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# Centre for Evidence Based Dermatology Annual Review 2010/2011

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# Welcome

I always get a bit soppy when looking through our annual report. Nobody asked us to form a Centre of Evidence Based Dermatology when we started back in 1998. We just did it, because we firmly believed in the importance of trying to do more to integrate the best external evidence into the routine care of skin patients, and to improve that evidence base by doing independent clinically relevant research. Now, some thirteen years on, we are a team of around thirty people who all share that vision, working with patient groups and producing high quality research output that informs clinical practice at an international level. You can see that I am proud of the people who work here and I am very grateful to all who collaborate with us and all who support us. Doing the research is also great fun, and we are so lucky to have the National Institute of Health Research that is able to support our work in so many different ways.

This year, we have restructured our report slightly so that it is easier to find out what we do, why we do it, and how it impacts on the UK National Health Service and other people with skin problems worldwide. I hope you enjoy thumbing through this annual report and that you will find at least one thing that catches your eye. Do also take a moment to read about the people who work here, as they are a terrific team.

Even if you have nothing to do with dermatology research, just remember that skin problems are very common – the number one reason for a new consultation with a GP according to our National Needs Assessment. That means that you have either had or will have a skin condition yourself at some stage, so do come to us as first stop if you want to find out more about the best evidence.

Professor Hywel C. Williams, Director of the Centre of Evidence Based Dermatology, October 2011

# About CEBD

The Centre of Evidence Based Dermatology (CEBD) has an international reputation for skin research and evidence-based practice. At CEBD we strive to summarise what is known about treatments and the prevention of skin disease through the Cochrane Skin Group and then address research needs by running randomised controlled trials through the UK Dermatology Clinical Trials Network. The findings are then disseminated by a variety of means.

CEBD produces around 25 peer-reviewed publications per year and is one of the highest income generators for non-commercial dermatology research in the world.

We also teach evidence-based dermatology through fellowships, our annual course and our evidence-based update meetings. The Centre is located at the University of Nottingham King's Meadow Campus and is closely linked to the excellent clinical dermatology department at the Queen's Medical Centre campus of Nottingham University Hospital NHS Trust.

At the core of our work are the needs of patients and the public, and this along with the synergy of the different groups working within the Centre is well represented by the CEBD '3 cogs' logo shown here. Further information about each of these 'cogs'

is outlined below. Details of our current research programme along with the impact of our work, collaborative links and our role in dermatology training can be found in the relevant sections of this report.



# Cochrane Skin Group



The CSG ([www.csg.cochrane.org](http://www.csg.cochrane.org)) is one of 52 Collaborative Review Groups that make up the editorial bases of the International Cochrane Collaboration ([www.cochrane.org](http://www.cochrane.org)). The editorial base of the CSG is at CEBD, where its output regularly informs other strands of work such as the need for new trials. CSG has no financial links with any pharmaceutical companies and receives infrastructure support from the National Institute of Health Research (NIHR).

The CSG was established in 1997, and has an international board of editors. It has 834 members worldwide; 62 are consumer referees and 625 are authors. All authors are volunteers. A particular strength is the involvement of consumers, as skin disease impacts on individuals' quality of life. Consumers are people who have a skin condition, and their relatives/carers. Many members of the group are also interested in evidence-based dermatology in general. CSG aims to provide the best evidence about the effects (beneficial and harmful) of interventions for skin diseases, in the form of Cochrane systematic reviews, so that health professionals, those who commission health services and the public can make well-informed decisions about treatments and their uncertainties.

Members are invited to propose titles for systematic reviews, which are published on our website. We operate a title prioritisation process, where we ask CSG members to vote which reviews should come next. Those interested in leading a review team have their application independently assessed. After title registration, the protocol is developed. This is a public statement by the authors of how they intend to systematically review the topic. The protocol and the subsequent review are peer reviewed before publication. Reviews are published in The Cochrane Library, the principal source of up-to-date quality evidence on the effects of health care interventions. UK access is free at: [www.thecochranelibrary.org](http://www.thecochranelibrary.org). Visit: [www.csg.cochrane.org](http://www.csg.cochrane.org) or e-mail: [csg@nottingham.ac.uk](mailto:csg@nottingham.ac.uk).

# The UK Dermatology Clinical Trials Network

The UK Dermatology Clinical Trials Network (UK DCTN) is a collaborative group spread across the UK and Ireland of more than 650 dermatologists, nurses, primary care staff, health care researchers and patients/carers.

Membership is free and is open to anyone with an interest in applied dermatology research. All members provide their time and expertise on a voluntary basis. The network is a registered charity (Reg: 1115745) and is an affiliate group of the British Association of Dermatologists (BAD).

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

The aim of the Network is simple; to develop and conduct independent, high quality randomised controlled clinical trials (RCTs) of interventions for the treatment or prevention of skin disease. Priority is given to trials that address questions of importance to clinicians, patients and the NHS and research gaps highlighted by Cochrane systematic reviews as described above.

The network is open to trial suggestions from any of its UK and Ireland based members, and these are then developed using a rigorous and pre-defined trial development process, which includes an initial assessment by the UK DCTN Trial Generation and Prioritisation Panel.

Funding for individual trials comes from external grant applications made to NIHR partners (eg, the HTA, RfPB and charitable bodies).

The network is run by an Executive Group with an independent Chair (Professor Andrew Finlay) and a steering group made up of around 30 members.

The steering group evaluates trial proposals and decides which ideas are developed further through the network.



The role of the UK DCTN Co-ordinating Centre, which is based within CEBD, is to develop and manage the network's portfolio of clinical trials and to develop the network as an organisation.

Specifically, with regard to trial development and support, the UK DCTN is able to:

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

Details of UK DCTN led studies such as PATCH, BLISTER and STOP GAP can be found in the current research section of this report. To find out more about the UK DCTN, please visit: [www.ukdctn.org](http://www.ukdctn.org) or e-mail: [ukdctn@nottingham.ac.uk](mailto:ukdctn@nottingham.ac.uk).



## NHS Evidence and Dermatology

NHS Evidence: Skin Disorders was one of 30 specialist collections funded by NICE through NHS Evidence, and until the end of March 2011 it was delivered by CEBD.

As from March 2011, NHS Evidence has launched a specialist evidence service to replace the specialist collections. The new service is easy to search and provides access to a wider choice of quality specialist evidence content. NHS Evidence is managed by NICE.

The reorganisation has meant that our Centre has lost our information specialist, Dr Douglas Grindlay, although we are pleased to announce that he has since taken up a post as information specialist in the new Centre for Evidence-Based Veterinary Medicine in the veterinary medicine school at The University of Nottingham.

Hywel Williams has been kept on as the dermatology expert adviser in the new NICE NHS Evidence resource. Annual evidence updates on new and important evidence covering common and important skin conditions such as acne,

eczema, psoriasis and skin cancer will continue, and the first new-look skin cancer update will appear in September 2011.

NHS Evidence allows everyone working in health and social care to access a wide range of health information to help them deliver quality patient care.

It can be accessed via the home page at:

[www.evidence.nhs.uk](http://www.evidence.nhs.uk).



# Research

Our research is based on the concept of three overlapping, but closely related, methodological disciplines: systematic reviews, clinical trials and epidemiology/ methodological research. Atopic eczema is our main disease interest because it is so common, the prevalence is rising, it causes a lot of suffering, and we understand little about its causes, treatment and prevention.

## Research Strategy

The research strategy of CEBD is very simple 'To do really good research'. We aim to do this by:

- Collaborating with the best people who bring different skills and perspectives
- Getting the right staff structures in place to support development and conduct of research
- Maintaining focus on being world leaders in just a few research areas
- Engaging with the community who use research to develop new ideas and to measure the impact of our research
- Taking advantage of the funding landscape: being in the right place with the right preliminary data at the right time
- Ensuring that research findings are disseminated credibly and accurately to funders, health care professionals and the wider community
- Conducting research that really matters to people - research that you would be proud of telling a member of the public about

## Summary of on-going research

Acronym	Title of Project	Funded by	Start date	End Date	Phase	Website
<b>Clinical Trials</b>						
PATCH I	Randomised controlled trial to investigate whether prophylactic antibiotics can prevent further episodes of cellulitis of the leg	Action Medical Research	01/07/2006	31/12/2010	Follow-up	www.patchtrial.co.uk
SINS	Surgery vs imiquimod for nodular and superficial basal cell carcinoma	Cancer Research UK (imiquimod provided by 3M)	16/09/2002	31/08/2012	Follow-up	
BLISTER	Randomised controlled trial to compare the safety and effectiveness of doxycycline (200mg/day) with prednisolone (0.5mg/kg/day) for initial treatment of bullous pemphigoid	NIHR Health Technology Assessment Programme	Mar 2008	Feb 2013	Recruiting	www.blistertrial.co.uk
LIMIT-1	Effect of topical imiquimod on lentigo maligna (Phase II RCT)	NIHR Research for Patient Benefit	Apr 2010	Aug 2011	Follow-up	www.ukdctn.org/ongoing/limit/
STOP GAP	Randomised controlled trial comparing use of prednisolone and ciclosporin for treatment of pyoderma gangrenosum	NIHR Programme Grant	Jan 2009	Aug 2013	Recruiting	www.stopgaptrial.co.uk
<b>Pilot studies</b>						
BEEP	Barrier Enhancement for Eczema Prevention: The BEEP feasibility study	NIHR Programme Grant	July 2009	Aug 2012	Follow-up	www.beepstudy.org
HI-Light for vitiligo	Pilot RCT of hand-held NB-UVB for home treatment of focal and early vitiligo	NIHR Programme Grant	Aug 2011	Aug 2012	Set up	www.vitiligostudy.org.uk
Erosive Lichen Planus case note audit	Case note review of normal practice for treatment of erosive lichen planus of the vulva (EVLP) in 11 UK hospitals	Nottingham University Hospitals NHS Trust	Feb 2011	Aug 2012	Analysis & write-up	
Squamous Cell Carcinoma (SCC) audit	Feasibility work to inform the development and design of an RCT for improving outcomes for the treatment of SCC	NIHR Programme Grant	May 2011	Aug 2013	Data collection	
<b>Funded systematic reviews</b>						
Eczema Treatments Review	Systematic review of treatments for atopic eczema	NIHR Programme Grant	Jan 2009	Dec 2011	Ongoing	
Eczema prevention umbrella review	The prevention of eczema in infants and children: An overview of Cochrane and non-Cochrane reviews	NIHR Programme Grant	Nov 2010	June 2011	In press	
Squamous Cell Carcinoma (SCC) treatment	Interventions for non-metastatic squamous cell carcinoma of the skin	NIHR Programme Grant	Jan 2009	Dec 2009	Published	www.thecochranelibrary.org
Review of observational studies for SCC treatment	Systematic review of observational studies of interventions for primary, non-metastatic SCC of the skin	NIHR Programme Grant	Dec 2009	Dec 2011	Ongoing	
<b>Other funded research</b>						
HOME initiative	Harmonizing Outcome Measures for Eczema	NIHR Programme Grant	Sept 2008	Aug 2013	Ongoing	www.homeforeczema.org.uk
Eczema Prioritisation Partnership	Collaboration with the James Lind Alliance to establish treatment uncertainties to prioritise for further research	NIHR Programme Grant	Jan 2011	Jan 2012	Data collection	www.homeforeczema.org.uk
Raman imaging	Raman spectral imaging for automated Mohs micrographic surgery of high-risk basal cell carcinoma	NIHR i4i	May 2010	April 2013	Ongoing	

Further details can be found in this section of the report and in the Impact section.

## NIHR Programme Grant Award Overview: Setting Priorities and Reducing Uncertainty for the Treatment and Prevention of Skin Disease (SPRUSD) — RP-RG-0407-10177

This NIHR-funded research programme has had a great impact on how the CEBD functions as a research group, and has been an excellent opportunity to develop and foster collaborative links globally. It includes work packages in five disease areas: eczema treatment, eczema prevention, skin cancer (squamous cell carcinoma), vitiligo, pyoderma gangrenosum.



**SPRUSD**  
**Setting Priorities & Reducing Uncertainties for people with Skin Disease**

### Key milestones for SPRUSD (2010/2011)

Three years into this five-year award, and important outputs have been completed that will have immediate implications for clinical practice. Four systematic reviews have been conducted as outlined below.

Systematic reviews	Comments
The prevention of eczema in infants and children: an overview of Cochrane and non-Cochrane reviews	This review is the first overview of reviews that our group has produced, and was greatly enhanced with the help and support of colleagues in the Cochrane Child Health Field. It summarises seven systematic reviews of interventions for the prevention of eczema, and will feed into guideline and evidence-based patient information resources. Unusually, this review included both Cochrane and non-Cochrane systematic reviews, increasing the scope and relevance of the review.
Systematic review of treatments for atopic eczema	This review is an update of the popular NIHR HTA systematic review of interventions for the treatment of atopic eczema. The review includes details of all trials published over the last 10 years and looks set to be an important resource for clinicians, researchers, guideline writers and people involved in providing evidence-based patient information resources. This review should be available towards the end of the year but, in the meantime, all trials included in the review can be found in the open-access GREAT Database ( <a href="http://www.greatdatabase.org.uk">www.greatdatabase.org.uk</a> ).
Cochrane review of interventions for non-metastatic squamous cell carcinoma (SCC) of the skin	This Cochrane review highlighted the shocking paucity of randomised controlled trial (RCT) data on the treatment of SCC. Our review, published in 2010, found just one RCT of SCC treatments.
Cochrane review of interventions for vitiligo	This Cochrane review was published in 2010 and identified 38 new trials. Unfortunately, the trials were so varied and difficult to interpret that few clinical conclusions could be reached. Nevertheless, the review has prompted a large collaborative prioritisation process in collaboration with the James Lind Alliance, and the treatment uncertainties identified are being considered by funding bodies.

### Key milestones for SPRUSD (2010/2011) contd.

These systematic reviews have been used to update NHS accredited information resources such as guidelines and patient information websites and have provided the starting point for a range of other research initiatives including:

- Two priority setting partnerships (PSP) in vitiligo and eczema. The vitiligo PSP was published in 2011 and highlighted a strong desire for further evidence around the use of UVB light therapy for the treatment of vitiligo (three of the top 10 treatment uncertainties included UVB treatment). The eczema PSP is ongoing, and over 1,000 submissions are being processed ready for the next stage of voting.
- A pilot RCT of emollient therapy (moisturisers) in newborns for the prevention of eczema. This pilot trial (now completed) has been extremely useful in helping us to design the main trial that will include around 3,500 children across the UK. A funding application for this trial has been submitted to the NIHR Health Technology Assessment programme.
- A pilot RCT of home UVB light therapy for the treatment of vitiligo. This trial is in set-up, but will compare active and placebo hand-held UVB devices. The trial has been designed to test out the feasibility of running a large multi-centre trial in the future.
- The development of an open-access database of quality-appraised eczema RCTs ([www.greatdatabase.org.uk](http://www.greatdatabase.org.uk)). This database is a unique international resource that is freely available to anyone with an interest in the evidence-base for the treatment of eczema. It is hoped it will prevent the duplication of effort in searching for relevant RCTs and increase opportunities for collaborative research activities. The database will be updated on a regular basis. Feedback and suggestions for collaborative projects are welcome.
- A further systematic review including observation studies of interventions for the treatment of SCC. This review was prompted following the lack of RCT evidence in the Cochrane review, and will be an important resource in summarising our knowledge on SCC treatment. This review will inform the design of two future trials: adjuvant radiotherapy in SCC treatment and SCC excision margins.

Further details are outlined later in this report.

## Current trials

Surgery vs Imiquimod for Nodular and Superficial basal cell carcinoma (SINS)

This study compares the gold standard for treating basal cell carcinomas (BCCs) — simple excision surgery — against imiquimod 5% cream (an immune response modifier), in low-risk BCC. Patients have been randomised to one of

the two treatments, and followed up for up to five years. Imiquimod was applied once a day for six weeks for those with superficial BCC, and 12 weeks for nodular BCC.

BCC is the most common malignant tumour in humans. While not usually life-threatening it can cause significant cosmetic disfigurement. Despite this, it is poorly researched, with little long-term recurrence data. Although imiquimod treatment has a lower success rate than surgery, it may still prove useful in reducing the heavy workload for the NHS by avoiding surgery and possibly improving cosmetic outcome and cost. We are comparing the long-term success rate, cosmetic effect, costs and side effects in this trial.

The SINS trial is funded by Cancer Research UK. It started in September 2002, with 501 participants recruited between June 2003 and February 2007, with the help of three dedicated research nurses, and a number of research network nurses. Despite the prevalence of BCC, recruitment was not as easy as we expected; many patients were unsuitable because their BCC was in a high-risk area. The three-year follow-up was completed in May 2010 and analysis is underway, with initial results set to be available by mid 2012. This will include our primary endpoint of success (no treatment failure/recurrence) at three years. Collection of five-year data is ongoing (to be completed by May 2012), with analysis of five-year results in summer 2012.

For information, please contact trial coordinator Mara Ozolins on: [Mara.Ozolins@nottingham.ac.uk](mailto:Mara.Ozolins@nottingham.ac.uk) or 0115 8468624.

Trial Management Group: Hywel Williams<sup>(1)</sup>, Fiona Bath-Hextall<sup>(1)</sup>, Mara Ozolins<sup>(1)</sup>

Trial Steering Group: Hywel Williams<sup>(1)</sup>, Fiona Bath-Hextall<sup>(1)</sup>, Mara Ozolins<sup>(1)</sup>, Sarah Armstrong<sup>(1)</sup>, William Perkins<sup>(2)</sup>, Graham Colver<sup>(3)</sup>, Irshad Zaki<sup>(4)</sup>, Jan Bong<sup>(1)</sup>, Jo Llewellyn<sup>(1)</sup>, Beryl Cunningham<sup>(1)</sup>, Sam Annasamy<sup>(1)</sup>, Paul Miller<sup>(5)</sup>, Graeme Perks<sup>(2)</sup>

**1;** University of Nottingham. **2;** Nottingham University NHS Trust. **3;** Chesterfield and North Derbyshire Royal Hospital. **4;** Solihull Hospital. **5;** Astra-Zeneca (previously at The University of Nottingham)

Data Monitoring Committee: Dr Nick Telfer<sup>(1)</sup>, Prof Stephen Walters<sup>(2)</sup>, Prof Carol Jagger<sup>(3)</sup>

**1;** Hope Hospital, Manchester. **2;** University of Sheffield. **3;** University of Newcastle

### Relevant publications

Ozolins, M., Williams, H.C., Armstrong, S.J. And Bath-Hextall, F.J., 2010. The SINS trial: A randomised controlled trial of excisional surgery versus imiquimod 5% cream for nodular and superficial basal cell carcinoma. *Trials*, 11(1), 42.

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



Prophylactic Antibiotics  
for the Treatment of  
Cellulitis at Home

In these two closely related studies we are studying the effect of prophylactic antibiotics on subsequent episodes of cellulitis of the leg. These trials have been designed to establish whether low dose penicillin given after an attack of cellulitis can prevent further attacks and complications, such as swelling and ulceration. Participants are randomised to receive either penicillin (250 mg bd) or placebo (bd) for a period of twelve months for PATCH I and six months for PATCH II.

Cellulitis of the leg is a common, painful infection of the skin and underlying tissue. Repeat episodes of cellulitis are frequent (30-50%) and cause significant morbidity. They also result in high health service costs due to hospital admission.

These trials are being run through the UK Dermatology Clinical Trials Network with 29 hospitals in the UK and Republic of Ireland. The PATCH I study has recruited 274 participants and the final follow-up was completed by August 2011 with analysis to follow in 2012. The PATCH II study recruited 123 participants and was completed in September 2010.

### PATCH II trial results

For most participants (79%), the index episode at baseline was their first episode of cellulitis. In the penicillin V group 12/60 (20%) had a repeat episode compared with 21/63 (33%) in the placebo control group. The hazard ratio showed a 47%, non-significant reduction in the risk of further episodes (HR 0.53, 95% CI 0.26 – 1.07,  $p = 0.08$ ). We found no difference between the two groups in the number of participants with oedema, ulceration or related adverse events. This trial is the largest to date to examine whether medium-term antibiotic prophylaxis for patients with previous cellulitis of the leg is beneficial. While this trial was limited due to slow recruitment (we failed to achieve our target sample size of 400 participants), and the results did not achieve conventional statistical significance (where  $p < 0.05$ ), the study provides some evidence of a potentially large effect. The PATCH I study results are eagerly awaited.

Trial Management Group: Hywel Williams<sup>(1)</sup>, Kim Thomas<sup>(1)</sup>, Katharine Foster<sup>(1)</sup>.

1; University of Nottingham.

Trial Steering Group: Peter Featherstone<sup>(1)</sup>, Sarah Meredith<sup>(2)</sup>, Andrew Nunn<sup>(2)</sup>, Angela Crook<sup>(2)</sup>, Hywel Williams<sup>(3)</sup>, Kim Thomas<sup>(3)</sup>, Katharine Foster<sup>(3)</sup>, Ingrid Salvary<sup>(4)</sup>, Peter Mortimer<sup>(5)</sup>, James Mason<sup>(6)</sup>, Nick Reynolds<sup>(7)</sup>.

1; Portsmouth Hospitals NHS Trust. 2; MRC Clinical Trials Unit. 3; University of Nottingham. 4; Queen Elizabeth King's Lynn Hospital NHS Trust. 5; St George's Healthcare NHS Trust. 6; University of Durham. 7; Newcastle-upon-Tyne Hospitals NHS Trust.

Data Monitoring Committee: Robert Hills<sup>(1)</sup>, Jane Daniels<sup>(2)</sup>, Beverley Adriaans<sup>(3)</sup>

1; Cardiff University. 2; University of Birmingham. 3; Retired – formerly Gloucestershire Hospitals NHS Trust.

### Relevant publications

Thomas KS and the UK Dermatology Clinical Trials Network's PATCH study group (UKDCTN). Studying a disease with no home – lessons in trial recruitment from the PATCH II study, *Trials*. 2010. 11, 22.

Prophylactic antibiotics for the prevention of cellulitis of the leg – results of the UK Dermatology Clinical Trials Network's PATCH II trial: Thomas KS and the UK Dermatology Clinical Trials Network's PATCH Trial Team (UKDCTN). (*British Journal of Dermatology*, In Press).

### Study of treatments for Pyoderma Gangrenosum Patients (STOP GAP)



In this study we are comparing head-to-head the two most commonly used systemic treatments for pyoderma gangrenosum. Participants are randomised to receive either prednisolone (0.75 mg/kg/day) or ciclosporin (4 mg/kg/day) for up to six months. A parallel observational study is being conducted in order to capture

prospective outcomes for participants treated with topical therapies such as corticosteroids or immunosuppressant ointments.

Pyoderma gangrenosum (PG) is a mutilating, very painful skin disease that often affects people with an underlying internal disease (such as inflammatory bowel disease, monoclonal gammopathy and rheumatoid arthritis). It starts as a reddish purple bump in the skin that develops into a large, deep, spreading ulcer within days. People with PG are often misdiagnosed, and spend a long time in hospital waiting for the affected areas to heal.

Many of the treatments for pyoderma gangrenosum are associated with unpleasant and damaging side-effects, but

their effectiveness has never been formally assessed in a randomised controlled trial.

This trial is being run through the UK Dermatology Clinical Trials Network. We aim to recruit 140 patients from 50 hospitals around the UK.

Thanks to an excellent team of dedicated clinicians and trial staff, the study is going well. As of August 2011 we have recruited 82 participants into the randomised controlled trial and 48 participants into the observational study of topical treatments. Recruitment will continue throughout the coming year and we anticipate results being available by early 2014.

For further information, please contact the trial manager at: [stopgap@nottingham.ac.uk](mailto:stopgap@nottingham.ac.uk) or on 0115 8844926. More information about the trial can be found at: [www.stopgaptrial.co.uk](http://www.stopgaptrial.co.uk). This work is being carried out as part of the SPRUSD NIHR Programme Grant Award.

**Trial Management Group:** Anthony Ormerod<sup>(1)</sup>, Kim Thomas<sup>(2)</sup>, Fiona Craig<sup>(1)</sup>, John Norrie<sup>(3)</sup>, James Mason<sup>(4)</sup>, Eleanor Mitchell<sup>(2)</sup>, Hywel Williams<sup>(2)</sup>

1; Aberdeen Royal Infirmary. 2; University of Nottingham. 3; University of Glasgow. 4; University of Durham.

**Trial Steering Committee:** Frank Powell<sup>(1)</sup>, Sarah Meredith<sup>(2)</sup>, Daniel Wallach<sup>(3)</sup>, Paul Mussell<sup>(4)</sup>

1; Mater Private Hospital Dublin. 2; MRC Clinical Trials Unit London. 3; Hôpital Tarnier Paris. 4; Patient Representative, York.

**Data Monitoring Committee:** Julia Schofield<sup>(1)</sup>, Angela Crook<sup>(2)</sup>, Alison McDonald<sup>(3)</sup>

1; University of Hertfordshire. 2; MRC Clinical Trials Unit London. 3; CHaRT Aberdeen

#### Relevant publications

Craig F, Thomas K, Layfield C et. al. Management of pyoderma gangrenosum by UK dermatologists: a pilot study to inform a trial. *Br J Dermatol*: 2009 161; 4-5.

Mitchell E RCT of treatments for pyoderma gangrenosum: time to get involved. *Wounds UK* 2010, 6 (4), 27-32.

#### The Bullous Pemphigoid Steroids and Tetracyclines Study (BLISTER)



This is a randomised controlled trial to compare the safety and effectiveness of doxycycline (200 mg/day) with prednisolone (0.5 mg/kg/day) for initial treatment of bullous pemphigoid (BP). BP is a serious condition occurring

mainly in the elderly with a significant associated morbidity and mortality rate. Widespread tense and haemorrhagic blisters, skin erosions and severe itching cause patients a great deal of distress and pain.

Untreated BP is typically self-limiting and usually remits within five years, with periods of spontaneous remissions and exacerbations. In most patients who are treated, BP remits within 1.5 to five years but may recur once medication is stopped (relapse rates of 9% have been documented). The mortality rate in treated patients is estimated to range from 20% - 40% at one year. Patients are often admitted to hospital for initial treatment; estimates of admission rates vary, but they are generally high (up to 100%) thus representing a significant cost to the NHS.

Dermatologists currently have mixed opinions about the role of steroids and tetracyclines for the treatment of bullous pemphigoid. The purpose of this study is to determine whether doxycycline is an effective and safe alternative treatment to oral steroids for the treatment of bullous pemphigoid. The study consists of two comparisons: 1) a non-inferiority comparison of the effectiveness of doxycycline compared to prednisolone and 2) a superiority comparison of adverse events of the two treatments.

This trial is being run through the UK Dermatology Clinical Trials Network, and 256 participants will be recruited to the study from around 45 UK hospitals and five German hospitals. Each centre will need to recruit around seven participants over a three-year period to meet the target. Thanks to an excellent team of dedicated clinicians and trial staff, the study is going well. By the end of August 2011, we had recruited 139 participants. Recruitment will close in February 2012.

For further information, please contact the trial manager: [caroline.onions@nottingham.ac.uk](mailto:caroline.onions@nottingham.ac.uk) or 0115 8844925.

**Trial Management Group:** Hywel Williams<sup>(1)</sup>, Andrew Nunn<sup>(2)</sup>, Daniel Bratton<sup>(2)</sup>, Fenella Wojnarowska<sup>(3)</sup>, Gudula Kirtschig<sup>(4)</sup>, Caroline Onions<sup>(1)</sup>

1; University of Nottingham. 2; Medical Research Council. 3; University of Oxford. 4; de Boelalaan, Amsterdam

**Trial Steering Committee:** Jonathan Barker<sup>(1)</sup>, Dr Pascal Joly<sup>(2)</sup>, Dr Jonathan Leonard<sup>(3)</sup>, Helena Haywood<sup>(4)</sup>

1; Guy's St Thomas. 2; Hôpital Charles Nicolle, France. 3; St Mary's Hospital. 4; Amerhsam Hospital.

**Data Monitoring Committee:** Sallie Lamb<sup>(1)</sup>, Robin Graham – Brown<sup>(2)</sup>, Tracey Young<sup>(3)</sup>

1; University of Warwick. 2; Leicester Royal Infirmary. 3; University of Sheffield.

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



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

Lentigo Maligna (LM) is an early form of cancer which usually appears as a dark patch of skin on the face and neck. LM can grow very slowly over several years, and at this stage is harmless because the cancer is in the outer layer of the skin. However, there is a small possibility that it could grow deeper in the skin, which increases the risk of the cancer spreading. Because of this risk, it is important that LM is treated effectively at an early stage.

The current treatment is surgery to remove all the cancerous cells. Although surgery cures most cases (90-95% cure rate at 5 years) the procedure is invasive, patients often find it stressful and unpleasant and it can result in scarring.

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

The target sample size for this trial is 40 patients, with 12 hospitals around the UK open to recruitment. Although recruitment has been slower than expected, we have recruited 30 participants into the study, with recruitment closing mid August 2011. For further information, please contact the trial manager: [nazia.boota@nottingham.ac.uk](mailto:nazia.boota@nottingham.ac.uk) or on 0115 8844924.

**Trial Management Group:** Dr Jerry Marsden<sup>(1)</sup>, Keith Wheatley<sup>(2)</sup>, Richard Fox<sup>(2)</sup>, Dan Simpkins<sup>(3)</sup>, Nazia Boota<sup>(3)</sup>

1; University Hospitals of Birmingham. 2; University of Birmingham. 3; University of Nottingham.

**Trial Steering Group:** Professor Chris Bunker<sup>(1)</sup>, Mr Simon Wharton<sup>(2)</sup>, Mr Stephen Brothwell<sup>(3)</sup>

1; University College London Hospital. 2; Russell Hall Hospital. 3; Patient Representative.

**Data Monitoring Committee:** Dr Catherine Harwood<sup>(1)</sup>, Dr Helen Ramsay<sup>(2)</sup>, Natalie Ives<sup>(3)</sup>

1; Barts and the London School of Medicine and Dentistry. 2; Royal Hallamshire Hospital. 3; University of Birmingham.

## Pilot/feasibility studies

### Barrier Enhancement for Eczema Prevention (BEEP)



Eczema is a common problem. It causes the skin to become dry, flaky and itchy, and can become red and inflamed and prone to infections. Emollients are first-line therapy for treating

eczema, but have not been properly explored as a disease prevention strategy. A definitive randomised controlled trial (RCT) is required to determine whether enhancement of the skin barrier in early life with emollients can prevent eczema, but before a large and expensive trial, it needed to be established whether parents found such intervention acceptable and whether a large trial is feasible. Therefore, we are conducting a pilot RCT of emollients for the prevention of eczema in three hospitals and one GP surgery in the Trent region in the UK and in Portland, USA.

Recruitment to this pilot RCT took place from April 2010 to March 2011. Babies with a family history of asthma, eczema or hay-fever in a first-degree relative were recruited. Mothers were identified during pregnancy. Within three weeks of giving birth, the family were randomised to either the intervention group (emollient applied to the baby's entire skin surface at least once a day for six months) or the control group (no emollient). The intervention group were offered a choice of emollients (in the UK this was Sunflower Seed Oil, Doublebase or 50:50 white soft paraffin / liquid paraffin). Both groups were given standardised care instructions, including avoiding soap. All babies were examined at six months for eczema and also earlier if eczema was suspected.

In the UK, 78 families were recruited into the study before December 2010. All participants have finished the six-month intervention phase and data cleaning is underway to prepare for analysis. The primary outcome measure is the proportion of families willing to be randomised — the most critical component of the success of any future RCT of this strategy. Secondary outcomes include proportion of families who found the interventions acceptable, adherence with intervention, effectiveness of blinding of outcome assessor and contamination of the control group (i.e. using emollients).

We are following this cohort until the children are two years old in order to collect longer-term data on eczema rates and to establish the feasibility of collecting longer term questionnaire data in the main RCT.

For further information, contact Joanne Chalmers on 0115 8232435 or at: [joanne.chalmers@nottingham.ac.uk](mailto:joanne.chalmers@nottingham.ac.uk). This work is part of the SPRUSD NIHR Programme Grant Award.

Trial Management Group: Joanne Chalmers<sup>(1)</sup>, Hywel Williams<sup>(1)</sup>, Eric Simpson<sup>(2)</sup>

1; University of Nottingham. 2; Oregon Health & Science University, Portland, USA.

#### Relevant publications

Simpson EL, Chalmers JR, Irvine AD, Cork MD, McLean WHI and Williams HC. Barrier Enhancement for Eczema Prevention; The BEEP Feasibility Study. *Allergo J* 2010, 19;340

Simpson EL, Keck L, Chalmers JR and Williams HC, How do you define an incident case of atopic dermatitis? A systematic review of Primary Prevention Studies. *Allergo J* 2010: 19;323

#### Treatment of squamous cell carcinoma of the skin

Cutaneous squamous cell carcinoma (cSCC) and basal cell carcinoma, classified together as non-melanoma skin cancers, are the most common malignancies in white-skinned populations worldwide, and have been increasing in incidence over recent decades. In 2008, over 98,500 new NMSCs were registered in the UK, although this is likely to be a significant underestimate due to incomplete registration of these tumours. Cutaneous SCC has the potential to metastasise and recur, even after apparently successful treatment, occasionally causing death. Treatment of cSCC is usually surgical, although other treatment modalities such as radiotherapy, electrodesiccation, or cryosurgery are sometimes used. However, despite the high burden of morbidity associated with cSCC, there has been very little in the way of high-quality research assessing treatments, as shown in our 2010 Cochrane systematic review of interventions for primary, non-metastatic SCC.

A prime objective of the current project, which forms one workstream of the NIHR programme grant, Setting Priorities and Reducing Uncertainties for People with Skin Disease (SPRUSD) awarded to the CEBD, is to develop a fully worked-up proposal for a future clinical trial based on a particular aspect of the treatment of cSCC ready for submission to funding bodies.

A survey of clinicians who are involved in managing patients with cSCC has helped us to identify two clinically important treatment-related research areas relating to excision margins and the role of adjuvant radiotherapy for higher risk lesions. Based on these topics a couple of trial scenarios are now being developed further and feasibility work is being done, which will help to inform the development of a future, multi-centre trial in terms of number of participants required, recruitment issues and identification of study centres.

The first phase of the feasibility work involves auditing the cSCCs which have been treated in Nottingham over the course of the last year, in order to assess the numbers and types of cSCC patients who would potentially be eligible for inclusion in a clinical trial. A web-based database is being used to collect histopathological and relevant follow-up data and the results will be analysed later this year when data collection is complete. The results of this work will help us to refine our proposed trial scenarios and will guide future feasibility work, which will involve patients and clinicians to help us identify potential recruitment centres, hypothetical recruitment rates, and possible barriers to recruitment. This work is being carried out as part of the SPRUSD NIHR Programme Grant Award.

People involved: Louise Lansbur<sup>(1)</sup>, Fiona Bath-Hextall<sup>(1)</sup>, Jo Leonardi-Bee<sup>(1)</sup> Dr William Perkins<sup>(2)</sup>

1; University of Nottingham. 2; Nottingham University NHS Trust.

#### Relevant publications

Lansbury L., Leonardi-Bee J., Perkins W., Goodacre T., Tweed J., Bath-Hextall F. Interventions for non-metastatic squamous cell carcinoma of the skin. *Cochrane Database of Systematic Reviews* 2010. Issue 4. Art.No. CD007869. DOI:10.1002/14651858.CD007869.pub2

#### Vulval Erosive Lichen Planus not adequately controlled with first line therapy: Is adjuvant systemic therapy better for long-term control?

Vulval erosive lichen planus (ELPV) is an uncommon skin condition causing painful erosions of the vulva and vagina and has a significant negative impact on quality of life. There is a risk of progression to malignancy of 1-3%. ELPV is often resistant to treatment and it therefore represents a drain on National Health Service resources through patients requiring multiple clinical visits and potentially needing long-term, expensive medications. There is currently no high quality randomised controlled trial (RCT) evidence on which to base treatment.

We are in the process of analysing data from a multi-centre case note audit to review management of ELPV in the UK. Funding of £9600 was successfully awarded in November 2010 by Nottingham University Hospitals Pump Priming competition to fund this work. More than 150 patients have been identified by ten participating centres over a 6-month data collection period.

The results of the audit will be used to inform the design of a multi-centre RCT that compares the most commonly used systemic treatment for ELPV against topical treatment alone. Patients will be eligible for the trial if they have not responded adequately to initial therapy.

Work performed to date includes a Cochrane Review: 'Interventions for erosive lichen planus affecting mucosal sites', which is due to be published in Summer 2011.

Both the International Society and British Society for the Study of Vulvovaginal Disease have been involved in pilot work for this study. Patient members of the UK Lichen Planus Support Group have completed a quality of life survey about living with the disease. The results of these preliminary studies will be used to provide evidence towards the development of a full RCT.

Trial Management Group: Dr Kim Thomas<sup>(1)</sup>, Dr Ruth Murphy<sup>(2)</sup>, Dr Rosalind Simpson<sup>(1)</sup>, Tessa Clarke<sup>(1)</sup>

1; University of Nottingham. 2; Nottingham University NHS Trust.

#### HI-Light vitiligo pilot trial



Vitiligo is a disease that causes patches of de-pigmentation of the skin, which is estimated to affect 0.5-1% of the world's

population. Studies showed that patients are frightened and embarrassed by vitiligo and experience discrimination, especially people with darker skin types or with vitiligo patches on visible sites such as face and hands. This disease has a negative impact on psychological wellbeing, self-esteem and sexual relationships. Vitiligo in childhood can be associated with significant psychological trauma.

Vitiligo is a chronic condition requiring long-term treatment, but there is a distinct lack of evidence for the treatments used in the condition. A 2010 update of the Cochrane systematic review 'Interventions for vitiligo' reviewed 57 randomised controlled trials (RCTs) of treatments for vitiligo, examining a wide range of treatments. Many of the RCTs were of poor quality or included very small numbers of participants. Most were of very short duration, yielding little information about the long-term efficacy of treatments and no clear conclusions could be drawn regarding the efficacy of specific treatments. Clearly there is a pressing need for large-scale, high-quality RCTs of the most commonly-used treatments for vitiligo.

To address this need, the CEBD has performed a number of research projects on vitiligo, in order to lay the foundation for future RCTs of treatments for vitiligo. These projects constitute one work stream of the NIHR programme grant being co-ordinated from the CEBD, and have led to the development of a pilot RCT looking at home NB-UVB light therapy for the treatment of vitiligo at home (HI-Light vitiligo

trial). The HI-Light pilot trial is a small randomised controlled trial that will compare active and placebo devices.

These small, hand-held devices are useful for treating small patches of vitiligo, which means that they are useful for people who do not want to expose their whole body to light therapy. They are also more convenient for patients to use as it means that they can treat the vitiligo at home without the need for repeated visits to hospital.

The proposed trial will assess willingness of vitiligo patients to take part in the trial, safety of the treatment when delivered at home, success of blinding, the educational package for participants in how to use the hand held phototherapy units and how to deal with side effects at home and suitability of the proposed outcome measures.

If you are interested in further information, please contact Viktoria Eleftheriadou (viktoria.eleftheriadou@nottingham.ac.uk or 0115 8468633). This work is being carried out as part of the SPRUSD NIHR Programme Grant Award.

Trial Management Group: Viktoria Eleftheriadou<sup>(1)</sup>, Hywel Williams<sup>(1)</sup>, Kim Thomas<sup>(1)</sup>, Dr Jane Ravenscroft<sup>(2)</sup>, Jonathan Batchelor<sup>(2)</sup>, Maxine Whitton<sup>(3)</sup>, Robert Dawe<sup>(4)</sup>

1; University of Nottingham. 2; Nottingham University NHS Trust. 3; Patient Representative London. 4; Ninewells Hospital Dundee

#### Relevant publications

- Whitton ME, Pinart M, Batchelor J et al Interventions for vitiligo. Cochrane Database of Systematic Reviews 2010, Issue 1. Art. No: CD003263. DOI: 10.1002/14651858.CD003263.pub4.
- Eleftheriadou, V., Whitton, M., Gawkrödger, D. et al (2011): Future research into the treatment of vitiligo: where should our priorities lie? Results of the vitiligo priority setting partnership. *British Journal of Dermatology*, 164: 530–536.
- U. Gonzales, M. Whitton, V. Eleftheriadou et al: Guidelines for designing and reporting clinical trials in vitiligo. *Archives of Dermatology*. Published online August 15, 2011. doi:10.1001/archdermatol.2011.235
- Eleftheriadou V, Thomas K: Have your say in research in to vitiligo. *Dermatological Nursing* 2009; 8 (4), 56-57.

# Involvement in other NIHR portfolio studies

CEBD employs two research nurses and two clinical trials administrators with the support of Trent CLRN. They support CEBD studies and other studies on the NIHR portfolio.

## **British Association of Dermatologists Biologic Interventions Register (BADBIR)**

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BADBIR (NIHR CRN portfolio number 8090) is a UK and Eire based observational study seeking to assess the long-term safety of biologic treatments for psoriasis. The primary endpoints of interest are malignancy, infection requiring hospitalisation, serious adverse events and death. Once enrolled in the study, patients are followed up over a five-year period and patients on both biologic drugs and conventional systemic therapies are eligible for inclusion. The main study began in August 2008 and over 2,000 patients have been recruited to date. NICE has recommended that all patients in the UK receiving these new therapies for psoriasis should be registered with this study. There are currently more than 100 hospital sites across the UK and Eire recruiting into BADBIR. One of these sites is the dermatology department at Queen's Medical Nottingham. The site has been recognised as the highest recruiting centre for the study in Trent and the West Midlands, with over 130 patients recruited to date. It is also the second highest recruiting centre for 2011, a reflection of the good support received from Trent CLRN and the dedication of the staff working on the project.

BADBIR is based at the University of Manchester. Further details can be found at: [www.badbir.org](http://www.badbir.org) or by contacting the study team on: [badbir@manchester.ac.uk](mailto:badbir@manchester.ac.uk).

## **Further studies**

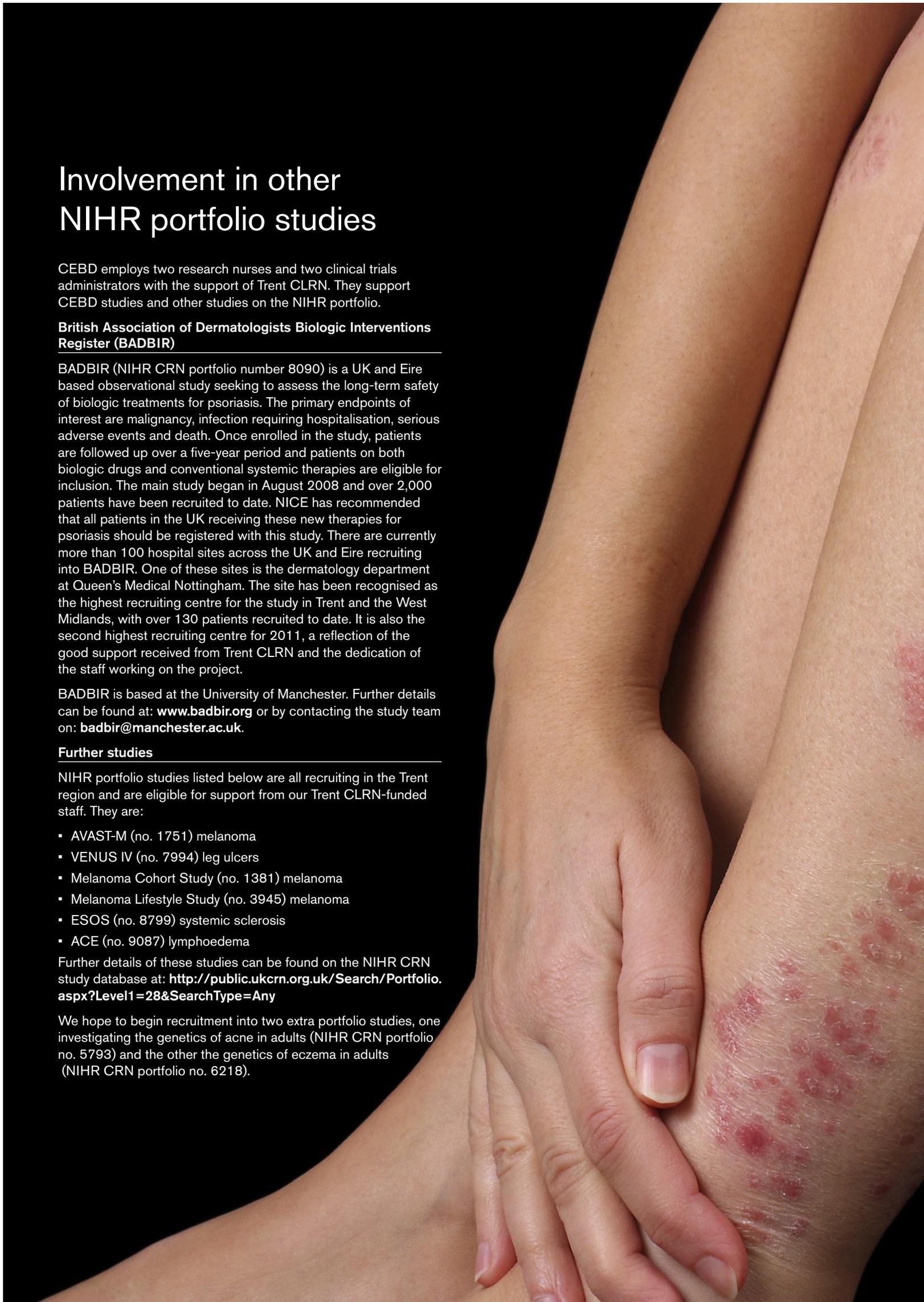
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NIHR portfolio studies listed below are all recruiting in the Trent region and are eligible for support from our Trent CLRN-funded staff. They are:

- AVAST-M (no. 1751) melanoma
- VENUS IV (no. 7994) leg ulcers
- Melanoma Cohort Study (no. 1381) melanoma
- Melanoma Lifestyle Study (no. 3945) melanoma
- ESOS (no. 8799) systemic sclerosis
- ACE (no. 9087) lymphoedema

Further details of these studies can be found on the NIHR CRN study database at: <http://public.ukcrn.org.uk/Search/Portfolio.aspx?Level1=28&SearchType=Any>

We hope to begin recruitment into two extra portfolio studies, one investigating the genetics of acne in adults (NIHR CRN portfolio no. 5793) and the other the genetics of eczema in adults (NIHR CRN portfolio no. 6218).



# Cochrane systematic reviews

## Systematic Reviews co-ordinated by the Cochrane Skin Group



The Cochrane Skin Group aims to publish seven protocols, four full reviews and three updates for previously published reviews each year. Details of reviews, updates and protocols published for the period April 2010 to August 2011 are outlined over the following pages.

## Reviews and Updates

**Issue 4, 2010: Interventions for non-metastatic squamous cell carcinoma of the skin** (Lansbury L, Leonardi-Bee J, Perkins W, Goodacre T, Tweed JA, Bath-Hextall FJ)

**Summary findings:** One trial involving 65 people was included. This compared the time to recurrence in participants with aggressive skin SCC who were randomised to receive either adjuvant 13-cis-retinoic acid and interferon alpha after surgery with or without radiation treatment, or no adjuvant therapy after their initial treatment. There was no significant difference in time to recurrence of tumour between the two groups (hazard ratio 1.08, 95% confidence intervals 0.43 to 2.72). Little evidence from RCTs comparing the efficacy of different interventions for primary cutaneous SCCs exists. There is a clear need for well-designed randomised studies in order to improve the evidence base for the management of this condition.

**Issue 6, 2010: Interventions for preventing occupational irritant hand dermatitis** (Bauer A, Schmitt J, Bennett C, Coenraads P-J, Elsner P, English J, Williams HC)

**Summary findings:** Four RCTs involving 894 participants from different occupations were included. Although the findings of this review were generally positive, no statistical significance was reached. At present there is insufficient evidence for the effectiveness of most of the interventions used in the primary prevention of occupational irritant hand dermatitis. Larger well designed RCTs are now needed in different workplaces to establish the effectiveness of various preventative strategies.

**Issue 6, 2010: Interventions for cellulitis and erysipelas** (Kilburn SA, Featherstone P, Higgins B, Brindle R)

**Summary findings:** Twenty-five studies with a total of 2488 participants were included. Only small single studies for duration of antibiotic treatment, intramuscular versus intravenous route, the addition of corticosteroid to antibiotic treatment compared with antibiotic alone, and vibration therapy were found, so there was insufficient evidence to form conclusions. Only two studies investigated treatments for severe cellulitis and these selected different antibiotics for their comparisons, so firm conclusions could not be made. There is a need for trials to evaluate the efficacy of oral antibiotics against intravenous antibiotics in the community setting due to the service implications.

**Issue 7, 2010: Interventions for melasma** (Rajaratnam R, Halpern J, Salim A, Emmett C)

**Summary findings:** Twenty studies were included with a total of 2125 participants covering 23 different treatments. Triple-combination cream was significantly more effective at lightening melasma when compared to hydroquinone alone or to dual combinations such as tretinoin and hydroquinone, tretinoin and fluocinolone acetonide, or hydroquinone and fluocinolone acetonide. Tretinoin was more effective at lightening melasma compared to placebo, as was the skin-whitening complex Thiospot. However, many studies were of a poor quality with only a small number of participants. High-quality randomised controlled trials on well-defined participants with long-term outcomes to determine the duration of response are needed.

**Issue 10, 2010: Interventions for bullous pemphigoid** (Kirtschig G, Middleton P, Bennett C, Murrell DF, Wojnarowska F, Khumalo NP)

**Summary findings:** Three new studies were included in this updated review making a total of 10 randomised controlled trials (with a total of 1049 participants) of moderate to high risk of bias. Very potent topical steroids are effective and safe treatments for BP, but their use in extensive disease may be limited by side-effects and practical factors. Milder regimens (using lower doses of steroids) are safe and effective in moderate BP. Starting doses of prednisolone greater than 0.75 mg/kg/day do not give additional benefit, lower doses may be adequate to control disease and reduce the incidence and severity of adverse reactions. The effectiveness of adding plasma exchange, azathioprine or

mycophenolate mofetil to corticosteroids, and combination treatment with tetracycline and nicotinamide needs further investigation.

**Issue 3, 2011: Interventions for rosacea** (van Zuuren EJ, Kramer S, Carter B, Graber MA, Fedorowicz Z)

**Summary findings:** Fifty-eight trials, including 27 from the original review, comprising 6633 participants were included in this updated review. Although the majority of included studies were assessed as being at high or unclear risk of bias there was some evidence to support the effectiveness of topical metronidazole, azelaic acid, and doxycycline (40 mg) in the treatment of moderate to severe rosacea, and cyclosporine 0.05% ophthalmic emulsion for ocular rosacea. Further well-designed, adequately-powered randomised controlled trials are required.

**Issue 5, 2011: Interventions for infantile haemangiomas (strawberry birthmarks) of the skin** (Leonardi-Bee J, Batta K, O'Brien C, Bath-Hextall FJ)

**Summary findings:** Four studies were included with a total of 271 participants. This review has found limited evidence from individual RCTs to support some of the existing interventions (corticosteroid and pulsed dye laser) for infantile haemangiomas. There is a need for further high-quality RCTs to validate the findings from these studies, and RCTs to assess the effect of other treatments, in particular relating to propranolol.

## Protocols

**Issue 5, 2010: Interventions for preventing and managing radiation-induced skin reactions in cancer patients** (Chan R, Webster J, Battistutta D, Chung B, Brooks L)

**Issue 7, 2010: Histamine H2-receptor antagonists for urticaria** (Hu N, Fedorowicz Z, Liu GJ, Zhong D, Xue S, Jiang X, Li L, Whamond L, Jagannath VA)

**Issue 8, 2010: Chinese herbal medicine for atopic eczema** (Gu SX, Pang C, Xue CC, Li CG, Yang AWH, Zhang W, Williams HC)

**Issue 10, 2010: Specific allergen immunotherapy for the treatment of atopic eczema** (Calderon MA, Boyle RJ, Nankervis H, García Núñez I, Williams HC, Durham S)



**Issue 11, 2010: Venom immunotherapy for preventing allergic reactions to insect stings** (Elremeli M, Bulsara MK, Daniels M, Boyle RJ)

**Issue 1, 2011: Ustekinumab for plaque psoriasis** (Roberts C, Angus JE, Williams HC, Villanueva E, Saeterdal I, Jobling R)

**Issue 1, 2011: Interferon alpha for the adjuvant treatment of cutaneous melanoma** (Mocellin S, Lens MB, Pasquali S, Pilati P)

**Issue 1, 2011: Interventions for mycosis fungoides** (Weberschock T, Rehberger P, Röllig C, Bunch C, Schmitt J, Bauer A)

**Issue 7, 2011: Interventions for skin reactions associated with targeted anticancer treatments** (Boers-Doets C, Lacouture M, Langenhoff J, van Zuuren EJ, Stijnen TT, Brakenhoff J, Ouwerkerk J, Galimont A, Bro W, Nortier H)

## Other systematic reviews

The following systematic reviews have all been funded as part of our ongoing SPRUSD NIHR Programme Grant Award.

### Systematic review of treatments for atopic eczema

This systematic review will update a comprehensive Health Technology Assessment (HTA) review of eczema treatments published in 2000. This update will include all randomised controlled trials on eczema treatments published from 2000 to 2010. This project will bring together all the up-to-date, good quality evidence about treatments for eczema.

The original HTA review included 254 trials on established eczema and the update will add over 250 more. The updated review will give an overview of the evidence on benefits and harms for each type of treatment, within broad treatment categories. Its design will make it easy and quickly accessible to clinicians, healthcare managers and policy makers as well as interested patients and carers.

The results of the updated review, which is due to be completed by the end of 2011, will be of major importance to those creating or updating eczema guidelines. It will also identify areas where future research could be directed.

People involved: Helen Nankervis<sup>(1)</sup>, Hywel Williams<sup>(1)</sup>, Kim Thomas<sup>(1)</sup>, Finola Delamere<sup>(1)</sup>

1; University of Nottingham.

### The Prevention of Eczema in Infants and Children: An Overview of Cochrane and Non-Cochrane reviews

This overview of reviews presents the most up-to-date evidence from Cochrane and non-Cochrane reviews on the efficacy and safety of interventions to prevent eczema in infants and children at different risk levels of developing allergic disease.

The pool of Cochrane and non-Cochrane reviews came from the 2010 NHS Evidence Skin Disorders Annual Evidence Updates on Atopic Eczema. Seven systematic reviews containing 39 relevant trials with 11,897 participants met our inclusion criteria and were included in this overview. They covered seven interventions for preventing eczema: 1) promotion of exclusive breastfeeding for a defined period of time; 2) hydrolysed protein formulas for infants who are not exclusively breastfed, 3) soy formulas for infants who are not exclusively breastfed, 4) maternal dietary antigen avoidance, 5) omega 3 or 6 fatty acid supplementation, 6) prebiotics, and 7) probiotics.

Overall, there was no clear evidence that any of these interventions reduced the incidence of eczema. There is some evidence that exclusive breastfeeding for at least six months and prebiotics might reduce eczema incidence in infants at higher risk of developing eczema but each of these findings was based on the results of a single small trial, and neither intervention reduced eczema incidence beyond the first two years of life. This review concludes that future research on prevention of eczema is needed and should examine different types of hydrolysed formulas, prebiotics and probiotics, as well as enhancement of the skin barrier and other novel approaches in infants at different risk levels for developing allergic disease. This overview has been accepted for publication in 'Evidence-Based Child Health: A Cochrane Review Journal'

People involved: Michelle Foisy<sup>(1)</sup>, Robert J. Boyle<sup>(2)(3)</sup>, Joanne R. Chalmers<sup>(4)</sup>, Eric L. Simpson<sup>(5)</sup>, Hywel C. Williams<sup>(4)</sup>

1; Cochrane Child Health Field, Canada. 2; Imperial College London. 3; National Institute for Health Research Comprehensive Biomedical Research Centre, London. 4; University of Nottingham. 5; Oregon Health & Science University, USA.

### Relevant publications

Foisy M, Becker LA, Chalmers JR, Boyle RJ, Simpson EL, Williams HC. Mixing with the 'unclean': including non-Cochrane reviews alongside Cochrane reviews in overviews of reviews. Poster accepted for Cochrane Colloquium, Madrid 2011.

### Treatment of squamous cell carcinoma of the skin – systematic review

Cutaneous SCC is the second most common skin cancer, yet despite its associated high burden of morbidity, there has been a striking lack of high-quality research which has assessed the treatment of this tumour. In 2010 we published a Cochrane systematic review, 'Interventions for primary non-metastatic squamous cell carcinoma of the skin,' the objective of which was to evaluate the evidence from RCTs of the effectiveness of treatments used for cSCC. Only one RCT was eligible for inclusion, highlighting the lack of evidence in this area. Current multiprofessional guidelines for the management of patients with primary SCC are based largely on case series.

Following on from our original review, we are now undertaking a second systematic review of SCC treatments, prompted by the lack of evidence from RCTs. This review will include observational studies of SCC treatments and,

inform the design of much-needed clinical trials in the area, as well as comprehensively summarising treatment data as it currently stands from other, non-RCT sources. Initial searching of the databases returned >2500 titles, with almost 200 studies, mostly case series, being identified as suitable for inclusion. Each study is being assessed for quality and risk of bias and, as meta-analysis is not considered appropriate due to the heterogeneity of the studies, the results will be presented narratively or graphically where possible.

The protocol for the current systematic review has been registered on the Prospero database (an international prospective register of systematic reviews), and it is envisaged that the completed review will be available in late 2011.

People Involved: Louise Lansbury<sup>(1)</sup>, Fiona Bath-Hextall<sup>(1)</sup>, Jo Leonardi-Bee<sup>(1)</sup> Dr William Perkins<sup>(2)</sup>

1; University of Nottingham. 2; Nottingham University NHS Trust.

#### Relevant publications

Lansbury L., Leonardi-Bee J., Perkins W., Goodacre T., Tweed J., Bath-Hextall F. Interventions for non-metastatic squamous cell carcinoma of the skin. *Cochrane Database of Systematic Reviews* 2010. Issue 4. Art.No. CD007869. DOI:10.1002/14651858.CD007869.pub2

#### NHS Evidence Annual Evidence Updates

Four Annual Evidence Updates were produced through NHS Evidence-skin disorders last year on the topics of skin cancer, eczema, acne and psoriasis as outlined below:

- **Skin cancer:** two guidelines, 23 systematic reviews, five invited clinical commentaries (10 May 2010)
- **Atopic eczema:** one guideline, 18 systematic reviews (13 September 2010)
- **Psoriasis:** five guidelines, 21 systematic reviews (1 November 2010)
- **Acne vulgaris:** two guidelines, five systematic reviews (28 February 2011)

Annual Evidence Updates were a key output for NHS Evidence-skin disorders and present the results of a search for new evidence in the form of guidelines and systematic reviews published or indexed in the last year, accompanied by a 'what's new?' commentary on the significance of the new evidence for clinical practice. Due to changes in NHS Evidence these are no longer available in this format but a new version will be available from 2012. As in previous

years, UK DCTN SpR Fellows took the lead in writing three of the commentaries with Hywel Williams; Dr Abby Macbeth, Dr Kave Shams and Dr Rosalind Simpson. For the psoriasis Annual Evidence Update, our colleagues Dr Amy Foulkes, Professor Christopher Griffiths and Dr Richard Warren at the University of Manchester kindly wrote the commentary.

A key educational aspect of the involvement of SpR fellows in the Annual Evidence Updates is the experience of preparing articles based on the Annual Evidence Update commentaries. These papers are published regularly in the refereed journal *Clinical and Experimental Dermatology*. In the period of this report we had five of these "what's new" papers published or accepted for publication. Feedback from our users indicates that these papers are popular for continuing professional development and journal clubs. They also help to spread the word about the Annual Evidence Updates and NHS Evidence to a wider, international audience. In 2010 we also published a paper in the journal *Trials*, with Dr John Ingram as lead author, which analysed the reporting quality of randomized controlled trials found for our 2009 Annual Evidence Update on acne, which identified many deficiencies and problems.

## Other research

#### Global Resource of Eczema Trials (GREAT) database:

This freely accessible, comprehensive online database holds records for all randomised controlled trials on eczema (otherwise known as atopic eczema or atopic dermatitis) treatments published since 2000 and is regularly updated. The database is categorised by treatment and gives a citation for each trial.

The main aim of this resource is to avoid duplication of effort by eczema researchers around the world when searching for randomised controlled trials on eczema treatments, thereby speeding up eczema research in areas such as systematic reviews and guideline writing in the future.

The trials included in the database are identified using searches of the electronic databases EMBASE, MEDLINE, AMED, CINAHL and LILACS. The searches for EMBASE and MEDLINE are based on the Cochrane highly sensitive search strategy combined with all known terms for eczema. The results of the searches are manually filtered to ensure that the database is as comprehensive as possible.

The database holds key information about each study including the interventions, duration, method of randomisation, blinding, withdrawals, outcomes and authors'

conclusions. This information is laid out in a systematic way in order to aid direct comparison of trials. The search facility enables users to search across all fields or just one for any term of interest. The database can also be easily searched by first author, journal title or year.

The last year has seen the GREAT database grow in size to over 260 trials as it has been periodically updated. The database has also been made easier to access as it is now highly ranked in Google. The GREAT database can be accessed at [www.greatdatabase.org.uk](http://www.greatdatabase.org.uk). This work is being carried out as part of the SPRUSD NIHR Programme Grant Award.

People involved: Helen Nankervis<sup>(1)</sup>, Hywel Williams<sup>(1)</sup>, Kim Thomas<sup>(1)</sup>, Alan Maplethorpe<sup>(1)</sup>

1; University of Nottingham.

#### Relevant publications

Nankervis, H., Maplethorpe, A., Williams, HC. Mapping randomized controlled trials of treatments for eczema — The GREAT database (The Global Resource of Eczema Trials: a collection of key data on randomized controlled trials of treatments for eczema from 2000 to 2010) *BMC Dermatology* 2011, 11:10

#### Decision aids for eczema

Many healthcare consultations involve treatment or screening decisions where there is currently no clear 'best choice'. Decision aids (also known as 'decision support interventions') have been developed in order to facilitate clinicians, carers and patients making these difficult decisions. This project will assess the needs of people who have to make eczema treatment decisions in order to decide whether to develop decision aids for eczema.

Decision aids are designed to be an aid to a clinical consultation and not to replace the input of a clinician. Decision aids can be used before, during or after a consultation. These tools have been presented in many different media such as DVD, paper, telephone consultation or on-line. This small mixed methods study will assess whether there is a need for patient decision aids to help patients and clinicians to make informed decisions regarding the treatment for eczema and whether decision aids would be accepted into routine clinical practice. The project also aims to elicit the best format and content for eczema decision aids, should they be needed and acceptable.

Focus groups with eczema patients, parents, carers, health professionals and family members involved in treatment decisions will be designed to gather needs and opinions. Relevant professional bodies, patient support groups and

guideline writers will be invited to become involved. This project is expected to last around 9 months and will finish in 2012. This work is being carried out as part of the SPRUSD NIHR Programme Grant Award.

People involved: Helen Nankervis<sup>(1)</sup>, Hywel Williams<sup>(1)</sup>, Kim Thomas<sup>(1)</sup>

1; University of Nottingham.

#### International Study of Asthma and Allergies in Childhood (ISAAC)

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

Until ISAAC's inception in 1991, little was known about the burden of asthma, hay fever, and eczema in developing nations. ISAAC is due to close in 2012 after a 21-year project history. It hopes to make all the data that was generated through the study free for the world to access for secondary studies after the study closes. ISAAC is composed of three phases:

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

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

**ISAAC Phase Three** (fieldwork 2001-2006) studied time trends in asthma and allergy prevalence through comparison with Phase One in 110 centres in 58 countries. Where populations have undergone rapid demographic change, marked by urbanisation and adoption of a western lifestyle, such as in cities in Africa, Latin America and parts of Asia, eczema and asthma has continued to be on the rise,

whereas there has been little change in disease burden where prevalence was already high in Phase One. Phase Three included an environmental questionnaire which revealed positive associations between allergy symptoms and paracetamol as well as antibiotic consumption in early life, and an increase in risk with exposure to truck traffic.

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

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

#### **Breast is best, but not for preventing eczema**

The most significant output on the eczema aspects of ISAAC since our last report was a study showing a lack of evidence that exclusive breastfeeding is protective against eczema. The study was part of ISAAC Phase II and led by Carsten Flohr in collaboration with Hywel Williams and colleagues at the University of Ulm, Germany. The study looked at data from 51,119 children aged eight to 12 years from 21 countries, and included an assessment of infant feeding practices as well as a standardised physical examination for eczema and skin allergy tests. There was no convincing protective effect of exclusive breastfeeding for at least four months on eczema outcomes, nor did exclusive breastfeeding seem to influence skin allergy. The findings are controversial because various authorities state that breastfeeding for six months or more may prevent eczema. The paper generated a lot of media interest, but hopefully the information will be of most use to health visitors and mothers who have eczema. Breastfeeding is clearly to be recommended as a generally good thing to do; it has many advantages such as enhanced child/mother bonding, protection against infections and good nutrition. But there is good evidence that exclusive breastfeeding does not prevent eczema, and mothers who are unable to breastfeed should not feel guilty if their child subsequently develops eczema.

#### **Relevant publications**

Flohr C, Aikhaleh N, Nagele G, Weinmayr G, Williams HC, Kleiner A, Strachan D. Lack of evidence for a protective effect of prolonged breastfeeding on childhood eczema: Lessons from the International Study of Asthma and Allergies in Childhood (ISAAC) Phase Two Br J Dermatol 2011 (In Press)

#### **A prospective study to evaluate the clinical response of skin disease to anti-retroviral therapy (ART) over a 2-year period in Uganda**

This project forms part of a PhD thesis for Dr Ser Ling Chua. It is 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 three years.

People involved: Ser Ling Chua<sup>(1)</sup>, Kieron Leslie<sup>(2)</sup>, Toby Maurer<sup>(2)</sup>, Phillip Leboit<sup>(2)</sup>, Grace Kituuzi Mulyowa<sup>(3)</sup>, David Bangsberg<sup>(4)</sup>

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.

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

Mid-infrared novel-glass fiber-optics have potential in medical systems for real-time sensing, imaging and analysis of tissue thereby hastening diagnosis, medical decisions and treatment planning and also for fibre laser surgery at new mid-infrared wavelengths. With Royal Society funding ("Mid-infrared transmitting optical fibre devices and systems for medicine" JP100296, 2010-2012), we continue to develop mid-infrared optical fibres as bright mid-infrared sources called 'supercontinuum generators' to help deploy remote mid-infrared spectroscopy in medicine.

In addition the group is developing the first mid-infrared fibre lasers (funding from the Laser Coalition/QinetiQ). Our vision is that of a remote mid-infrared probe guided by the surgeon's hand carrying out imaging and spectral mapping in situ during surgery to locate malignant tissue leading to its precise excision at its extreme borders to cellular tolerances, to preserve anatomical features as far as possible, in one go during the surgery which would cut medical consultant time

and unnecessary patient suffering. For further details on this work please contact Prof Angela Seddon at: [angela.seddon@nottingham.ac.uk](mailto:angela.seddon@nottingham.ac.uk).

People Involved: Professor Angela B Seddon<sup>(1)</sup>, Dr David Furniss<sup>(1)</sup>, Dr Sandeep Varma<sup>(2)</sup>, Professor Hywel Williams<sup>(2)</sup>

1; Faculty of Engineering, University of Nottingham. 2; Queen's Medical Centre, Nottingham.

#### Relevant publications

Seddon, A.B. A prospective for new mid-infrared medical endoscopy using chalcogenide glasses *Int J App Glass Sci* 2011 2;3 177-191

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

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

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

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

Basal cell carcinoma was discriminated from healthy tissue with 90±9% sensitivity and 85±9% specificity in a 70%-30% split cross-validation algorithm. This

multivariate model was then applied on tissue sections from new patients to image tumour regions. The RMS images showed excellent correlation with the gold standard of histopathology sections, BCC being detected in all positive sections.

New funding has been obtained from the NIHR to develop the technology. The main aims are to expand the database of tissue to include more types of basal cell carcinomas and healthy conditions which can be confused with basal cell carcinoma and to improve the speed of data acquisition and image analysis to levels acceptable to surgeons — a few minutes. Further details about the project can be obtained by contacting Ioan Notingher on: [ioan.notingher@nottingham.ac.uk](mailto:ioan.notingher@nottingham.ac.uk).

Investigators: Ioan Notingher<sup>(1)</sup>, Hywel Williams<sup>(2)</sup>, William Perkins<sup>(3)</sup>, Sandeep Varma<sup>(3)</sup>, Sarah Armstrong<sup>(2)</sup>, Tracey Sach<sup>(2)</sup>

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

#### Relevant publications

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

Ioan Notingher, William Perkins, Sandeep Varma, Hywel Williams Development of Raman micro-spectroscopy for automated detection and imaging of Basal Cell

Carcinoma, Patent Application. Filing Date: 13/05/2009 Application number: 0908204.1



# Impact

CEBD conducts clinical research that has a direct impact on patients and their care. The following sections demonstrate the breadth of our activities, and highlight some of the key areas of impact for the year.

# Implementation of research

2010/11 has been a good year for the CEBD, with three national clinical trials being published in quick succession:

- Softened Water Eczema Trial: [www.swet-trial.co.uk](http://www.swet-trial.co.uk)
- Prophylactic Antibiotics for the Prevention of Cellulitis of the Leg: [www.patchtrial.co.uk](http://www.patchtrial.co.uk)
- Effectiveness of Verrucae Treatments: [www.verrucatrial.co.uk](http://www.verrucatrial.co.uk)

All these trials present results that provide clear and useful guidance for clinicians and other health professionals when treating these common skin conditions, and have the potential to change clinical practice.

## SWET trial



The results of this study show that water softeners provide no additional clinical benefit to usual care in children with eczema, so the use of ion-

exchange water softeners for the treatment of moderate to severe eczema in children cannot be recommended.

“This is the most important RCT with an apparently negative result I am aware of because it has made us think exactly how water interacts with the skin. This is not the end of the hard water and atopic eczema story but a new beginning.”

Prof Mike Cork, Academic Unit of Dermatology Research, University of Sheffield

## PATCH II Trial



This trial presents evidence that prophylactic antibiotics for the prevention of cellulitis of the leg may reduce the incidence of further attacks. The trial reported a 47% reduction in the number of repeat episodes

compared to the placebo control group, even when the majority of patients included in the trial did not have a history of recurrent disease. The trial was stopped early due to slow recruitment, but results of the PATCH I trial (which recruited to target and has greater power to answer this question) are eagerly awaited later in 2011.

## EVERT Trial



This trial confirmed the findings of other recent studies in suggesting that cryotherapy is no better than self-applied salicylic acid for the treatment of verrucae, but is considerably more expensive. An updated Cochrane review is to be published shortly.

## Relevant publications

Thomas KS, Koller K, Dean T, O'Leary CG, Sach TH, Frost A, et al. A multicentre randomised controlled trial and economic evaluation of ion-exchange water softeners for the treatment of eczema in children: the Softened Water Eczema Trial (SWET). *Health Technol Assess* 2011;15(8):1-156.

Thomas KS, Dean T, O'Leary C, Sach TH, Koller K, Frost A, Williams HC and the SWET Trial Team. A randomised controlled trial of ion-exchange water softeners for the treatment of eczema in children. *PLOS Medicine* 2011; 8 (2):

Cockayne S, Curran M, Denby G, Hashmi F, Hewitt C, Hicks K, et al. EVERT: Cryotherapy versus salicylic acid for the treatment of verrucae – a randomised controlled trial. *Health Technol Assess* 2011;15(xx).

Cockayne ES, Hewitt C, Hicks K, Shalmini J, Kang'ombe AR, Stamuli E, Turner G, Thomas KS, Curran M, Denby G, Hashmi F, McIntosh C, Torgesson D, Watts I Cryotherapy versus salicylic acid for the treatment of verrucae: A randomised controlled trial and cost-effectiveness analysis. *BMJ* 2011: 342, d3271

Thomas KS and UK Dermatology Clinical Trials Network PATCH Study Group Studying a disease with no home – lessons in trial recruitment from the PATCH II study. *Trials* 2010, 11:22.

UK Dermatology Clinical Trials Network's Patch Study Group. Prophylactic Antibiotics for the Prevention of Cellulitis. *Journal of Lymphoedema*, 2007; 2(1), 34-37.

Thomas, K.S., Cox, N.H., Savelyich, B.S.P., Shipley, D., Meredith, S., Nunn, A., Reynolds, N., Williams, H.C., On Behalf Of The UK Dermatology Clinical Trials Network (UK DCTN) Feasibility study to inform the design of a UK multi-centre randomised controlled trial of prophylactic antibiotics for the prevention of recurrent cellulitis of the leg. *Trials* 2007, 8;3.

Given the known difficulties in translating research evidence into clinical practice, we are implementing effective dissemination strategies. All our published studies will be included in updated systematic reviews, and we are working with both guideline writers and the teams responsible for maintaining on-line information resources to ensure these important results are included.

As part of the dissemination of the results of the PATCH cellulitis prevention trials, we are conducting a pilot study looking at the possibility of encouraging clinicians to become early evidence adopters by asking them to reflect on the importance of the trial findings prior to release of the trial results.

For further information, please contact Kim Thomas at: [cebd@nottingham.ac.uk](mailto:cebd@nottingham.ac.uk).

## Influencing Service Provision

We strive to ensure that the most up-to-date evidence is incorporated into national guidelines, and on-line patient information resources. Organisations that we work with include:

- National Institute for Clinical Excellence (NICE)
- British Association of Dermatologists (BAD)
- Royal Colleges
- Clinical Knowledge Summaries (CKS)
- Scottish Intercollegiate Guidelines Network (SIGN)
- Map of Medicine
- NHS Choices
- NHS Direct
- Patient Support Groups

## Guidelines contributed to in 2010/11

### NICE guidelines, Technology Appraisals and Evaluation Pathways

- Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis
- Belimumab for the treatment of active autoantibody-positive systemic lupus erythematosus
- Regenlite® laser for the treatment of inflammatory acne

### BAD Guidelines

- Concise version of BAD vitiligo guidance published

### Clinical Knowledge Summaries

- Vitiligo module: [www.cks.nhs.uk/vitiligo](http://www.cks.nhs.uk/vitiligo)
- Eczema module: [www.cks.nhs.uk/eczema\\_atopic](http://www.cks.nhs.uk/eczema_atopic)
- Corticosteroids – topical (skin, nose and eyes): [www.cks.nhs.uk/corticosteroids\\_topical\\_skin\\_nose\\_and\\_eyes/view\\_whole\\_topic](http://www.cks.nhs.uk/corticosteroids_topical_skin_nose_and_eyes/view_whole_topic)

### Sign Guidelines

- Management of Eczema in Primary Care: [www.sign.ac.uk/guidelines/fulltext/125/index.html](http://www.sign.ac.uk/guidelines/fulltext/125/index.html)

### Royal Colleges

- Royal College of Paediatric and Child Health Allergy care pathways. Allergy Care Pathways for children eczema: [www.rcpch.ac.uk/allergy](http://www.rcpch.ac.uk/allergy)

### Map of Medicine

- Atopic eczema care pathway (available through NHS Choices): [www.nhs.uk/Conditions/Eczema-\(atopic\)/Pages/MapofMedicinepage.aspx](http://www.nhs.uk/Conditions/Eczema-(atopic)/Pages/MapofMedicinepage.aspx)

### Relevant Publications

1. Gawkrödger D, Ormerod A, Shaw L, Mauri-Sole I, Whitton M, Watts M, Anstey A, Ingham J, Young K. Vitiligo: concise evidence based guidelines on diagnosis and management. *Postgrad Med J* 2010;86:466-471. Doi:10.1136/pdmj.2009.093278
2. Rodgers M, Griffin S, Paulden M et al Alitretinoin for severe chronic hand eczema. A NICE single technology appraisal. *Pharmacoeconomics* 2010; 28:351-62.
3. Cox H et al Emollients, education and quality of life: the RCPCH care pathway for children with eczema – a national evidence-based and consensus approach. *Archives of Disease in Childhood* (in press)

## Patient information resources contributed to in 2010/11

### NHS Choices

Vitiligo module: [www.nhs.uk/conditions/vitiligo/pages/introduction.aspx](http://www.nhs.uk/conditions/vitiligo/pages/introduction.aspx)

Eczema module: [www.cks.nhs.uk/eczema\\_atopic](http://www.cks.nhs.uk/eczema_atopic)

### NHS Direct

We are working with NHS Direct to produce a patient decision aid for the treatment of eczema

### Patient support groups

Nottingham Support Group for Carers of Children with Eczema

Dutch Association for People with Atopic Dermatitis

### TalkHealth

Jonathan Batchelor participated in the Open Clinics for Eczema event hosted by TalkHealth in collaboration with NHS Choices.

It takes time for impact to become apparent. A good example of this is Skin Conditions in the UK: A Health Care Needs Assessment published by CEBD in 2009, which has proved to be an important document in determining service provision in the UK. It was used to support a submission to the Propriety Association of Great Britain, in response to their document Self Care Campaign for Minor Illnesses, which suggested that conditions such as eczema, psoriasis and acne were mild conditions that should be self-treated without reference to their GP. A copy of the Executive Summary of the report was also distributed at a meeting hosted by the Danish Ambassador last year; delegates for the meeting included specialists in NHS Commissioning, the chair of the NHS Alliance and National Prescribing Centre (NPC), and government ministers.

Dermatologists in the USA are now in the process of producing their own Dermatology Health Care Needs Assessment on the basis of the UK document.

“.....an impressive book, full of useful and important information that would otherwise be hard to access.”

Professor Alex Anstey, Consultant Dermatologist, Royal Gwent Hospital

# Synthesis and dissemination of research evidence

## Annual evidence-based updates

With the editorial base of the Cochrane Skin Group located at CEBD, we have a long tradition of conducting and disseminating systematic reviews. However, one of the great success stories of the last few years has been the regular dermatology evidence-based updates produced by NHS Evidence – Skin Disorders.

These updates have proved so popular that we now publish each update in a peer-reviewed journal, which provides an excellent training opportunity for the UK DCTN Clinical Fellows who join us each year.

As from March 2011, NHS Evidence has launched a new specialist evidence service to replace the specialist collections. The new service is easy to search and provides access to a wider choice of quality specialist evidence content. NHS Evidence is managed by NICE.

The reorganisation has meant that our Centre has lost our information specialist, Dr Douglas Grindlay, although Hywel Williams has maintained links with the new service in the role of dermatology expert adviser.

Annual evidence updates on new and important evidence covering common and important skin conditions such as acne, eczema, psoriasis and skin cancer will continue, and the first new-look skin cancer update will appear in September 2011.

“I positively look forward to these updates so I can feel confident in being up to date in my eczema clinic for the forthcoming year.”

Dr Jane Ravenscroft, Consultant Dermatologist, Nottingham University Hospitals NHS Trust

“I am so grateful for your excellent and honest work in dermatology clinical research and the promotion of evidence-based practice. There is so much unreliable information in the literature in our field, and I am so thankful to have your unbiased and critical annual reviews.” Dr Lisa Williams, Seattle, USA

### Relevant publications

SMITH, E V, GRINDLAY, D J C and WILLIAMS, H C, 2011. What's new in acne? An analysis of systematic reviews published in 2009-2010. *Clinical and experimental dermatology*, 36(2), 119-22.

BATCHELOR, J M, GRINDLAY, D J C and WILLIAMS, H C, 2010. What's new in atopic eczema? An analysis of systematic reviews published in 2008 and 2009. *Clinical and experimental dermatology*, 35(8), 823-7.

INGRAM, J R, GRINDLAY, D J C and WILLIAMS, H C, 2010. Management of acne vulgaris: an evidence-based update. *Clinical and experimental dermatology*, 35(4), 351-354.

INGRAM, JOHN R, GRINDLAY, DOUGLAS J C and WILLIAMS, HYWEL C, 2010. Problems in the reporting of acne clinical trials: a spot check from the 2009 Annual Evidence Update on Acne Vulgaris. *Trials*, 11, 77.

WARREN, R B, BROWN, B C, GRINDLAY, D J C and GRIFFITHS, C E M, 2010. What's new in psoriasis? Analysis of the clinical significance of new guidelines and systematic reviews on psoriasis published in 2008 and 2009. *Clinical and experimental dermatology*, 35(7), 688-91; quiz 692.

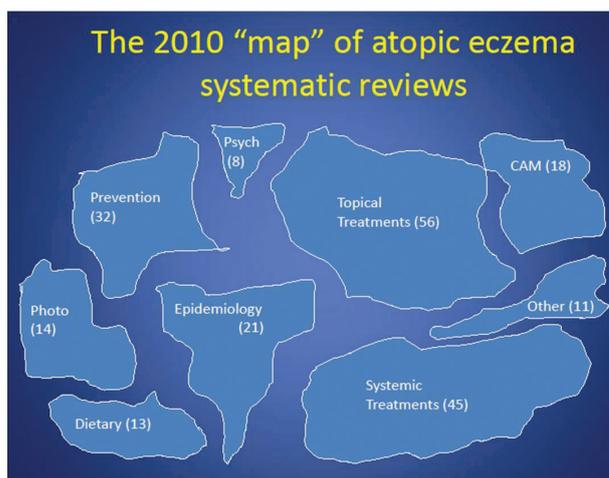
WILLIAMS, H C and GRINDLAY, D J C, 2010. What's new in atopic eczema? An analysis of systematic reviews published in 2007 and 2008. Part 1. Definitions, causes and consequences of eczema. *Clinical and experimental dermatology*, 35(1), 12-5.

WILLIAMS, H C and GRINDLAY, D J C, 2010. What's new in atopic eczema? An analysis of systematic reviews published in 2007 and 2008. Part 2. Disease prevention and treatment. *Clinical and experimental dermatology*, 35(3), 223-227.

## Collation of research evidence

### Maps of systematic reviews

The NHS Evidence searches used to produce the Annual Evidence-Based updates are also used to maintain a “map of systematic reviews” in the key topic areas of eczema and acne ([www.nottingham.ac.uk/dermatology](http://www.nottingham.ac.uk/dermatology)). Non-Cochrane reviews of treatments for skin disease are increasingly common, and these popular systematic review “maps” provide a single point of access for all published reviews.



Prof Hywel Williams said: “I use these maps on a weekly basis. Other sources of evidence end up giving you hundreds of hits, whereas these maps of systematic reviews in common skin diseases organised according to prevention, risk factors, treatment, etc, are so easy to navigate. If you are thinking about an issue in acne or eczema and ask yourself ‘has a systematic review been published on this topic?’ then look no further than our maps.”

### GREAT Database

Allied to the maps is the GREAT Database (Global Resource of Eczema Trials), published online in 2010. It is freely available for anyone ([www.greatdatabase.org.uk](http://www.greatdatabase.org.uk)). It’s been developed as part of our NIHR Programme Grant award and for the first time brings together all randomised controlled trials published on eczema treatments since 2000. A systematic review (of the 2000 publication) summarising trial evidence over the last 10 years will be published shortly, but the Database will continue to be updated and expanded beyond this. It is our hope that this global resource will:

- Provide a readily available source of quality information for guideline writers and producers of patient information.
- Stimulate collaborative endeavours with researchers

throughout the world – particularly in promoting and highlighting areas for methodological advancement.

- Prevent duplication of effort in searching for eczema randomised controlled trials.

### Relevant publications

Lawton S (2011) Atopic Eczema and Evidence-Based Care. *Journal of the Dermatology Nurses’ Association*. 3 (3). DOI: 10.1097/JDN.0b013e31821c0b59

Nankervis H, Maplethorpe A, Williams HC, Mapping randomized controlled trials of treatments for eczema – The GREAT database, *BMC Dermatology* 2011 11:10

## National Institute for Health Research (NIHR) links

The NIHR is a government-funded organisation for delivering high-quality research within the UK NHS. CEBD has received considerable NIHR funding and support due largely to the shared goals of conducting high-quality research that is relevant to patients, clinicians and the NHS. Most of our trials are funded through NIHR funding streams. We are delighted to have received an NIHR Programme Grant award for the last three years, and Prof Williams receives support for his role as Chair of the Dermatology Specialty Group (SIG), Chair of the NIHR HTA Commissioning Board, and as an NIHR Senior Investigator.

CEBD hosted two NIHR Academic Clinical Fellows (2010 and 2011), to support medical trainees at an early stage in their academic career. Two of our past Clinical Fellows, Dr Carsten Flohr and Dr Sinead Langan (funded prior to the development of the NIHR), have received funding as NIHR Clinician Scientists – prestigious and highly competitive national awards. Dr Flohr completed his PhD in Nottingham in 2007 and was awarded an NIHR Clinician Scientist Award in 2009. He is working on a project looking at how genes that contribute to breakdown of the natural skin barrier interact with environmental influences, and how these can lead to eczema and food allergies. Dr Langan completed her PhD here in 2008. She was awarded a Clinician Scientist Award in 2011 for a project looking at the natural history and management of herpes zoster, and the impact of moderate immunosuppression from common diseases.

## Dermatology Speciality Group

Professor Hywel Williams is chair of the NIHR Specialty Group for Dermatology (DSG) and Carron Layfield (UK DCTN Network Manager) provides support for this group. The Dermatology Speciality Group (DSG) is comprised of local leads from each Comprehensive Local Research Network (CLRN) where dermatology has been identified as a local priority. To date, 18 of the 25 CLRNs across England have identified dermatology as a local research priority along with Scotland and Wales. The primary role of the group is the successful delivery of the NIHR portfolio of dermatology studies, and providing advice regarding the adoption of industry studies onto the portfolio. Following on from a review of all Speciality Groups in March 2011, the DSG was one of nine (out of 26 groups) to be awarded a Green rating in recognition of its success. Further information about the group's work in helping to deliver dermatology research can be found at: [www.crncc.nihr.ac.uk/about\\_us/ccrn/specialty](http://www.crncc.nihr.ac.uk/about_us/ccrn/specialty).

## Prof Hywel Williams explains what it means to be an NIHR Senior Investigator

I was very proud to be the recipient of an NIHR Senior Investigator award in the first round of 100 in 2008. The competition is a tough one, based not only on traditional factors such as research publications and grant income, but also on contribution to the NIHR and NHS as a whole. In addition to attending National Senior Investigator meetings to learn from other research leaders, the award has provided me with an opportunity to learn more about leadership skills from Ashridge Consulting. This included one to one mentorship with senior life coaches including Phil Glanville, from whom I have learnt a lot. In fact, the work gave me confidence to apply for my current post as Chair of the NIHR HTA Commissioning Board. The award also comes with some modest funding which has been very helpful for plugging vital gaps to develop new researchers and to allow research to progress.

To date, the funds associated with my Senior Investigator award have been used to:

1. Support core staff at the UK DCTN co-ordinating centre (based within CEBD).
2. Allow a dermatology trainee (Viktoria Eleftheriadou) to complete her research training.

3. Provide joint funding with the British Association of Dermatology for a joint research taster fellowship, one of which was awarded to Evguenia Galinskaya, who has already visited CEBD.
4. Dedicated funding to permit a newly appointed consultant (Dr Jonathan Batchelor) to work one day a week on clinical research at the CEBD.
5. A year's pump priming for a dermatology trainee (Dr Rosalind Simpson) to work up a project for an external Fellowship.

"The goal of the National Institute for Health Research (NIHR) is to create a health research system in which the NHS supports outstanding individuals, working in world-class facilities, conducting leading-edge research that is focused on the needs of patients and the public."

[The National Institute for Health Research \(NIHR\) website](http://www.nihr.ac.uk)

## Prioritisation of research



The CEBD works with the James Lind Alliance (JLA) in identifying areas of treatment uncertainty that require further research. Building on the success of the vitiligo priority setting partnership of 2009, we have become the first group to work with the JLA on a second partnership. The topic is eczema, and we are collecting and collating submissions via our online survey ([www.homeforeczema.org](http://www.homeforeczema.org))

All treatment uncertainties submitted to the CEBD (on any topic) are added to the Database of Uncertainties about the Effectiveness of Treatments ([www.library.nhs.uk/duets](http://www.library.nhs.uk/duets)), and this database is now increasingly used by funding bodies in determining their research priorities.

The UK Dermatology Clinical Trials Network (UK DCTN) runs its own Trial Generation and Prioritisation Panel, which comments on topic suggestions submitted by members of the UK DCTN, and makes recommendations as to whether or not a trial suggestion should be developed further.

On behalf of the British Association of Dermatologists, the UK DCTN is an affiliate group for the NIHR Health Technology Assessment Clinical Evaluation and Trials programme. Trial suggestions prioritised by the group are submitted to the NIHR for consideration for funding.

Initiatives have also taken place this year to identify skin topics of priority in primary care. Kim Thomas attended a Primary Care Portfolio Review Workshop convened by the Primary Care Research Network and the Scottish School of Primary Care. Kim is also a member of the Medicines for Children Clinical Studies Group for general paediatrics, and is advising the group on how to conduct a priority setting partnership relevant to the needs of the group.

### Relevant publications

V.Eleftheriadou, M.E. Whitton, D.J. Gawkrödger, J. Batchelor, J. Corne, B. Lamb, S. Ersser, J. Ravenscroft and K.S. Thomas on behalf of the vitiligo priority setting partnership. Future research into the treatment of vitiligo: where should our priorities lie? Results of the vitiligo priority setting partnership. *British Journal of Dermatology* 2011 164 (3): 530-536.

Ridd M, Thomas K, Wallace P, O'Sullivan F. Dermatology research in primary care: why, what and how? *British Journal of General Practice*. 2011 61 (583): 89-90.

"I looked forward to working with the CEBD team for the eczema project in 2011. Having worked with the team and their partners the previous year, I knew they'd be efficient, friendly and have an inclusive approach. The team are reflective in their practice and decisions, and not afraid to push the boundaries in research."

Sally Crowe, Chair of the James Lind Alliance Monitoring and Implementation Group.

## Improving dermatology research quality



### Harmonizing Outcome Measures for Eczema (HOME)

One of the most exciting initiatives to have taken place during 2010/11 is the development of the international

consensus group for the development of core outcome measures for use in eczema trials (Harmonizing Outcome Measures for Eczema – HOME). This group will be building on the initiatives first established by the OMERACT Group in the field of Rheumatoid Arthritis, and more recently with the COMET group – which is promoting the use of core outcome measures for all effectiveness trials: [www.liv.ac.uk/nwhtmr/comet/core\\_outcomes.htm](http://www.liv.ac.uk/nwhtmr/comet/core_outcomes.htm)

We are delighted that the HOME project is included as a key output for our NIHR Programme Grant (SPRUSD). To date, the HOME group has completed:

- An international, multi-professional Delphi exercise to define core outcome domains. This stage included input

from patients, clinicians, methodologists, representatives from regulatory agencies and journal editors.

- HOME I meeting, Munich 2010. The exploratory HOME I meeting, held in Munich in 2010 indicated overwhelming support from the international community for working together to develop core outcome measures for eczema.
- HOME II meeting, Amsterdam 2011. This meeting was attended by 44 delegates from all over the world, including clinicians, patients, methodologists and representatives from industry. Consensus was reached over the core domains to be included in future eczema trials (eczema signs, eczema symptoms, long-term control and quality of life). Several work packages were identified for development prior to the HOME III meeting, and these will now be led by specific project teams.

The next meeting of the HOME Group (HOME III) will concentrate on achieving consensus over the best instruments to be used when measuring the core outcome domains. Further details at: [www.homeforeczema.org](http://www.homeforeczema.org).

"I was particularly intrigued by the work on HOME — and the fact that there are not, already, harmonised outcome measures for eczema....to a member of the public it seems totally bizarre that such a situation could exist. How on earth can comparisons be made on therapies and remedies if they are not compared to identical measures of success and indeed importance (to patients and clinicians)."  
[Lester Firkins, Chair of the James Lind Alliance](#)

#### Relevant Publications

Schmitt J, Williams H; HOME Development Group. Harmonising Outcome Measures for Eczema (HOME). Report from the First International Consensus Meeting (HOME 1), 24 July 2010, Munich, Germany. *Br J Dermatol*. 2010;163:1166-8.

Schmitt J, Langan S, Stamm T et al. (2011) Core outcome domains for controlled trials and clinical recordkeeping in eczema: international multi-perspective Delphi consensus process. *J Invest Dermatol* 131:623-30

## Quality of Trial Reporting

Hywel Williams continues to be an active member of the EQUATOR Group ([www.equator-network.org](http://www.equator-network.org)), which is an international initiative that seeks to enhance the reliability and value of medical research literature by promoting transparent and accurate reporting of research studies.

Over the last year Hywel has been working with colleagues from EQUATOR and the Royal College of Physicians to develop a statement on the principles of clear research reporting, the aim of which is to ensure that all evidence is published in an accessible, honest and accurate way.

As a department we are keen to support initiatives to encourage the registration of trial protocols prior to initiation of the trial, which should reduce both the impact of selective reporting of trials (where positive trials are more likely to be published) and selective outcome reporting (where outcome measures are changed or given greater emphasis during the reporting of trials).

#### Relevant publications

INGRAM, JOHN R, GRINDLAY, DOUGLAS J C and WILLIAMS, HYWEL C, 2010. Problems in the reporting of acne clinical trials: a spot check from the 2009 Annual Evidence Update on Acne Vulgaris. *Trials* 11, 77. [Flagged as being highly accessed].

U. Gonzalez, M. Whitton, V. Eleftheriadou, M. Pinart, J. Batchelor, J. Leonardi-Bee. Guidelines for designing and reporting clinical trials in vitiligo. *Archives of Dermatology* 2011 (in press)

## Institutional exchanges and invited lectures

### Visitors to CEBD

We are always pleased to welcome international visitors to CEBD as this gives us the opportunity to share experiences with others, and to learn from the differences and variations in practice around the world.

"Thank you so much for your generosity with your time. It did leave me quite in awe of the amount of different projects you are undertaking and the amount of work going on at your centre."

Dr Miriam Santer, NIHR Fellow, Southampton University

We particularly welcome visitors from developing countries, and offer a travel bursary through the British Epidermo-Epidemiology Society (BEES) for clinicians based in Africa to attend our popular Getting to Grips with Evidence-Based Dermatology three-day course. This year, we were disappointed to find that difficulties in obtaining travel visas meant that our colleagues from Moshi, Tanzania were unable to join the course, and so a signed copy of the Course Book (Evidence-Based Dermatology) was sent out to them.

"We hope that with these tools at our hands, our daily clinical practice will never be the same again. By the time you visit Moshi next time, it's my hope that all the book pages will be bearing coffee stains as a result of late-night reading."

Dr Baraka Chaula, Moshi, Tanzania

We were delighted to welcome Professor Pascal Joly at the visiting Stiefel lecturer in May of this year. Professor Joly gave an excellent lecture on Evidence Based Management of Bullous Pemphigoid, followed by discussions within the department covering some of our more recent research activity.



"I have been very impressed by the work you have made to organise and professionalise your clinical research. It was great to meet you again and spend time with you."

Professor Pascal Joly, Stiefel Visiting Lecturer 2011

CEBD is a popular place for other researchers and trainees to visit in order to gain more experience of clinical research. We're pleased to have been joined by Evgeunia Galinskaya (NIHR Senior Investigators / British Association of Dermatologists research taster bursary) and Akerke Baibergenova (mentorship award funded by the Women's Dermatologic Society) during 2010/11.

"CEBD is full of enthusiastic and warm people who really care about what they do and truly believe in improving the lives of patients with skin conditions through vigorous high-quality research. I'd like to thank everyone at CEBD for making me feel welcome and inspired."

Dr Evgeunia Galinskaya, Research Taster Bursary, Cambridge.



Prof Hywel Williams with Dr Akerke Baibergenova

“CEBD was a great place to have my research elective. Even in my three-week visit I learned a lot through working on a stimulating research project. The team was welcoming, friendly and supportive.”

[Dr Akerke Baibergenova, Mentorship Award, Toronto, Canada](#)

We are also looking forward to working with Dr Masaki Futamura from Japan, who was joining the centre as a visiting fellow for a year in January 2012.

#### Invited lectures given by members of CEBD

Members of CEBD have represented the centre by giving presentations and posters at various meetings, training days and conferences around the world as follows:

- Annual Evidence Based Update Meeting (Eczema), Loughborough May 2010
- Psoriasis Association AGM, Northampton May 2010
- Primary Care Dermatology Society, Birmingham June 2010
- BAD Annual Meeting, Manchester July 2010
- International symposium Atopic Dermatitis, Munich July 2010
- First Eastern Asia Dermatology Congress, Japan October 2010

- International symposium on comparative effectiveness research in dermatology, Denver, USA October 2010
- Cochrane Colloquium, Keystone, Colorado USA October 2010
- University of Hertfordshire MSc Training Module, October 2010
- British Hair and Nails Research Day, London January 2011
- Regional Dermatology Meeting, Exeter January 2011
- Getting to Grips with Evidence Based Dermatology Course, University of Nottingham February 2011
- University of Hertfordshire MSc Training Module, February 2011
- BEES Summer School, University of Nottingham August 2011

In addition, Prof Hywel Williams was honoured to be an invited as visiting Professor to the dermatology department at Duke University in North Carolina in October 2010. He was looked after very well by Professor Russ Hall and his staff. He delivered lectures on evidence-based dermatology and focused workshops on research projects that were being undertaken by the dermatology trainees.

“Thank you for a fantastic Visiting Professor visit and I hope a turning point in the program for our residents. The lecture was spectacular and I have gotten really great feedback on the Friday session.”

[Professor Russell Hall, Duke University North Carolina](#)

Viktoria Eleftheriadou was awarded a travel scholarship from the University of Nottingham (BESTS award) to visit Professor Mauro Picardo at the San Gallicano Dermatological Institute in Rome, where she spent two weeks earlier this year.

This visit strengthened relations between CEBD and the San Gallicano Dermatological Institute, and provided the opportunity to learn more about techniques being used to treat vitiligo patients in other countries that are not currently available in the UK.

COLLABORATIVE LINKS





# Collaborative links

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



# National Institute of Health Research (NIHR) Clinical Research Networks

## Comprehensive Local Research Networks (CLRN)

All trials run through the CEBD are registered on the NIHR portfolio of trials <http://www.crncc.nihr.ac.uk/index/clinical/> portfolio and, as such, are eligible for support from CLRN. We have been extremely grateful to have received continued support from the Trent CLRN in the form of research nurse time, clinical trials administrators and PA sessions for clinicians based locally. Similar support has also been made available to some investigators across England involved in our multi-centre trials from their respective CLRN. Indeed, over the past year over £1.5 million pounds was allocated to specifically support dermatology studies across England in this way. Such additional support has made an enormous difference in our ability to successfully recruit into our multi-centre trials.

## Medicines for Children Research Network (MCRN)



Dr Kim Thomas has represented the interests of dermatology on the Medicines for Children's Clinical Studies Group for general paediatrics for the past five years. Having built up excellent links

with the MCRN whilst recruiting into the Softened Water Eczema Trial (SWET), they have continued to support our work by providing assistance for the Barrier Enhancement for Eczema Prevention study (BEEP) by co-adopting the study and providing nurse support in Lincoln and Derby. The MCRN young people's groups have also helped us with the development of a study idea looking at the prevention of acne in older children and young teenagers. Further information can be found at: [www.mcrn.org.uk](http://www.mcrn.org.uk).

## Primary Care Research Network (PCRN)



The majority of dermatology consultations take place in primary care, and we have established close links with the Primary Care Research Networks (PCRN) ([www.crncc.nihr.ac.uk/about\\_us/pcrn](http://www.crncc.nihr.ac.uk/about_us/pcrn)) to help deliver dermatology research in this setting. We worked with the PCRN to help successfully deliver both the Softened Water Eczema Trial (SWET) and the study of prophylactic antibiotics for the prevention of cellulitis (PATCH). Our

local PCRN, East Midlands and South Yorkshire (PCRN EMSYNET), were particularly helpful in helping to identify primary care practices to become involved in recruiting participants into the Barrier Enhancement for Eczema Prevention study (BEEP).

Links with the primary care community have been further enhanced over the past year by increasing collaborations with Dr Matthew Ridd, an NIHR lecturer in Primary Care at Bristol University who is involved in a number of CEBD projects, notably the eczema treatments prioritisation process. Dr Ridd has been responsible for establishing a Primary Care Dermatology Research Specialist Interest Group within the Society for Academic Primary Care and both Professor Hywel Williams and Dr Kim Thomas are members of this newly formed group.

## Health Technology Assessment Programme



Hywel Williams, Director of CEBD, continues in his role as Chair of the NIHR Health Technology Assessment (HTA) commissioning board. The HTA commissioning board considers the scientific merit of research applications to promote health, prevent and treat disease and improve rehabilitation and long-term care. He is also the Deputy Director of the HTA programme, which is the largest independent funding source of clinical trials in the UK. Information about the HTA and related funding opportunities is available at: [www.hta.ac.uk](http://www.hta.ac.uk).

# Clinical trials units and academic institutions

## The Nottingham Clinical Trials Unit (CTU)

Trials developed by CEBD are increasingly developed in collaboration with the Nottingham Clinical Trials Unit and we are working jointly on the delivery and management of several of our trials.

### MRC Clinical Trials Unit, London



Collaborative links with colleagues at the MRC Clinical Trials Unit were first established in 2002. Dr Sarah Meredith and Professor Andrew Nunn are members of the UK Dermatology

Clinical Trials Network Steering Committee and provide invaluable methodological and statistical advice to the group. Statisticians at the unit have conducted the statistical analysis for the SWET, PATCH I and PATCH II trials.

### Birmingham Clinical Trials Unit



Two large pilot studies on different forms of skin cancer have been developed between the UK Dermatology Clinical

Trials Network and the Birmingham Clinical Trials Unit. Both trials have been funded by the Research for Patient Benefit Programme. The LIMIT-1 study, investigating the use of imiquimod to treat lentigo maligna, completed recruitment in August 2011 while the SPOT study, looking at the field directed prevention of squamous cell carcinoma in organ transplant patients, will begin recruiting shortly.

### East Midlands Research Design Service (RDS)

CEBD works with the East Midlands Research Design Service on grant applications submitted to the local Research for Patient Benefit funding scheme.

- Higher Education institutions and related groups
- We have a history of successful collaborative links with other Higher Education Institutions as outlined below:
- University of East Anglia: SWET (eczema)
- University of York: EVerT (verrucae)
- University of Aberdeen: STOP GAP (Pyoderma Gangrenosum)
- University of Oxford: BLISTER (Bullous Pemphigoid)
- University of Glasgow & University of Durham: SPRUSD NIHR Programme Grant (eczema, vitiligo, Pyoderma Gangrenosum, SCC)
- Universities of Portsmouth, Southampton and Bristol: Joint applications to the HTA for a commissioned study on the treatment of infected eczema in young children (eczema)

- Cochrane Child Health Field, Alberta Canada: Overview of systematic reviews for eczema prevention (eczema)

## Working with patients and carers

### CEBD Patient Panel

CEBD has a long history of Patient and Public Involvement (PPI) in all stages of the research process. This has traditionally included activities such as:

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

We have formalised this activity over the past 18 months by establishing the CEBD Patient Panel. Funded by the NIHR Programme Grant, the panel has been set up to provide support and training to those who wish to become more involved in our work. In turn, this helps the Centre to be more effective with regards to PPI and our research as we have access to a trained cohort of individuals to assist us in this way. The panel has over 30 members spread across the UK and many are becoming increasingly involved in our activities. Please see the training section of this report for details of the Patient Panel training days held over the past year.

### James Lind Alliance

The UK Dermatology Clinical Trials Network and the Cochrane Skin Group are both members of the James Lind Alliance. The James Lind Alliance aims to identify the most important gaps in knowledge about the effects of treatments, and has been established in order to bring patients and clinicians together in Working Partnerships to identify and prioritise the unanswered questions that they agree are most important. More information can be found at: [www.lindalliance.org](http://www.lindalliance.org)

This partnership was greatly enhanced by the vitiligo workstream of the NIHR Programme Grant which has resulted in a pilot study in this area, more details of which can be found in the on-going research section of this report.

Following the success of this project, we have continued to work with the James Lind Alliance over the past year on another NIHR Programme Grant workstream, a priority setting partnership to prioritise research uncertainties in the area of eczema treatment. Over 400 individuals have submitted questions and these will be narrowed down to give a list of top ten uncertainties over the next 6 months.

All research questions identified through these processes are submitted into the Database of Uncertainties about the Effects of Treatment (DUETs): [www.duets.nhs.uk](http://www.duets.nhs.uk)

#### Involvement

All CEBD studies which have involved patients and carers in the trial development process are registered on the Involve database and our work has been highlighted in various Involve newsletters and reports.

#### Patient support groups

The following patient support groups have all been actively involved in helping with the work of CEBD over the past year from promoting individual studies, advertising the CEBD Patient Panel, assisting with the development of studies and disseminating the results of completed studies to patients and carers.

- The National Eczema Society: [www.eczema.org](http://www.eczema.org)
- The Vitiligo Society: [www.vitigosociety.org.uk](http://www.vitigosociety.org.uk)
- The Psoriasis Association: [www.psoriasis-association.org.uk](http://www.psoriasis-association.org.uk)
- The Lymphoedema Support Network: [www.lymphoedema.org](http://www.lymphoedema.org)
- Skcin: [www.skcin.org](http://www.skcin.org)
- DebRA: [www.debra.org.uk](http://www.debra.org.uk)

We would particularly like to recognise the contribution of The Vitiligo Society and The National Eczema Society as members of the Working Partnership for the vitiligo and eczema treatment workstreams of the NIHR Programme Grant Award respectively.

As part of our longstanding interest in atopic eczema, some members of CEBD staff along with colleagues from the clinical dermatology department at Queen's Medical Centre, Nottingham (Sandra Lawton, Jane Ravenscroft, Ruth Murphy and Hywel Williams) have worked closely with volunteers who run the Nottingham Eczema Support Group (Colin Gibb and Amanda Roberts).

They have done a fantastic job in setting up a useful resource that now gets hits from all over the world. We are proud to

include this short report of their work in our annual report, since it is such an important way of disseminating results from our studies to those affected by eczema.

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

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

#### Highlights of the past year:

- Atopic Conditions Through the Ages local education day for professionals (2010)
- Redesign and relaunch of the website (an average of 2986 visits a month)
- Establishment of a Facebook page
- 2000th follower of our Twitter feed, with over 33,000 tweets to date
- 119th visitor nation to our website, with top visiting nations being Russia and Canada
- Over 30 patient information leaflets, over half of which are now available in audio format
- Recognition by organisations such as BAD and NICE
- Involvement in the research priorities for eczema treatments uncertainties being run by CEBD
- Exhibition stands at 2010 Eczema Evidence Based Update and 2011 Nottingham Baby Fayre
- Cited in Liberating the NHS: An Information Revolution, DOH 2010
- Contributed to the QNI (Queen's Nursing Institute) work on Information Technology in 2011

Looking to the future, planning has begun for an event for GPs to coincide with National Eczema Week in September and we will be participating in a NHS Choices web forum on eczema which is run in connection with Talk Eczema.

"@eczemasupport who do a great job of keeping us up to date with all the latest in the allergy world."

"A mine of information my son has suffered chronic eczema since birth wish I had found @eczemasupport earlier."

“One of the most compassionate, caring, kind, considerate and truly delightful tweets to chat with is [@eczemasupport](#).”

“Thanks for all the support. I feel happier knowing there's a solid network out there!”

# Professional bodies and NHS organisations

## British Association of Dermatologists (BAD)

Both the UK Dermatology Clinical Trials Network (UK DCTN) and the British Epidermo-Epidemiology Society (BEES) are Special Interest Groups of the BAD. The UK DCTN acts as an affiliate group for the British Association of Dermatologists for topic prioritisation through the HTA programme. We are extremely grateful to the BAD for providing funding for the post of the UK DCTN Senior Trials Development Manager for the period January 2011 to December 2013.

## British Dermatology Nursing Group (BDNG)

We work with the BDNG to encourage nurses to become more actively involved in dermatology clinical research. This includes quarterly updates of UK Dermatology Clinical Trials Network (UK DCTN) activities in the journal *Dermatological Nursing* and liaising with members of the BDNG Scientific Committee.

## Nottingham University Hospitals NHS Trust

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

## NHS Trusts

All CEBD led trials are multi-centre studies requiring collaboration with many NHS Trusts throughout the UK. This is particularly well demonstrated by the BLISTER and STOP GAP studies as approximately 50 centres across the UK are involved in recruiting patients into these trials.

## NHS Choices

We work closely with NHS Choices to ensure that all relevant evidence (particularly systematic reviews) produced by the Centre is disseminated through this channel and quickly fed into relevant patient information.

## NHS Direct

NHS Direct will be hosting any Patient Decision Aids on eczema treatments that arise from the NIHR Programme Grant.

## NICE

CEBD are registered as a stakeholder with NICE and regularly comment on relevant NICE guidelines and appraisals. NHS Evidence, a resource of reliable information for NHS Health Care Professionals, is now also managed by NICE. Hywel Williams is employed by NHS Evidence as their dermatology expert and will be leading the development of annual evidence updates of new and important evidence on common skin diseases through NHS Evidence ([www.evidence.nhs.uk](http://www.evidence.nhs.uk)).

## RCP

Hywel Williams is working with the RCP (in collaboration with the EQUATOR group) to develop a statement on the clear reporting of research studies.

# Training

## Individuals

Staff at CEBD recognise the importance of training new researchers and are keen to support anyone with an interest in evidence-based dermatology. They do this in several ways.

### PhD studentships

We have four PhD students registered with the University of Nottingham as outlined below. Three are working on projects funded by the NIHR Programme Grant awarded to the centre in September 2008 and further information on the individual projects can be found in the on-going research section of this report. Below is the student, the title of their PhD thesis and the expected date of completion:

- Helen Nankervis: Setting Priorities and Reducing Uncertainties for People with Eczema (September 2013)
- Louise Lansbury: An Evidence Based Approach to Optimising the Management of Squamous Cell

Carcinoma of the Skin (September 2013)

- Viktoria Eleftheriadou: Setting Priorities and Reducing Uncertainties for People with Vitiligo (September 2012)
- Ser-Ling Chua: The clinical response of skin disease to anti-retroviral therapy (ART) in Uganda (December 2011)

### NIHR Academic Clinical Fellows (ACFs)

CEBD has hosted a dermatology ACF position for the last two years.

These posts allows medical trainees at an early stage of their career to experience a research environment and to develop projects that lead to an external fellowship and continuing academic career.

Dr Kyle Tang joined the centre in July 2010 and is developing a project investigating the early aggressive treatment of eczema and Dr Ketaki Bhate, who joined us in July 2011, is looking at potential areas of acne research to follow up.

### Clinical Research Fellows

Based on Hywel Williams' status as an NIHR Senior Investigator, CEBD have been fortunate to obtain Flexibility and Sustainability Funding (FSF) from NUH Trust for two Clinical Research Fellows. Dr Jonathan Batchelor, a Consultant Dermatologist, works with us for one day a week to help with developing grant applications, publications and engagement with the clinical community. Dr Rosalind Simpson an ST5 Trainee, works with us for four days a week to develop a fellowship application for a study on erosive lichen planus which will hopefully lead to a PhD. Both have been successful applicants for the UK DCTN SpR Fellowship Scheme which is outlined below

### UK Dermatology Clinical Trial Network Awards

#### Specialist Registrar (SpR) Fellowships

Established in 2007, a two-year fellowship of £1500 is awarded each year by the UK DCTN to two or three

outstanding dermatology trainees. In 2011, the UK DCTN Neil Cox SpR Fellowship Award was introduced in memory of the late Professor Neil Cox (lead clinician of the PATCH trials) and this will be awarded each year to the highest scoring applicant for the Fellowship. The aim of the UK DCTN SpR Fellowship is to develop skills in clinical trials and critical appraisal to help cultivate the next generation of research active and aware dermatologists. It is interesting to note that Dr Jonathan Batchelor and Dr John Ingram, the inaugural SpR Fellowship awardees, are now not only developing their own clinical research programmes but are both also Section Editors for the British Journal of Dermatology. The Fellowship involves

- attending the British Epidermo-Epidemiology Society (BEES) three day course
- spending three days at the UK DCTN co-ordinating centre in Nottingham
- developing critical appraisal skills by working closely with the Network Chair, Professor Hywel Williams



- joining the UK DCTN Steering Committee to review research proposals
- joining a clinical trial development team or a Cochrane systematic review team
- attending the CEBD Annual Evidence Based Update Meeting

Successful applicants for the 2010 fellowships were Dr Kave Shams (Glasgow), Dr Rosalind Simpson (Nottingham) and Dr Abby Macbeth (Norwich). 2011 fellowships were awarded to Dr Donna Torley (Lanarkshire) and Dr Suyin Ong (Oxford) with Dr Rubeta Matin (Buckinghamshire) attaining the first Neil Cox award

#### **Staff and Associate Specialist (SAS) Award**

This award was introduced in 2010 to encourage more SAS doctors to pursue research opportunities in dermatology. The award follows a similar programme of activities to the SpR Fellowship outlined above but is carried out over a three year rather than a two year period to take into account the lower amount of study leave that SAS doctors receive. Up to two awards of £1500 each are awarded each year. The winner of the first UK DCTN SAS Award was Dr Alison Devine (Rhyl) with Dr Penny Thomson (Hertfordshire) being successful in obtaining the 2011 award.

#### **Nursing Prize Award**

To strengthen links with the dermatology nursing community, a UK DCTN nursing prize has also been set up. Up to 2010, this was a one year award and consisted of a £750 stipend to cover funds to attend a relevant training course as approved by the UK DCTN Executive Committee in addition to an opportunity to spend two days at the UK Dermatology Clinical Trials Network co-ordinating centre to gain experience in the management and conduct of clinical trials. The successful applicant was also given the opportunity to join the UK DCTN Steering group to gain further experience in the background and development of clinical trials. The 2010 winner was Jane Grundy (St Mary's Hospital, Isle of Wight) for her outstanding work on the SWET Study. Following discussions with the dermatology nursing community we have redeveloped the Nursing Prize Award so that it now reflects those awards offered to clinicians and from 2011 onwards a two year award of £1500 will be offered with activities mirroring those of the SpR Fellowship Award.

## Events

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

#### **Annual Evidence Based Update Meetings**

Each spring CEBD holds an Annual Evidence Based Update Meeting, chaired by CEBD Director Hywel Williams. The day is aimed mainly at dermatologists, specialist dermatology nurses and GPs with a special interest in dermatology.

The meeting summarises the most recent evidence in the form of systematic reviews and recently completed trials for the treatment and management of the chosen topic.

This topic varies each year in response to feedback from the previous years delegates. The programme also includes a popular Q&A session, where delegates submit clinical questions to an expert panel composed of the speakers from the day and representatives from the patient community. The meeting is written up for the Conference Reports Section of the British Journal of Dermatology (BJD).

The subject topic for the 2010 meeting was eczema. Speakers included Jochen Schmitt who presented a study on ciclosporin versus prednisolone for severe atopic eczema; Doris Staab who gave an update on education schools to support atopic eczema management and Robert Boyle who discussed a Cochrane Systematic Review on probiotics for treating eczema.

Psoriasis was covered by the 2011 event with speakers including Chris Griffiths who gave an overview on how to stop biologics; Jonathan Barker who spoke about implications for personalised medicine; Peter Wolf who presented the results of new studies investigating the use of UV311nm with biologics and Anne Mason who gave an update of a Cochrane Systematic Review on topical treatments for psoriasis. Presentations can be found at: [www.ukdctn.org/meetings/evidence/index.asp](http://www.ukdctn.org/meetings/evidence/index.asp).

Feedback from delegates indicates a very high overall satisfaction rating for the meeting, with the Q&A session and the open, interactive nature of the day being the highlights for many.

Particularly rewarding is the feedback that the meeting is useful with regards to impact on future clinical practice, with well over 50% of delegates indicating that attending the meeting will affect their practice in some way.

We seek to include presentations from European experts in the field, as the feedback indicates that gaining a European

perspective on a subject is extremely useful.

#### **What the delegates said**

“Excellent meeting with lots of practical hints and tips based on evidence from experts in psoriasis. Good opportunity to compare practice between different countries.”

“It is great to get up to date, evidence based, practical tips for me in clinics. This is the first one of these days I have attended and I will definitely strive to attend future meetings.”

“It’s reassuring to know that my practice is good and within current guidelines and research evidence.”

The next meeting will be held on Thursday 10 May 2012 and will cover acne and rosacea. For further details, please contact the UK DCTN Network manager Carron Layfield at: [carron.layfield@nottingham.ac.uk](mailto:carron.layfield@nottingham.ac.uk).

#### **British Epidermo-Epidemiology Society (BEES) annual course: Getting to Grips with Evidence Based Dermatology**

This three-day course is taught by staff from the CEBD along with colleagues from the Primary Care and Rheumatology departments. It covers areas such as study design, statistics, clinical trials, and writing scientific papers. Places are limited to 24 in order to retain small teaching groups. The course — now in its 16th year — is always fully booked. A one-day BEES Summer School is also held every other year which focuses on writing and publishing papers.

#### **What the delegates said**

“I gave my first presentation today after attending the course. The course definitely helped me. I was very happy to critically appraise the article as I knew how to attempt to do it — and I really enjoyed it! I went back to the course folder and found all the tips I needed.”

“Very informative course in a friendly atmosphere. Now I have a good understanding of how to read a paper.”

“Excellent course, it lifted a cloud. I will use the knowledge I have obtained and build on this.”

For further details of the next three day course (25-27 January 2012), contact Margaret Whittingham at: [margaret.whittingham@nottingham.ac.uk](mailto:margaret.whittingham@nottingham.ac.uk) or visit the BEES website at [www.bees.org.uk](http://www.bees.org.uk)

#### **CEBD Patient Panel Training Events**

Two training events for members of the CEBD Patient Panel have been held over the past year. The first took place

on 14th June 2010 at Attenborough Nature Reserve in Nottingham with nine panel members attending.

The programme for the day included an inspiring presentation by guest speaker Derek Stewart OBE, a pioneer in Patient and Public Involvement (PPI) in cancer research and Clinical Research Network Associate Director for PPI. The day also included a jargon busting session to try and de-mystify some of the technical language used in clinical research along with an amusing and thought-provoking workshop on how to spot a good (or bad) clinical trial led by CEBD Director Prof Hywel Williams.

Following excellent feedback about the venue and format of the training days, we decided to hold the next one at the same location.

Eleven panel members attended the event which was held on 7 March 2011 and included a session on the importance of PPI in Cochrane Systematic Reviews and an afternoon workshop on patient decision aids and what is needed for these to be effective tools in the management of skin conditions.

Guest speaker Anthony Hubbard (a Trustee of the skin cancer awareness charity Skcin) gave a lecture to the group on the science of sun care and protecting your skin from the sun while CEBD Patient Panel Member Amanda Roberts gave a wider view of activities that panel members could get involved with to utilise their new skills.

#### **What the delegates said**

“It was lovely to meet you all and I thoroughly enjoyed the day. So glad I found out about the CEBD and what you do and so pleased to be involved. Can’t wait for the next one!”

“Thanks for an excellent day, I managed to speak to some very interesting people and learned a lot too. Lunch and refreshments were also excellent.”

“All the talks were very informative and provided some very useful information to follow up.”

#### **National Skin Surgery Course**

Each year the clinical Dermatology Department runs a two day National Skin Surgery Course for nurses organised by Skin Cancer Nurse Specialist Gill Godsell, OBE. The course focuses on the practical skills required to undertake skin surgery. For further details please contact Gill Godsell at: [gill.godsell@nuh.uk](mailto:gill.godsell@nuh.uk)



# Meet the team

## Professor Hywel Williams, Director of CEBD

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

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

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



STAFF PROFILES

## CEBD Deputy Director



**Dr Kim Thomas, Associate Professor (non-clinical)**

Kim was appointed Associate Professor in April 2005, after six years at CEBD as a Senior Trial Manager. She is responsible for the conduct and supervision of clinical trials. She has a particular interest in clinical trial methodology (especially outcomes

research) and is a founder member of the UK Dermatology Clinical Trials Network. Kim is currently acting as Programme Manager for the department's NIHR programme grant award — Setting Priorities and Reducing Uncertainties for the prevention and treatment of Skin Disease (SPRUSD), and is a member of the School Research Committee. She is an adviser 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. She is assistant section editor for Evidence-based Dermatology in the *Journal of the Spanish Academy of Dermatology and Venereology (Actas Dermosifiliograficas)*.

## Research Staff



**Dr Jonathan Batchelor, Consultant Dermatologist**

Jonathan graduated from The University of Nottingham Medical School in 2000. After a year of work as a junior doctor, he spent two years in Japan on a Daiwa Anglo-Japanese Foundation Scholarship. The focus of this visit

was research into the reliability of medical information on the internet and patients' ability to discriminate between reliable and unreliable sources. He also undertook a clinical attachment at Showa University Hospital Department of Dermatology. He returned to the UK to complete his medical training at King's College Hospital in London and Brighton and Sussex University Hospitals, gaining Membership of the Royal College of Physicians in 2005. He undertook his dermatology specialist training at Addenbrooke's Hospital, Cambridge. During this time he was awarded one of the first UKDCTN SpR Fellowships, and worked on an update of a Cochrane review of interventions for vitiligo. He was also involved in the vitiligo Priority Setting Partnership organised in conjunction with the James Lind Alliance. In 2010 he moved to Queen's Medical Centre as a consultant dermatologist. He combines his clinical work with research projects.



**Dr Fiona Bath-Hextall, Associate Professor**

Fiona is an Associate Professor and Reader in Evidence-Based Health Care in the School of Nursing, Midwifery and Physiotherapy, and Honorary Associate Professor in CEBD. She has been involved with the Cochrane

collaboration since 1995 and has authored around 23 Cochrane reviews. For the last six years her main research area has been non-melanoma skin cancer. Fiona is leading the squamous cell carcinoma stream of work for the recently funded NIHR grant. She is the grant-holder for the SINS study, funded by Cancer Research UK. She is the PI for the SCENE study (a mixed methodology study looking at the needs and experiences of people with Non-Melanoma Skin Cancer, from clinical diagnosis through treatment and one year post-treatment), funded by The Burdett Trust. She has also been involved in using primary care databases (THIN database) to look at the incidence of BCC in primary care and to investigate the relationship of smoking with BCC. She is involved in a collaborative project with the British Geological Survey looking at arsenic as a BCC risk factor.



**Nazia Boota, Clinical Trial Manager**

Having completed a degree in biological sciences, Nazia spent three years in the Oncology & Haematology Trials Unit (UHL NHS Trust) as a clinical research assistant. This varied role involved the collection of data for patients mainly on early phase

commercial trials. She then went on coordinate paediatric leukaemia and brain tumour trials for the Children's Cancer and Leukaemia Group (CCLG). Nazia joined the UK DCTN in 2009 to manage the LIMIT-1 study. This is a multicentre, open-label, single-arm trial to establish the pathological complete regression rate of lentigo maligna following topical treatment with imiquimod. Nazia is also studying part-time for an MSc in oncology.



**Dr Joanne Chalmers, Research Fellow**

Following a degree and a PhD in Biochemistry from the University of Sheffield, Joanne spent five years in clinical research in the pharmaceutical industry. She joined CEBD in 2003, and has been involved in the design and implementation of several studies

including a study of cost-effectiveness of treatments for cutaneous warts, an RCT to determine whether prophylactic

antibiotics can prevent cellulitis, an RCT to compare doxycycline and prednisolone for bullous pemphigoid, a proof of principle trial to establish whether imiquimod is suitable for treating lentigo maligna and a study of antibiotics for wound healing in epidermolysis bullosa. Joanne is working on the eczema prevention workstream of the SPRUSD programme grant, undertaking an RCT to investigate whether regular emollient use from birth can prevent the onset of eczema in high-risk babies and a systematic review of eczema prevention strategies.



Ser Ling Chua, HIV Dermatology Fellow, University of California, San Francisco

Ser Ling graduated from Guy's, King's and St Thomas' School of Medicine and Dentistry in 2000. She joined the Department of Dermatology at the Queen's Medical Centre in 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 at The University of Nottingham. She is working under the mentorship of Dr Toby Maurer at the Department of Dermatology, University of California, San Francisco.



Tessa Clarke, UK DCTN Senior Clinical Trial Development Manager

Following a degree in biology from The University of Nottingham, Tessa spent 14 years in clinical research working for academic institutions, contract research organisations and in the pharmaceutical industry as a trial manager. She joined

CEBD in 2011, and provides expertise in the design and conduct of clinical trials within the UK DCTN. Tessa works closely with clinical colleagues to progress trial suggestions to fully developed funding applications and trial protocols.



Susan Davies Jones, Trent CLRN-funded Research Nurse

Since qualifying in 1995, Sue has worked in a variety of adult nursing specialities, including endoscopy, theatre recovery, rheumatology and dermatology. Sue joined the CEBD in March 2007 as a research nurse

working on the Softened Water Eczema Trial (SWET), investigating whether water softeners help reduce the severity of eczema in children. Since SWET completed

recruitment in September 2009, she has worked as a CLRN-funded clinical research nurse on various other trials, including the PATCH studies, BEEP, STOP GAP, BLISTER and BADBIR.



Finola Delamere, Managing Editor, Cochrane Skin Group

Finola's biochemistry-based PhD involved investigating the forensic identification of human seminal plasma. She then worked for the Forensic Science Service on cases involving crimes against the person and gave

evidence at the Old Bailey. In Nottingham she undertook laboratory-based research in cystic fibrosis and asthma.

Finola works closely with Cochrane review author teams to help them produce protocols and reviews. She helps authors once their work has been submitted for the editorial process. The finished protocols and reviews are published in the electronic Cochrane Library, which is disseminated internationally. Finola is the lead author on the Cochrane systematic review 'Interventions for alopecia areata' and co-author on 'Dietary exclusions for established atopic eczema', the updated systematic review 'Drugs for discoid lupus erythematosus' and the protocol 'Dietary supplements for established atopic eczema'.



Liz Doney, Trials Search Co-ordinator, Cochrane Skin Group

Liz joined CEBD as Trials Search Co-ordinator to the Cochrane Skin Group in September 2010. She became a chartered librarian in 1999 and has worked in health libraries since 2001. She has a Masters in Information

Studies and a Postgraduate Certificate in Public Services Management. Liz works with Cochrane authors to design highly-sensitive search strategies, and identify relevant studies for their reviews. She is also responsible for building and maintaining the Skin Group's specialised register of skin-related clinical trials, and making quarterly submissions of the register to The Cochrane Library's Central database.



Dr Viktoria Eleftheriadou MD, PhD Student and Research Associate

After completing her Medical degree and pre-registration jobs in Greece, Viktoria decided to continue her medical career in the UK. She worked for the NHS for two years, mainly in medicine

and A&E. Always aspiring to a career as a Consultant Dermatologist and having a great interest in Evidence-based Medicine, Viktoria joined the CEBD as a Research Associate in August 2009 working on the vitiligo workstream of the NIHR-funded programme, 'Setting Priorities and Reducing Uncertainties in People with Skin Disease'. She is also studying for a PhD on vitiligo at The University of Nottingham.



**Dr Katharine Foster, Clinical Trials Manager**

Katharine 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. Katharine joined the CEBD 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. The PATCH I trial reached its recruitment target in December 2009 and the results should be available early 2012.



**Louise Lansbury, PhD Student and Research Associate**

After graduating in Medicine and completing pre-registration jobs she worked as a clinical microbiologist in hospitals around the UK. She also undertook laboratory-based research, on projects ranging from virus survival in glycerol-preserved cadaveric skin, to the relationship between pathogenicity and the flagellar proteins of *Helicobacter pylori*. After a few years in France, she became the UK study co-ordinator for a pan-European project investigating the impact of antibiotic-resistant *S.aureus* and *e.coli* bloodstream infections. Louise joined CEBD in 2008, and is working on the Squamous Cell Carcinoma (SCC) workstream of the NIHR-funded programme, Setting Priorities and Reducing Uncertainties in People with Skin Disease. She has undertaken a Cochrane systematic review of RCTs of treatments of SCC, and is working on a systematic review of observational studies of treatments and undertaking feasibility work which will guide the development of a proposal for a clinical trial of SCC treatment. She is also studying for a PhD.



**Jo Llewellyn, Trent CLRN-funded Clinical Research Nurse**

After obtaining a BA (Hons) in Nursing Studies, Jo's previous roles have included being a team leader for a CRO, a Drug Surveillance Executive for Roche and a Clinical Project Manager at ClinPhone, Nottingham. Jo joined CEBD in January 2003 and has worked as a Research Nurse on both the SINS trial and the PATCH studies. During this time, Jo obtained an MSc in Science from the Open University. She is currently working as a CLRN-funded Research Nurse on the following trials: STOP GAP, BLISTER, BADBIR and LIMIT-1.



**Eleanor Mitchell, Clinical Trial Manager**

Eleanor is the Trial Manager for the STOP GAP Trial, which is a multi-centre trial (approx. 50 sites) investigating treatments for Pyoderma Gangrenosum. She is based in the Nottingham Clinical Trials Unit at the Queen's Medical Centre, where the study is being co-ordinated. She joined the CEBD in 2008 having previously worked in clinical research for eight years as a Project Co-ordinator and Research Manager for Academic Rheumatology at The University of Nottingham. During this time she managed a large gene-environmental interaction study for patients with osteoarthritis, and oversaw a variety of epidemiological studies and trials. She also completed a degree in Business Studies while she was in Rheumatology. Eleanor will return from maternity leave in early 2012.



**Helen Nankervis, PhD Student and Research Associate**

Helen studied at Leeds University for a Degree in Medical Microbiology. After graduating, she spent a year designing A-Level Microbiology practical experiments for the Society for General Microbiology. Helen also worked on clinical trial data before joining the CEBD in 2005 as the editorial assistant for the Cochrane Skin Group. She is working as a research associate on the eczema treatments workstream of the SPRUSD programme grant which involves undertaking a systematic review of all treatments for eczema, creating a database of RCTs of eczema treatment and researching shared decision-making for eczema. She is also studying for a PhD.



**Caroline Onions, Clinical Trial Manager**  
After completing her degree in Medical Science incorporating a year working in drug discovery for AstraZeneca, Caroline worked as hospital service manager in the NHS for five years and in the health service in New Zealand. She then moved into clinical trials, setting

up and managing a large 2x2 multi-centre trial looking at treating moderate to severe Alzheimer's Disease. Caroline joined the UK DCTN in October 2008 as the trial manager for the BLISTER trial, a multi-centre randomised, controlled trial looking at prednisolone compared with doxycycline for the treatment of bullous pemphigoid, which is now recruiting in over 40 UK sites.



**Mara Ozolins, Clinical Trials Manager**  
Mara worked for 12 years as a statistician in the pharmaceutical industry. In 1997 she became a clinical trial co-ordinator with The University of Nottingham, working on a large multi-centre, community-based study of antimicrobial treatments for mild

to moderate acne. This trial completed in 2002, and was published in *The Lancet* (December 2004) and as an HTA monograph (January 2005), generating a lot of interest. Alongside her trial management, Mara has delivered lectures in trial management and statistical topics and in 2007 achieved associate teacher status. In 2002 Mara took over responsibility for the SINS trial — a randomised controlled trial of Surgery vs Imiquimod 5% in Nodular and Superficial basal cell carcinoma. This multi-centre, hospital-based trial completed a three-year follow-up of 501 participants in May 2010, and analysis of the data is currently underway. Five-year follow-up of hospital and GP notes is also ongoing.



**Dr Rosalind Simpson, Dermatology Clinical Research Fellow**  
Rosalind studied at The University of Nottingham Medical School and completed a BMedSci degree in 2002 and BMBS degree in 2004. She has worked at Derby Hospitals NHS Foundation Trust, Nottingham University

Hospitals and University Hospitals Leicester throughout her clinical medical training and gained membership to the Royal College of Medicine, MRCP (UK) in 2006. She started dermatology specialist training in 2008 at Leicester Royal Infirmary and moved back to Nottingham University Hospitals in 2010. She was awarded a UK DCTN SpR Fellowship in

February 2010 and has been responsible for developing a project on Vulval Erosive Lichen Planus; funding for £9,600 has been achieved to perform a multi-centre case note audit. In June 2011 Rosalind started a full time Clinical Research Fellow Post at CEBD to progress this work.

#### Administrative, Professional and Managerial



**Julie Barnes, Trial Administrator**  
Julie joined the CEBD in October 2008. Her role is to provide administrative support to the STOP GAP trial and the BLISTER trial, and the trial managers – Eleanor Mitchell and Caroline Onions.



**Lisa Charlesworth, Trent CLRN Funded Clinical Trials Administrator**  
After working as an administrator at the Clinical Trials Unit at Nottingham for three years, Lisa joined CEBD in 2009 to work on projects funded by the UK DCTN. With a BA (Hons) in Communication Studies, she previously worked in marketing and for a graphic design agency.



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



**Dr Douglas Grindlay, Information Specialist, NHS Evidence: skin disorders**  
Douglas was Information Specialist for NHS Evidence: skin disorders (formerly the National Library for Health Skin Disorders Specialist Library) from 2004 until March 2011 when the post was relocated to Manchester. He set up the specialist collection from scratch and is responsible for its maintenance and development. He also co-ordinates the Skin Disease module in the UK Database of Uncertainties about the Effects of Treatments (DUETs).

Douglas made a late change in career when he took an MA in Information and Library Studies at Loughborough University. Previously he worked in crop science research and as a scientific officer and administrator in the Civil Service. Douglas is a Chartered member of CILIP, the Chartered Institute of Library and Information Professionals.



**Dr Carron Layfield, UK Dermatology Clinical Trials (UK DCTN) 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 working for a variety of companies before returning to the University in November 2006. Carron is now Network Manager for the UK DCTN and as such is responsible for developing and promoting the Network. She also has a number of general departmental duties including being the lead for the CEBD Patient Panel, organising the Annual Evidence Based Update Meeting and co-ordinating CEBD publicity. In addition, Carron supports Prof Hywel Williams in his role as Chair of the NIHR Dermatology Specialty Group.



**Alan Maplethorpe, IT Programmer**

Alan's role within CEBD involves the design and development of databases and websites, including key aspects of data capture and data presentation. He has contributed to the following projects: BLISTER website and data entry, STOP GAP website, Vitiligo Study website and the GREAT Database and HOME for eczema website.



**Margaret McPhee, UK DCTN Administrator**

Margaret joined CEBD in 2007. She provides administrative support to both the UK DCTN Senior Clinical Trials Manager and Network Manager. Her role involves managing the membership database and the UK DCTN website, producing publicity material, monitoring finances, arranging conferences, and assisting with clinical trial set-up.



**Johanna Perdue, Trent CLRN-funded Clinical Trials Administrator**

Johanna joined the CEBD in 2009, initially in a temporary capacity helping the trial manager on the PATCH study, before beginning a fixed, two-year contract as Clinical Trials Administrator, funded by Trent CLRN. Before joining CEBD, Jo had worked in the upholstery textile trade (marketing, design and customer care). While working full-time, she achieved a long-held ambition to return to study, graduating from the Open University in 2006 with a first-class honours degree in Literature.



**Laura Prescott, Editorial Assistant, Cochrane Skin Group**

Laura works as the Editorial Assistant for the Cochrane Skin Group (CSG), providing support to the Managing Editor, Finola Delamere. She assists in all aspects of the editorial process, including communicating with authors and other contributors, copy-editing, and the management of channels of dialogue throughout production. Her role includes working with authors to ensure deadlines are met. She also manages and organises the folders within the electronic and paper systems and maintains the Group membership's contact details. She also maintains the CSG website and helps organise the Skin Group annual meeting.



**Margaret Whittingham, Administrator to Professor Williams & Academic Secretary in Dermatology**

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

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## Contact:

### Centre for Evidence-based Dermatology

The University of Nottingham

King's Meadow Campus

Nottingham NG7 2RD

United Kingdom

t: +44 (115) 8232434

e: [cebd@nottingham.ac.uk](mailto:cebd@nottingham.ac.uk)

[www.nottingham.ac.uk/scs/divisions/evidencebaseddermatology](http://www.nottingham.ac.uk/scs/divisions/evidencebaseddermatology)

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November 2011