prevalence of eczema symptoms has changed over a span of five to eight years in over half a million children who underwent repeat surveys (ISAAC Phase I and Phase III) using exactly the same questionnaires. It showed that eczema is indeed on the increase in most countries, especially in younger children (aged 6 to 7 years). There was some hope for older children (aged 13 to 14 years) though, as some of the countries like UK and New Zealand that previously showed very high levels of eczema (around 22%), the prevalence seems to be stable or even falling, suggesting that there might be a finite proportion in any population who are susceptible to this common but enigmatic disease.
To find out more, please look at the ISAAC website at:
http://isaac.auckland.ac.nz/

Or read the original publication:

Williams H, Stewart A, von Mutius E, Cookson B, Anderson HR and the International Study of Asthma and Allergies in Childhood (ISAAC) Phase One and Three Study groups. Is eczema really on the increase worldwide? *Journal Allergy and Clinical Immunology* 2008;121:947-54.

Also of note is that Carsten Flohr has joined the ISAAC Phase II team to ensure that eczema issues are not forgotten in favour of asthma research. Carsten looked at all those taking part in ISAAC Phase II (which involved less countries but in a more intensive manner that included examining childrens' skin and doing some biological tests), and found that the relationship between allergy (the tendency to develop antibodies in the blood towards specific allergens like house dust mite) and eczema was not that convincing. In some developing countries, there was not much of an association between atopy and eczema, but a clear association between economic income and atopy. Carsten's work suggests that whilst allergy is important for eczema in some people living in developing countries, atopy may be an epiphenomenon of disease rather than a cause, and dividing all eczema into atopic and non-atopic eczema may not be that helpful. Please read the full report at:

Flohr C, Weiland SK, Weinmayr G, Björkstén B, Bråbäck L, Brunekreef B, Büchele G, Clausen M, Cookson WOC, von Mutius E, Strachan DP, Williams HC and the ISAAC Phase Two Study Group. The role of atopic sensitization in flexural eczema: Findings from the International Study of Asthma and Allergies in Childhood (ISAAC) Phase *Two Journal Allergy and Clinical Immunology 2008;121:141-7 .*

Publications arising from this study:

AW, Strachan D, Weiland SK, Williams HC. International study of asthma and allergies in childhood (ISAAC): rationale and methods. *European Respiratory Journal 1995;8:483-91*

The ISAAC Steering Committee. Worldwide variation in the prevalence of symptoms of asthma, allergic rhinoconjunctivitis and atopic eczema. The International Study of Asthma and Allergies in Childhood (ISAAC). *Lancet 1998;351:1225-32*.

Strachan D, Sibbald B, Weiland S, Williams HC. Worldwide variations in the prevalence of symptoms of allergic rhinoconjunctivitis in children: The International Study of Asthma and Allergies in Childhood (ISAAC). *Paed Pulmonol 1997;8:161-76*.

Asher MI, Andersen HR, Stewart AW, Williams HC. The ISAAC Steering Committee. Worldwide variation in the prevalence of asthma symptoms: The International Study of Asthma and Allergies in Childhood (ISAAC). *European Respiratory Journal 1998;12:315-35*.

Williams HC, Robertson CF, Stewart AW on behalf of the ISAAC Steering Committee. Worldwide variations in the prevalence of atopic eczema symptoms. *Journal of Allergy & Clinical Immunology* 1999, 103:125-138.

46. Mallol J, Clayton T, Asher I, Williams H, Beasley R. ISAAC findings in children aged 13-14 years - an overview. Allergy & *Clinical Immunology International 1999;11:176-182.114*.

Asher MI, Bjorksten B, Lai CKW, Strachan DP, Weiland SK, Williams HC and the ISAAC Phase Three Study Group. Worldwide time trends in the prevalence of symptoms of asthma, allergic rhinoconjunctivitis, and eczema in childhood: ISAAC Phase Three multi-country cross-sectional survey. *Lancet 2006:368:733-43*.

Williams HC, Stewart A, Von Mutius E, Cookson B, Anderson HR, International Study of Asthma and Allergies in Childhood (ISAAC) Phase One and Three Study groups. Is eczema really on the increase worldwide? *Journal of Allergy & Clinical Immunology 2008;121:947-54.*

RESEARCH

Other Related Research

Multi-Disciplinary Assessment of Technology Centre for Health (MATCH)

This national project funded by the Engineering and Physical Sciences Research Council (EPSRC) and a consortium of other funders seeks to develop better methods for assessing the value of medical devices in the UK and beyond. The traditional phases of randomised controlled trials is not ideal for the short life cycle of medical devices, and there is currently much wastage in the medical devices sector. Health economic modelling and better engineering system processes are being explored by a multi-disciplinary team lead by Professor Terry Young at the University of Brunel. Five universities (Brunel, Nottingham, Ulster, Kings College and Birmingham) are involved. Hywel Williams, John Crowe and Steve Morgan lead a group at Nottingham with interests in developing better valuation methods, engineering processes, and understanding the role of the user in medical device development. It is anticipated that this project will lead to links into the Centre of Evidence Based Dermatology's work by identifying new modelling methods that explore the health economics of new interventions before embarking on full scale RCTs. Indeed, such a project has already been undertaken through the health economic modelling of wart treatments for the NIHR HTA scheme. A major external review of MATCH was undertaken in early 2007. The review was successful leading to a five-year extension of the project.

Start date: 2004
End Date: 2013
Funded by: Engineering and Physical Sciences Research Council, NPSA, PASA

Publications arising from this study:

Johal S, Williams H. Decision-making tools for medical device development. *Journal of the ABPI* 2007:20-22.
Johal S, Oliver P, Williams HC. Better decision making for evaluating new medical devices projects: a real options approach. *Journal of Medical Marketing 2008:8:101-112*

RESEARCH

Other Related Research

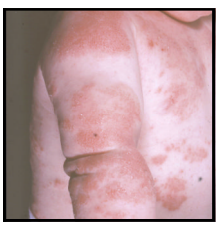
A prospective observational study of environmental factors affecting atopic eczema in children

Investigators: *Sinéad Langan, Paul Silcocks, Hywel Williams*
University of Nottingham

This project explores possible environmental factors that may cause eczema to flare. The study identifies how much of eczema activity can be explained using currently known or suspected flare factors, whether singly or in combination.

The research is designed to answer the following questions:

1. What causes atopic eczema flares?
2. Does atopic eczema truly represent a complex disease model?
3. Are there "summer" and "winter" types of atopic eczema?



Atopic Eczema
©Dermatlas; http://www.dermatlas.org.

This information will be crucial to our understanding of the disease process and may lead to increased understanding of disease mechanisms, with the potential to lead to a trial of therapeutic interventions.
Data collection for this study is now complete and analysis is underway. This is due to be completed by the summer of 2008.

RESEARCH

Other Related Research

Start date: January 2006
End date: February 2008
Funded by: Trust fellowship, January 2005 to January 2006. then BUPA Foundation and a Bastow Research grant from the Special Trustees for Nottingham University Hospitals.

Publications arising from this study:

Langan SM, Bourke JF, Silcocks P, Williams HC. An exploratory prospective observational study of environmental factors exacerbating atopic eczema in children. *British Journal of Dermatology* 2006;154:979-80.

Langan SM, Thomas K, Williams HC. What is meant by a "flare" in atopic dermatitis? *Archives of Dermatol*ogy 2006;142(9):1190-6

Langan SM, Williams HC. What causes worsening of eczema? A systematic review. *British Journal of Dermatol*ogy 2006;155(3):504-14

Langan SM, Flohr C, Williams HC. The role of furry pets in eczema: a systematic review. *Archives of Dermatology 2007;143(12):1570-7.*

Schmitt J, Langan SM, Williams HC. What are the best outcome measures for atopic eczema? A systematic review. *Journal of Allergy & Clinical Immunology 2007;120(6):1389-98*

RESEARCH

Other Related Research

Evaluating the effect of skin disease using a Runyankore-version of Skindex-16 in Mbarara, Uganda

Investigators: *Ser Ling Chua[1], Toby Maurer[2], Grace Kituuzi Mulyowa[3], Mary-Margaret Chren[2]*

[1]Queen's Medical Centre, Nottingham, UK, [2]University of California San Francisco, USA,[3]Mbarara National Referral Hospital, Uganda

This study aims to cross-culturally adapt Skindex-16, a validated quality of life instrument widely used in dermatology studies, for use in the mainly Runyankore-speaking community in Mbarara, Uganda for the purposes of dermatology research. Skindex-16 has been administered on 47 patients attending the Dermatology clinic of Mbarara National Referral Hospital as well as 47 non-patient participants. Recruitment was completed in January 2008. Preliminary findings have been presented at the Regional Dermatology Training Centre's (Moshi, Tanzania) annual meeting in 2008.

RESEARCH

Other Related Research

A prospective study to evaluate the clinical response of skin disease to anti-retroviral therapy (ART) over a 1-year period in Uganda

Investigators: *Ser Ling Chua[1], Kieron Leslie[2], Toby Maurer[2], Phillip Leboit[2], Grace Kituuzi Mulyowa[3], David Bangsberg[4]*

[1]Queen's Medical Centre, Nottingham, [2]University of California San Francisco, USA, [3]Mbarara National Referral Hospital, Uganda, [4]Harvard School of Public Health and Harvard Initiative for Global Health, USA

A study examining the utility of the presence of active skin disease after more than 15 months of anti-retroviral therapy as a predictor for treatment failure

This project involves two studies. The first study is a prospective cohort study looking at the natural history of skin disease in HIV-infected persons starting anti-retroviral therapy (ART) in Mbarara, Uganda. This study recruits from the Uganda Anti-Retroviral Therapy Outcomes (UARTO) cohort established in Mbarara in July 2005.
The second study is a nested case control study looking at the utility of resurgent or persistent skin disease as a predictor for failure of ART in HIV-infected persons in Mbarara, Uganda. This study also recruits from the UARTO cohort.
Recruitment started for both studies in December 2007 and is expected to continue for 18 months.

RESEARCH

Other Related Research

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

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

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

Basal cell carcinima (BCC) is the commonest cancer in humans. Although Mohs' micrographic surgery is the treatment of choice for high risk BCCs, its availability in 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 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 BCC 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 BCC regions obtained during surgery will be analysed to determine the ability of raman spectroscopy to discriminate the BCC. Two dimensional biochemical images will be built to image the BCC regions in tissue sections. The conditions under which measurement time can be reduced to levels acceptable to surgeons (few minutes) will be identified.

Start date: 1st February 2008
End date: 31st January 2009
Funded by: National Institute for Health Research and Nottingham University Hospital Charity.

RESEARCH

Other Related Research

Application of the mid-infrared spectral region to medical diagnosis and sugery in dermatology.

Investigators: *Angela Seddon[1], D Furniss[1], Sandeep Varma[1], Hywel Williams[2]*

[1]Queens Medical Centre, Nottingham, [2]University of Nottingham.

The Royal Academy of Engineering and Leverhulme Trust have awarded Prof Seddon a Senior Research Fellowship 2007/2008 to explore use of the mid-infrared spectral region in dermatology; the work is also supported by NEAT.

The approach is to work with clinicians in the Centre for Evidence Based Dermatology, and Queens Medical Centre, to investigate use of novel infrared optical fibres in medical applications via development of optical fibre based devices and systems that are robust, functionally designed and cost effective.

High silica glass optical fibres are the 'work-horse' of the Internet, being transparent conduits transferring voice, video and data as high-bit-rate optical pulses in the near-infrared. However, silica glass is opaque at longer wavelengths and novel glasses are required for mid-infrared light transmission.

In the Faculty of Engineering, Prof. Seddon & Dr D Furniss have commissioned a unique facility in the UK for making highest optical quality, mid-infrared-transmitting, novel glass fibres. Fibreoptic sensing in the mid-infrared will potentially access tissue molecular signatures based on vibrational absorption. For skin diagnostics, the reference standard at present is visual inspection by an experienced dermatologist, but this is time-consuming and dependent on human judgement.

Objectives

The first objective is to explore development of a mid-IR fibreoptic device for skin evaluation and possible early detection of cancer.

A second objective is to develop flexible-fibre power delivery in the mid-infrared at 10.6 μm (the carbon dioxide laser wavelength) for surgery.

RESEARCH

Other Related Research

The Fellowship is enabling personal development in terms of learning in detail what is required by clinicians, in order to map their needs onto what is achievable in engineering infrared devices. Professor Seddon would like in particular to thank Dr Sandeep Varma Consultant Dermatologist and Dermatological Surgeon in Queens Medical Centre for many pertinent explanations and the opportunity to work-shadow. She also thanks Professor Hywel Williams, Head of the Centre for Evidence Based Dermatology, QMC, for his help in overcoming boundaries between engineering and medicine and his encouragement.

Start Date: October 2007

End Date: February 2009

Funded by: The Royal Academy of Engineering and Leverhulme Trust, the Medical Research Council and New & Emerging Applications of Technology (NEAT), Dept of Health

Class-10,000 Cleanroom Facility in the School of Mechanical, Materials and Manufacturing Engineering, co-located with QMC. Prof Seddon's team are drawing mid-infrared fibre for medical devices.

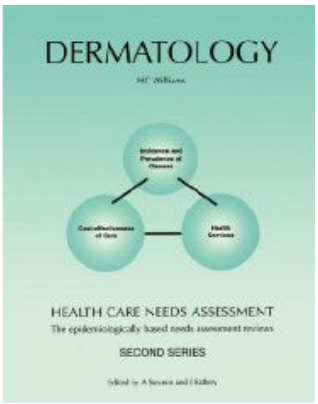
RESEARCH

Other Related Research

Health Care Needs Assessment for Patients with Skin Conditions

Investigators:*Julia Schofield*[1]*, Douglas Grindlay*[2]*, Hywel Williams*[2]

[1]*St Albans City Hospital,* [2] *University of Nottingham*



In 1997 Professor Hywel Williams authored '*Dermatology: Health Care Needs Assessment'* a Chapter in *The Epidemiologically Based Needs Assessment Reviews, Second Series'* published by Radcliffe Medical Publishing.

This document has proved to be an extremely helpful and relevant text which is referred to often in the context of informing commissioners and providers around specifying services for people with skin disease. It is referenced extensively in many of the All Party Parliamentary Group on Skin Disease reports. The only problem with that report is that it is now out of date.

Since 1997 there have been very significant changes in the delivery of health care in the UK and the NHS reform agenda has created a very challenging environment in which to ensure that patients with skin disease received high quality care. Several new studies have been published which relate to the UK Dermatology Needs Assessment, and new datasets have become available for populating the key tables.

Dr Julia Schofield is working with Professor Williams and his information specialist, Dr. Douglas Grindlay to update and re-publish the original Dermatology Health Care Needs Assessment taking account of evidence that has become available since the work was published 10 years ago.

Start date: March 2008
End date: July 2008
Funded by: Julia Schofield has been awarded the British Association of Dermatologists sabbatical fellowship and is also in receipt of financial support from the Primary Care Dermatology Society and the Psoriasis Association

Impact of the Centre's Research

RESEARCH

Impact of the Centre's Research

The Centre of Evidence Based Dermatology is proud of its reputation for conducting non-commercial, patient-focused research that is able to answer questions of importance to clinicians, patients and health providers. This is evidenced by the range of randomised controlled trials currently being undertaken in the Centre e.g. water softeners for the treatment of eczema; penicillin for the prevention of cellulitis; head-to-head comparisons of treatments for basal and squamous cell carcinomas. 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.

Direct impacts on clinical practice

Once daily topical steroids for atopic eczema

A summary of the available evidence in favour of a change in clinical practice from twice daily to once daily application of topical corticosteroids was recently published by the *British Medial Journal.* This article was included under the "BMJ Change Page". This page aims to alert clinicians to the immediate need for a change in practice, to make it consistent with current practice.

Williams HC Established corticosteroid creams should be applied only once daily in patients with atopic eczema. *British Medical Journal* 2007; 334:1272.

Eczema Guidelines

Work conducted in the department has been quoted in the new guidelines for the use of emollient therapy for atopic eczema (Ersser *et al,* 2007), the Royal College of Nursing guidelines for caring for children and young people with atopic eczema – guidance for nurses (www.rcn.org.uk/__data/assetspdf_file/0004/156172/003228.pdf), and in the NICE guidelines for the management of atopic eczema in children (www.nice.org.uk/CG057).

Ersser S, Maquire S, Nicoli N, Penzer R, Peters J A best practice statement for emollient therapy – A statement for healthcare professionals. *Dermatological Nursing* 2007: 1-19.

Cochrane systematic review of toxic epidermal necrolysis (TEN)

The Cochrane Skin Group's review of interventions for TEN helped to defeat a recent court case against doctors in the USA.

Acne trial included in a report looking at the impact of HTA funded research

Our randomised controlled trial of common acne treatments (funded by the NIHR's Health Technology Assessment programme) was included as a case study in the recent HTA report that evaluated the impact of research funded through the programme. For further details see: www.hta.ac.uk/project/1440.asp

National Knowledge Weeks for the National Library for Health Skin Disorders Specialist Library

The Skin Disorders Library has now run four National Knowledge Weeks in which recent evidence is synthesised and appraised for the reader. Guest editorials by experts in the field are presented alongside detailed summaries of the available evidence.

Topic	Date
Skin Cancer	5th – 9th May 2008
Acne Vulgaris	3rd – 7th March 2008
Psoriasis	5th – 9th Nov 2007
Atopic eczema	17th 21st Sept 2007

Further details are available at:
www.library.nhs.uk/skin/

Hitting the headlines

The Centre of Evidence Based Dermatology has been hitting the headlines recently with its cutting edge research. Articles have appeared in local and national newspapers and several radio broadcasts over the last 12 months. We always work with patient support groups to help with the dissemination of our research findings and are increasingly working with the media to help with participant recruitment.

RESEARCH

Impact of the Centre's Research

National Institute of Clinical Excellence (NICE) appraisals

The Centre of Evidence Based Dermatology and the Cochrane Skin Group have been involved in providing expert advice and comment on NICE protocols and guidance relevant to dermatology, as summarised in the table below.

Summary of NICE reviews the Centre has commented on
Atopic eczema in children: management of atopic eczema in children from birth up to the age of 12 years
Temozolomide for advanced and metastatic melanoma
Grenz rays therapy for inflammatory skin conditions
Adalimumab for psoriatic arthritis
Leflunomide for psoriatic arthritis
Reducing Ineffective Practice Consultation - Tetracyclines for acne vulgaris
Infliximab for the treatment of psoriasis
Guidelines for management of skin cancer
Improving outcomes for People with Skin Tumours including Melanoma
Once versus twice daily topical steroids for atopic eczema
Topical pimecrolimus and tacrolimus for atopic eczema
Efalizumab and etanercept for the treatment of psoriasis

We have also worked with the National Horizon Scanning Centre in order to inform a priority list of topics for further investigation by NICE, and have commented on a report looking at alitretinoin for chronic hand eczema.

RESEARCH

Impact of the Centre's Research

Impact on the Research Agenda and Priority Setting

The UK Dermatology Clinical Trials Network acts as an affiliate group (on behalf of the British Association of Dermatologists) for the NIHR HTA programme.

In addition, the Network has established a trial prioritisation panel, the remit of which is to assess the need, feasibility and clinical relevance of trial suggestions submitted to the group. It is anticipated that these existing structures will be used to support the newly formed Specialist Groups that are currently being established through the Comprehensive Research Network.

Later in 2008, we shall be starting a 5 year programme of work looking at setting research priorities and reducing uncertainties for the prevention and treatment of people with skin disease. This work includes two work streams, that will be working closely with the James Lind Alliance and patient support groups in order to establish the most important research questions to be addressed.

Through the NHL Skin Disorders Specialist Library the Centre contributes to the expansion of the DUETs database in identifying current uncertainties in healthcare and is proactive in seeking out unanswered questions from patient support groups and from gaps in up-to-date systematic reviews.

Examples of systematic reviews that have resulted in clinical trials being conducted, or trials in development within the Centre are listed in the table below.

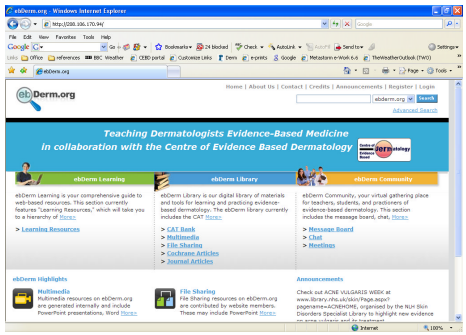
RESEARCH

Impact of the Centre's Research

Support for the Promotion of Evidence-Based Dermatology

Ebderm.org

The Centre of Evidence Based Dermatology is now working in collaboration with ebderm.org to provide information and training support for dermatologists wishing to develop their skills in Evidence-Based Medicine. Do visit the site at www.ebderm.org.



Publishing your research

We have been instrumental in encouraging major journals to publish both Critically Appraised Topics *(Archives of Dermatology)* and trial protocols *(British Journal of Dermatology)*. Both of these publication types are now accepted and are a useful way of disseminating your ongoing research.

For further information about critically appraised topics, see:
http://208.106.170.94/CAT_List.aspx

Contribution to research guidelines

Hywel Williams has commented on the SQUIRE and the STROBE guidelines. These guidelines aim to improve the reporting of epidemiological and observational studies.

For further information see:
http://www.equator-network.org/

RESEARCH

International Research Activity

European links

Hywel Williams is Chair of the European Dermato-epidemiology network (EDEN) 2004-2008. EDEN is an active group of researchers in the field of dermato-epidemiology. The group aims to expand the role of epidemiology in dermatology and to produce high quality collaborative work.

EDEN activities over the last year2007/08 have included:

1. Completing a Cochrane systematic review on interventions for hand eczema (lead Prof Pieter Jan Coenraads).

2. Developing a protocol for trans-cultural assessment of quality of life in Europe (Lead Prof Jean-Jacques Grob).

3. Setting up a large prevalence survey of fragrance allergy in Europe (lead Prof Luigi Naldi).

4. Developing a teaching CD-rom for practical procedures in dermatology (lead prof Luigi Naldi).

5. Updating the EDEN review of psoriasis clinical trials (lead Prof Luigi Naldi).

6. A systematic review of outcome measures for atopic eczema (lead Prof Hywel Williams).

Links between the UK DCTN and other dermatology colleagues interested in clinical trials were strengthened following an important EDEN workshop on independent dermatology research in Rome in December 2006. Colleagues in Germany and the Netherlands have now agreed to collaborate on a bullous pemphigoid trial that has recently been funded by the NIHR Health Technology Assessment Programme.

RESEARCH

International Research Activity

EDEN also holds its own congress along with the International Dermato-Epidemiology Network every 3 to 4 years. The last EDEN/IDEA Congress was held in Venice in October 2004. The 2008 Congress will be held at Nottingham in September 2008 (see www.idea2008.net for meeting website). The 2008 Congress is again being held in conjunction with the International Dermatoepidemiology Association (IDEA), an umbrella organisation that includes other dermato-epidemiology groups such as the American Dermato-Epidemiology Network. The local organising committee includes Prof Hywel Williams, Dr. Sinead Langan, Dr. Carsten Flohr, Mrs. Margaret Whittingham and Mr. Daniel Simpkins.

EDEN website:
http://orgs.dermis.net/content/e02eden/e01aims/e01programm/index_ger.html
IDEA website:
www.idea2008.net

Links with non-European countries

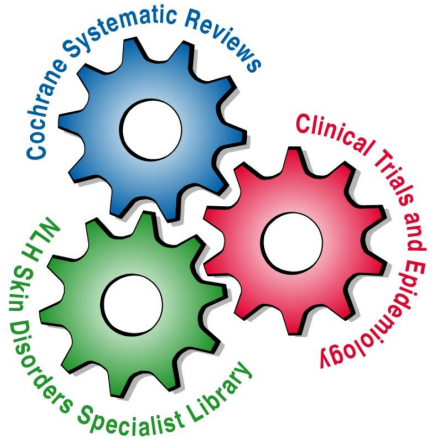
Several of our Centre's projects involve colleagues from developing countries. Carsten Flohr has recently returned from Vietnam where he was evaluating the association between eradication of helminthic parasites and allergic disease in Vietnam.

Ser Ling has recently returned from Uganda having spent a year working with HIV patients in Mbara in order to evaluate the clinical response of skin disease to anti-retroviral therapy.

The ISAAC study (see page36) has reported data on allergic diseases for the first time from many developing countries. Of note, eczema symptoms appears to be on the increase in many developing countries, especially in younger age groups.

Each year, two trainee dermatologists from the Regional Dermatology Training Centre in Moshi, Tanzania, are awarded a travelling fellowship of £1200 by the Centre of Evidence Based Dermatology to allow them to attend the annual course on 'Getting to grips with evidence based dermatology'.

Training Events within the Centre of Evidence Based Dermatology



TRAINING EVENTS

Annual Evidence Based Update meetings

Each Spring the Centre of Evidence Based Dermatology holds an Annual Evidence Based Update meeting. 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. Topics have included: infectious skin disorders (2007); bullous diseases (2008); and we are plan to cover urticaria and allergy in 2009. All proceeds from the day are donated to the UK DCTN.

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.

Feedback from the 2007 event indicated that over 50% of the delegates would be changing their clinical practice following attendance at the meeting.

TRAINING EVENTS

British Epidermo-Epidemiology Society (BEES) Annual Course

Getting to Grips with Evidence Based Dermatology

The annual Evidence Based Dermatology course was fully subscribed again in February 2008, with 24 participants from all over the UK. This three-day course is taught by staff from the Centre of Evidence Based Dermatology along with colleagues from the Trent Research Development Support Unit. It covers areas such as study design, statistics, clinical trials, and writing scientific papers. The two Overseas Travelling Fellowships, made available through profits from previous courses, were awarded this year to Dr Harvey Molope and Dr Mebratu Tabor from the Regional Dermatology Training Centre in Tanzania.

Attendees of the BEES 2008 course "Getting to Grips with Evidence Based Dermatology" run by the CEBD.

For further details of the next course (4th-6th February 2009), 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.

Excellent course—already recommended to other registrars I know. Like the biology of the skin course, this should be compulsory for all first year dermatology registrars!

TRAINING EVENTS

The European Dermato-Epidemiology Network (EDEN)

The next EDEN Congress held in association with the American Dermato-Epidemiology Network (under the overarching umbrella of the International Dermato-Epidemiology Association – IDEA) will be hosted in Nottingham 7th-9th September 2008. A Scientific The theme will be assessing the burden of skin disease, to coincide with the World Health Organisation's global burden of skin diseases project. Anyone interested in coming should visit the excellent website:
www.idea2008.net

EDEN also has a forum for young researcher to discuss new research ideas. Just send an email outlining your project to edenforum@eadv.es and get help from the EDEN community.

British Epidermo-Epidemiology Society (BEES) Annual Meeting

The 16th meeting of BEES was held over three days in April 2007, in conjunction with the British Society for Investigative Dermatology, at the University of Nottingham. The chair of the meeting was Professor Graham Ogg, with local organisers being Professor Hywel Williams and Dr Andrew Birnie. Highlights included genetics of atopic dermatitis by Irwin McLean who discussed filaggrin; a discussion of epigenetics by Professor Keith Godfrey, who has been looking at the effects early environmental influences may have on genetic/physiological make-up that can be passed onto future generations; and of course the chief drone himself, Hywel Williams, who discussed the role of environment in childhood eczema. The Keynote Guest Speaker was Professor Irma Thesleff, from the University of Helsinki, who described the pathogenesis of ectodermal dysplasia syndromes. The British Photodermatology Group Guest Lecture was given by Professor Steve Ullrich, from the University of Texas, on "Sunlight and skin cancer: lessons from the immune system." The BEES Guest Speaker was Richard Smith, former Editor of the *British Medical Journal*, who gave an enjoyable polemic on the trouble with medical journals, Local Guest Speaker, Professor David Pritchard from the University of Nottingham, discussed how worms, maggots and bacteria may play an important role in the future development of drugs.

The 2008 BEES annual conference has been delayed in order to coincide with the International Dermato-Epidemiology Association conference, September 2008.

TRAINING EVENTS

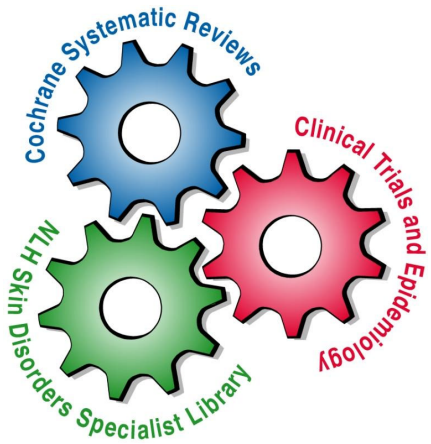
National Skin Surgery Course

Each spring the Dermatology Department runs a National Skin Surgery Course organised by Skin Cancer Nurse Specialist Gill Godsell. The two day course focuses on the practical skills required to undertake skin surgery

British Contact Dermatitis Course

Every two years the British Contact Dermatitis Society holds the Contact Dermatitis Course in Nottingham. This is run by Dr John English, Consultant Dermatologist. The aim of the course is to improve the dermatologist's diagnostic management of patients with suspected contact dermatitis. The course was held in March 2007 and was attended by 22 delegates. The three day programme included a series of lectures, patch testing in the dermatology clinic, and a full day at Boots at Beeston for a factory visit.

Collaborative Links



COLLABORATIVE LINKS

The Centre works closely with many partners and stakeholders throughout the UK. These include links with other academic departments, NHS partners, charitable bodies and industry.

Topic Specific Research Networks

With the introduction of Topic Specific Research Networks following the report on "Best Research for Best Health", the unit has developed ties with several Networks. All of our funded trials are eligible for inclusion on the UK Clinical Research Network's trials portfolio, and we have received support from both the Medicines for Children Research Network and the Primary Care Research Network.

Both the EVERT study (Effective VERrucae Treatments trial) and the SWET trial (Softened Water Eczema Trial) have been adopted by the Medicines for Children Research Network and by the Primary Care Research Network. The MCRN are now providing a research nurse in London & Lincoln in order to support recruitment into the SWET trial. Kim Thomas is a member of the MCRN's General Paediatrics Clinical Studies Group and advises on the suitability of trials for adoption.

The SINS Study (Surgery versus Imiquimod of Nodular and Superficial skin cancer) is supported by the National Cancer Research Network and have helped in setting up new recruitment centres.

COLLABORATIVE LINKS

DUETs and the James Lind Alliance

The Skin Disorders Specialist Library, UK Dermatology Clinical Trials Network and the Cochrane Skin Group are all members of the James Lind Alliance and are fully supportive of the DUETs initiative (Database of Uncertainties about the Effects of Treatments).

www.jameslindlibrary.org
www.duets.nhs.uk

Work is ongoing to establish how best the Centre may facilitate the development of the DUETs database.

Douglas Grindlay, of the NLH Skin Disorders Sepcialist Library, is now co-ordinating the collection of Uncertainties on skin disorders and is responsible for entering them into the DUETs database.

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

- Commenting on Cochrane systematic reviews.
- Leading Cochrane systematic reviews.
- Participating in trial development groups and becoming a member of Trial Steering Groups.
- Commenting on trial design, patient information sheets and other study materials.
- Helping with Focus Group discussions in order to inform trial design

COLLABORATIVE LINKS

Collaboration with Research Support Units throughout the UK

MRC Clinical Trials Unit

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

Centre for Healthcare Randomised Trials

The Centre for Healthcare Randomised Trials (CHaRT), at the University of Aberdeen, have been involved in developing the study looking at treatments for pyoderma gangrenosum. This is one of a portfolio of trials managed through the UK Dermatology Clinical Trials Network.

Birmingham Clinical Trials Unit

A study looking at the use of imiquimod for the treatment of lentigo maligna is being developed in collaboration with the Birmingham Clinical Trials Unit and the UK Dermatology Clinical Trials Unit. An application for a phase II trial has been submitted under the NIHR Research for Patient Benefit Scheme.

The Nottingham Clinical Trials Unit

Hywel Williams is the Director of the Nottingham Clinical Trials Unit at the University of Nottingham. The need for such a professional unit has come about due to an expanding portfolio of clinical trials at the University of Nottingham, and because of the extra work incurred by the EU Clinical Trials Directive. Trials developed by the Centre of Evidence Based Dermatology are increasingly using the services of the Nottingham Clinical Trials Unit and we are working on a collaborative basis on several trials.

Trent Research and Development Support Unit

The Centre works closely with the Trent Research & Development Support Unit in providing training events and in conducting primary research.

Collaboration with the Trent RDSU has mainly involved methodological support in statistics and health education. Several studies based in the Centre have accessed the Trent Focus Collaborative Research Network with great success and it is hoped that similar work will continue through the local Primary Care Research Networks.

COLLABORATIVE LINKS

Other Higher Education Institutions (HEIs)

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

- University of East Anglia - an NHS HTA funded warts economic decision model. (www.ncchta.org/execsumm/summ1025.htm)
- University of Leeds - an NHS HTA funded RCT looking at antimicrobial treatments for acne. (www.ncchta.org/execsumm/summ901.htm)
- Brunel University – Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH) is a national collaborative study in which Hywel Williams leads the Nottingham group.
- Universities of Oxford & Leeds – Carsten Flohr has recently returned from the Oxford University Clinical Research Unit in Vietnam on a project looking at the impact of endoparasites on allergic disease.
- University of York – co-applicants on an RCT looking at treatments of warts in children (EVERT study).
- University of Aberdeen – joint applicants in applying for funding for an RCT looking at treatments for Pyoderma Gangrenosum
- University of Oxford – joint applicants in applying for funding for an RCT looking at treatments for Bullous Pemphigoid

Staff at the Centre of Evidence Based Dermatology

STAFF PROFILES

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.

Dr Fiona Bath-Hextall
Associate Professor (Senior Lecturer)

Fiona is the Biological Sciences lead for teaching and research in the School of Nursing. She teaches Evidence-Based Practice (level 4) on the Postgraduate Diploma, Non Medical Prescribing, Advanced Nursing Practice, and the MSc Advanced Clinical Practice courses.
Her work within CEBD began by performing a systematic review, looking at the treatment of basal cell carcinomas (BCCs). This review identified gaps in the research area which led Fiona and Hywel to write a proposal for a phase III multi-centre clinical trial. This trial compares excision surgery vs imiquimod 5% cream for the treatment of nodular and superficial basal cell carcinoma (SINS). The trial is funded by the Cancer Research UK. In addition to this trial there is an add-on trial looking at genetic markers. Fiona has just finished a pilot study, for which she is principal investigator, examining patterns in incidence, risk factors, and treatment in primary care using the THIN database. Another case control study looking at smoking and skin cancer using the THIN database is near completion.
Fiona also represents the Cochrane Skin Group which is a registered stakeholder for the consultation on NICE guidelines 'Improving outcomes for patients with skin tumours including melanoma'.

Ser 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.

Brenda Cooper
Clinical Trial Administrator
Brenda joined the Centre in November 2006 and provides administrative support to the PATCH trial.
Previous to joining the Centre she provided administrative support for the Tombola Trial (Trial Management of Borderline and Low grade Smears) and the Clinical Trial Support Unit. Prior to this her career was in logistics and marketing for a large pharmaceutical company.

Susan Davies Jones
Research Nurse
Sue is originally from North Wales and trained as a Staff Nurse at Bodelwyddan Hospital.
Since qualifying in 1995, she has worked at Glenfield Hospital, Leicester in Endoscopy and Theatre/ Recovery, where she remained for three years.
Sue then worked briefly at Theatre/ Recovery, Maidstone Hospital, Kent before starting her work within chronic disease management, firstly at the Dermatology Department, Meadway Maritime Hospital, Kent.

Sue now has over nine years experience working in chronic disease management. Since moving to Nottingham in 2000 she has worked at the Dermatology Department at QMC where she has gained a wide range of valuable experiences in the area.
In 2004, Sue took on an additional two year developmental role as Clinical Nurse Specialist for Rheumatology, which has lead to her first research nurse post.
Since 2006 Sue has been working on a third phase international study to evaluate the efficiency and safety of various treatment regimens of rituximab in combination with methotrexate in patients with rheumatoid arthritis.
While continuing with this part time post, Sue has recently joined the Centre of Evidence Based Dermatology in March 2007 and is working as a research nurse on the Soft Water Eczema Trial (SWET), covering the areas of Nottingham and Leicester.

Dr Finola Dlamere
Acting Review Group Co-ordinator

Finola's first degree was in Biochemistry following which she undertook a PhD investigating proteins present in human seminal plasma that could be used for the forensic identification of semen in the absence of spermatozoa.
After the completion of her PhD she worked at the Metropolitan Police Forensic Science Laboratory, initially continuing her research and then on cases involving crimes against the person which entailed giving evidence at the Old Bailey as well as other criminal courts.
When she married and moved to Nottingham she spent several years doing laboratory-based research in cystic fibrosis and asthma.

As the Trials Search Co-ordinator of the Cochrane Skin Group, Finola is building a Specialised Register of controlled trials that have been carried out on skin diseases. This database forms part of the CENTRAL Database within the Cochrane Library and is an important resource for those who wish to write systematic reviews on healthcare interventions in dermatology. She has also developed and maintains the Cochrane Skin Group's web site www.csg.cochrane.org which contains the Ongoing Skin Trials Register. As well as assisting other Cochrane authors with the searches for their reviews, Finola is the lead author on the Cochrane systematic review of alopecia areata and co-author on the Cochrane systematic reviews on Dietary exclusions and dietary supplements in atopic eczema.

Dr Carsten Flohr
Clinical Research Fellow

After graduation from Oxford University Medical School in 1998, Carsten trained as a paediatrician (MRCPCH) in Newcastle and gained six months clinical experience in dermatology at the University Hospital of North Durham.
Carsten joined the Centre for Evidence Based Dermatology in August 2002 as Clinical Research Fellow to Professor Williams. He has recently returned from his field research at the Oxford University Clinical Research Unit in Vietnam, where he studied the links between intestinal parasites and allergic diseases, including eczema.

STAFF PROFILES

Dr Katharine Foster
Clinical Trial 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. PATCH is a double-blind randomised controlled trial to investigate the effect of prophylactic antibiotics in the prevention of recurrence of cellulitis of the leg and is the first full clinical trial to come under the umbrella of the UK DCTN.

Dr Douglas Grindlay
Information Specialist, NLH Skin Disorders Specialist Library

Douglas started as Information Specialist for the Skin Disorders Specialist Library in April 2004, and has been responsible for setting up the Library and its subsequent maintenance and development since its official launch in March 2005. Douglas is also now responsible for a pilot exercise compiling the Skin Module in the 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 agricultural research and as a scientific officer and administrator in the Civil Service.
In 2007 Douglas was awarded Chartership (MCLIP) by CILIP, the Chartered Institute of Library and Information Professionals, on the basis of a professional portfolio describing his work on the NLH Skin Disorders Specialist Library.

Diane Horsley
Administrative Assistant (Cochrane Skin Group)

Diane joined the Cochrane Skin Group in August 2008 to give administrative support to the Editorial base. Her role involves tracking the reviews in the editorial process, finding referees, hand searching journal, as well as proof reading and editing reviews prior to publication

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).

Dr Sinéad Langan
Clinical Research Fellow

Dr Sinéad Langan graduated in medicine from the Queen's University of Belfast in 1996. She commenced training in Dermatology on the Irish

higher medical training programme in July 2001 and obtained her CCST in June 2005. Sinead joined the Centre of Evidence-based Dermatology in January 2005 as Clinical Research Fellow to Professor Hywel Williams.
Sinéad is studying the effect of environmental influences on existing eczema in children and the relationship to disease flares. This project has been preceded by a pilot study performed in Cork, Ireland in June 2003. She is currently completing analysis of the study and writing up her PhD. During her time at the CEBD, she has also completed an MSc in Epidemiology at the London School of Hygiene and Tropical Medicine.
She is honorary secretary for the European Dermatoepidemiology Network (EDEN) and is involved in the organisation of the International Dermatoepidemiology Network (IDEA) meeting in Nottingham in September 2008.

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 Manager for the UK Dermatology Clinical Trials Network and is responsible for developing and promoting the UK DCTN. This involves areas such as advertising and publicity, securing sponsorship funding for the Network and also organizing meetings - including the annual evidence based update meeting.

Dr Tina Leonard
Review Group Co-ordinator
Cochrane Skin Group
Tina is the Managing Editor and Review Group Co-ordinator of the Cochrane Skin Group. She trained at Birmingham and Nottingham Universities and worked for many years as a lab-based research biochemist. Her PhD was in Applied Biochemistry and Nutrition and her post-doctoral work in Oxford was in ophthalmology and anaesthetics.
Before taking up her present post, Tina held senior NHS posts in clinical audit, quality management and clinical effectiveness. She has extensive experience of project management, and a particular interest in improving the quality and effectiveness of health services, and using research evidence to inform decision making and policy formulation.
Tina is also interested in evaluating the effectiveness of complementary therapies. She has published a Cochrane review on 'Chinese herbal medicine for atopic eczema' and has just completed a review on 'Complementary therapies for acne'.

Joanne Llewellyn
Research Nurse
After studying for a degree in Nursing Studies, Joanne began her career as a Staff Nurse on an orthopaedic ward at the Royal Hallamshire Hospital in Sheffield, where she remained for four years.
Joanne was then employed as a Research Nurse at Hammersmith Medicines Research, a CRO, based at the Central Middlesex Hospital in London. Whilst there she was promoted to Senior Research Nurse and then to Team Leader.
Following this Joanne commenced employment as a Drug Surveillance Executive at Roche Products Ltd, in Welwyn Garden City, where her job consisted of collecting and investigating

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adverse events for marketed drugs and reporting eligible spontaneous and clinical trial adverse events to the Medicines Control Agency. Whilst in this post Joanne completed a Postgraduate Certificate in Pharmacovigilance.

After relocating to Nottingham, Joanne started work as a Clinical Project Manager at ClinPhone, where she was responsible for liaising with pharmaceutical companies and designing Interactive Voice Response Systems (IVRS) to assist with data collection and transfer in Clinical Trials.

Joanne joined the Centre of Evidence Based Dermatology in January 2003 and is currently 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 QMC (Nottingham) and KMH (Sutton-in-Ashfield). In 2006, Joanne received her MSc in Science (distinction) from the Open University.

Helen Nankervis
Editorial Assistant
Cochrane Skin Group

Helen studied at Leeds University for a Degree in Medical Microbiology. After graduating, she worked at Nottingham University for a year designing A-Level Microbiology practical experiments for the Society for General Microbiology. Helen has worked with Clinical Trial Data, specialising in Serious Adverse Event reporting, prior to taking up this post.

Mara Ozolins
Clinical Trials Co-ordinator

Mara started her career working as a statistician in the pharmaceutical industry. After a good number of years, she decided it was time for a change, and secured a job as clinical trial co-ordinator with the University of Nottingham in November 1997. She worked on a large multi-centre, community-based study of antimicrobial treatments for mild to moderate acne. The acne trial completed in 2002, and was published in the *Lancet* (Dec 2004), and as an HTA monograph (Jan 2005). It generated a lot of interest, and still continues to do so.

Alongside her trial management Mara delivers occasional lectures for Trent RDSU's Health Services Research MSc/ Diploma in trial management and statistical topics.

In 2002 Mara took over responsibility for the SINS trial, which is a randomised controlled trial of imiquimod 5% versus excisional surgery of superficial and nodular basal cell carcinoma. It is a multi-centre hospital based trial which is has just entered the non-intervention follow-up phase.

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, especially the development of appropriate outcome measures for use in clinical trials. She is a founder member of the UK Dermatology Clinical Trials Network (www.ukdctn.org). Kim is programme manager for the recently funded NIHR programme grant. She is also responsible for a portfolio of studies including: Water Softeners for the Treatment of Eczema (SWET study), two studies looking at the use of prophylactic

antibiotics for the prevention of cellulitis (PATCH I and PATCH II) and a study looking at the use of objective markers of disease activity in children with eczema. Kim is also on the Trial Management Group for a study co-ordinated from the University of York looking at treatments for verrucae (EVERT trial). 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.

Margaret Whittingham Administrator to Professor Williams & Academic Secretary in Dermatology

Margaret 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, and supporting the BEES course and annual meetings.

Professor Hywel Williams Head of Department

Hywel Williams was brought up in a South Wales mining village. He trained in medicine at Charing Cross Hospital, London. After further training at Hammersmith Hospital, Charing Cross Hospital, Kingston Hospital and King's College Hospital, London, he obtained 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 when he worked at St John's Dermatology Centre, London. That year, he was appointed as Senior Lecturer in Dermatology to the clinical dermatology department at Nottingham and became Foundation Professor of Dermato-Epidemiology in April 1998.

Hywel's main interests are evidence-based dermatology and the epidemiology and treatment of childhood eczema.

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 now directs the University of Nottingham Clinical Trials Support Unit which has recently received provisional accreditation from the UKCRN.

Hywel also undertakes research commissioning activities by chairing the Research for Patient Benefit Programme for East Midlands, and by sitting on the main HTA Commissioning Board.

Hywel has published over 240 peer-reviewed articles, including papers in Nature, the NEJM, Lancet and BMJ, and three books. He has raised over £7m 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.

Peer-reviewed publications related to the Centre of Evidence Based Dermatology's work

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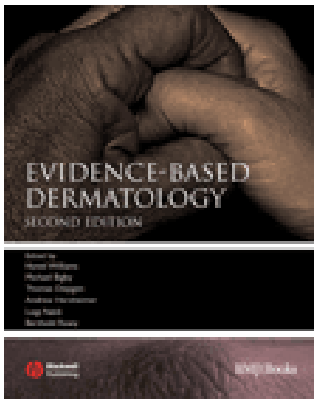
Books, book chapters and manuals



May 2008 saw the launch of the second edition of the textbook on Evidence-Based Dermatology. The book is very much 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 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. The first third of the book is a "toolbox" of methods to help readers critically appraise the literature, and is followed by detailed question-driven and highly structured summaries of up to date evidence for the treatment of all common and most of the uncommon skin diseases.

For further information, please see
http://www.blackwellpublishing.com/book.asp?ref=9781405145183&site=1

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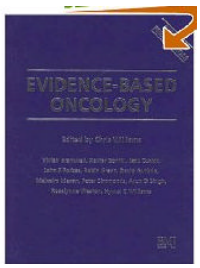

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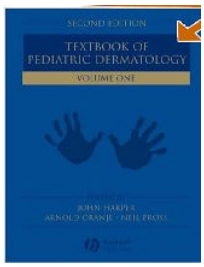

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