



The University of
Nottingham

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Centre for Evidence Based Dermatology Annual Review 2011/12

www.nottingham.ac.uk/dermatology



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Editorial team

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Individual sections were written by the relevant research teams as appropriate.

Welcome



I know it sounds sycophantic, but I still can't get over what a wonderful bunch of colleagues I work with here at the Centre of Evidence Based Dermatology and in the clinical areas at the Queen's Medical Centre campus and Treatment Centre at Nottingham University Hospitals NHS Trust.

If a visitor pops into our office, someone gets up to meet them. If a phone goes off and the person is not at their desk, someone picks up the phone and tries to help them. If one of our staff goes to Devon on holidays, they come back with some fudge to share with colleagues. When someone is struggling with a grant submission or paper, colleagues readily offer to help with sorting out the references. I can't tell you how nice it is to witness such a pleasant and collaborative work environment. That does not mean that we are all nice to each other 100% of the time, but it means that we are a functional unit that embraces diversity.

And it tells in our work. This annual report for instance is an idea that I was very keen on when I started in order to provide a record of what we have done year on year. But this year, I have had very little to do with pulling the report together thanks to the excellent production team and co-operation from colleagues, many of whom work hectic schedules. When our Centre started, it all used to be me, me, me, but nowadays, I see many projects taking off and achieving important things without my interference. That is a great thing to witness and it is also very humbling. Some of the highlights of our work over the last year for me have been:

- completing our first two UK Dermatology Clinical Trials Network randomised controlled trials on antibiotics to prevent recurrences of cellulitis of the leg
- in the last two years publishing over 70 peer-reviewed publications, some of which are in the top general and specialist journals
- achieving a good ending to the 20-year International Study of Asthma and Allergies in Childhood
- working with an international group to try and harmonise the way we measure benefits of eczema treatments
- generating useful information such as the world's first database of all randomised controlled trials and systematic reviews of eczema treatment which is freely available in the public domain
- increasing our output of high quality Cochrane reviews that reduce uncertainties in treating people with skin disease.

But perhaps the thing that continues to excite me most is the way that our collaborations with colleagues and patients outside of our Centre continue to flourish. We work with the best people in order to do excellent research, and we work with a range of stakeholders including the public and patients in order to make sure that we do the right studies in the right way and that we get our results to the right people in a timely manner. Otherwise our research amounts to nothing. We are indeed a highly promiscuous group in this regard, so it is only a matter of time before you, as a reader, will end up working with us in some way!

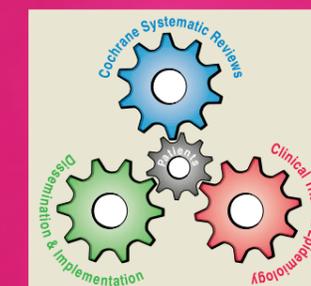
I do hope you find at least something in our annual report that interests you, even if it is just flicking through the many images that depict the humanistic side of our work. Everyone (or their family members) develops a skin problem at some stage, so you never know when you might need us.

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

About CEBD

The Centre of Evidence Based Dermatology (CEBD) has an international reputation for skin research and evidence based practice. 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, including publications in peer reviewed journals, to the public and patients via patient support groups and the media, and of course NHS Evidence (www.evidence.nhs.uk). We produce around 25-35 peer-reviewed publications per year and we are 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 and NHS Treatment Centre at 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 our 'Cogs'. Further information about each of these 'cogs'

is outlined. 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 Cochrane Skin Group (www.skin.cochrane.org) is one of 53 Collaborative Review Groups that together make up the editorial bases of the international Cochrane Collaboration (www.cochrane.org). The editorial base of the Cochrane

Skin Group is located at the Centre of Evidence Based Dermatology, where its output regularly informs other strands of work, such as the need for new trials. The Cochrane Skin Group has no financial links with any pharmaceutical companies and receives infrastructure support from the National Institute of Health Research (NIHR).

The Cochrane Skin Group was established in 1997 and has an international board of editors. It currently has 913 members worldwide, of whom 63 are consumer referees and 676 are authors. Nearly all authors are volunteers, and one of the particular strengths of the skin group is the involvement of consumers, who help in many ways, because skin disease impacts mainly on the quality of life of the individual. We define consumers as people who have a skin condition and their close relatives/carers. Many members of the Group are also interested in evidence-based dermatology in general. We aim 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.

Anyone can propose titles for systematic reviews, which are periodically prioritised by the Group's panel of editors. The most prominent titles are then advertised on our website. Those interested in leading a review team also have their application assessed independently by our editors. After title registration, the protocol is developed. The protocol is a public statement by the authors about how they intend to systematically review the topic. The protocol and the subsequent review are peer reviewed before publication.

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

If you are interested in finding out more about the Cochrane Skin Group, please visit the website: www.skin.cochrane.org or email: csg@nottingham.ac.uk

The UK Dermatology Clinical Trials Network



The UK Dermatology Clinical Trials Network (UK DCTN) is a collaborative group of over 700 dermatologists, nurses, primary care staff, health care researchers and patients/carers. Membership of the UK DCTN is free and open to anyone with an interest in applied dermatology research. Members provide their time and expertise on a voluntary basis. The Network is a registered charity (charity number 1115745) and an affiliate group of the British Association of Dermatologists (BAD). The ever increasing membership numbers and active participation in our trials are testament to the genuine and growing interest of the dermatology community in conducting high quality clinical research.

The UK DCTN was established in 2002 by Professor Hywel Williams and colleagues 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 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 in addressing research gaps highlighted by Cochrane systematic reviews. The Network is open to trial suggestions from any of its UK based members which are then developed using a rigorous predefined trial development process. Funding for individual trials comes from grant applications made to the National Institute of Health Research (NIHR) and its partners.

The Network is run by an Executive Group with an independent Chair and a Steering Group. These groups are responsible for evaluating trial proposals and deciding which ideas are developed further. The

role of the Co-ordinating Centre, which is based within the Centre of Evidence Based Dermatology, is to develop the UK DCTN portfolio of trials and develop the Network as an organisation.

With regards to trial development and support, the UK DCTN is able to:

- facilitate and advise on trial development
- coordinate study development teams
- conduct membership surveys to assist with trial development

As part of the Network's 10th birthday celebrations a themed research call was launched in 2012. Themes will change on an annual basis to match that of the Annual Evidence Based Update Meeting (see training section); the theme for 2012 was acne and rosacea. Further landmarks for the Network in the past year were major trials, PATCH I and PATCH II, coming to a close with the PATCH I study being awarded the best research paper presentation at the July 2012 BAD Annual Meeting. In addition, the LIMIT I study completed recruitment this year with the Chief Investigator for the study, Dr Jerry Marsden (Birmingham) stating,

"The UK Dermatology Clinical Trials Network made all of this possible. It is a remarkable organisation, and we should recognise how lucky we are to have such an innovative resource. Without it, we simply could not have done this study. They provided support right at the outset, when it was far from clear that this study would be funded."

Plans for the coming year include the launch of an International Federation of Dermatology Clinical Trial Networks and the development of a wider national research trainee group, building on the success of our SpR Fellowship award scheme.

Details of UK DCTN led studies such as PATCH, BLISTER, STOP GAP and LIMIT can be found in the current research section of this report. Details of the awards schemes we offer are located in the training section. To find out more about the UK DCTN in general, please visit the website www.ukdctn.org or email: ukdctn@nottingham.ac.uk



Dissemination and Implementation

As a research group we are well aware that creating research is just the first step to making a difference to patients' lives, or causing a change in clinical practice. As such, we work hard to ensure that our research output is disseminated widely and in a variety of formats.

We work closely with NHS Choices and patient support groups to ensure that our reviews and trial evidence are incorporated into patient information resources, and we continue to produce annual evidence updates and maps of systematic reviews for common skin diseases such as eczema and acne.

Hywel Williams works as an expert adviser for NICE NHS Evidence, which provides a wide range of health information to help healthcare professionals to deliver better and more efficient patient care. It can be accessed at: www.evidence.nhs.uk

We have also been working with the local Collaboration for Leadership in Applied Health Research and Care (CLAHRC) team to produce evidence summary bites for our research. They are:

- water softeners for the treatment of eczema
- treatments for verrucas

These are available from: http://tiny.cc/CLAHRC_bites

Research

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



Summary of on-going research 2011/2012

Acronym	Title of Project	Funded by	Start date	End Date	Phase	Website
Clinical Trials						
PATCH I	Randomised controlled trial to investigate whether prophylactic antibiotics can prevent further episodes of cellulitis of the leg	Action Medical Research	July 2006	Dec 2011	Completed	www.patchtrial.co.uk
SINS	Surgery vs imiquimod for nodular and superficial basal cell carcinoma	Cancer Research UK (imiquimod provided by 3M)	Sep 2002	Aug 2012	Analysis & write-up	www.trialsjournal.com/content/11/1/42
BLISTER	Randomised controlled trial to compare the safety and effectiveness of doxycycline with prednisolone for initial treatment of bullous pemphigoid	NIHR Health Technology Assessment Programme	March 2008	March 2015	Recruiting	www.blistertrial.co.uk
LIMIT-1	Effect of topical imiquimod on lentigo maligna (Phase II RCT)	NIHR Research for Patient Benefit	April 2010	March 2012	Analysis	www.ukdctn.org/ongoing/limit
STOP GAP	Randomised controlled trial comparing use of prednisolone and ciclosporin for treatment of pyoderma gangrenosum	NIHR Programme Grant for Applied Research	Jan 2009	Aug 2013	Follow-up	www.stopgaptrial.co.uk
Pilot studies						
BEEP	RCT of Barrier Enhancement for Eczema Prevention: The BEEP feasibility study	NIHR Programme Grant	July 2009	Aug 2013	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	Dec 2012	Follow-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 2011	Completed	
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 for Applied Research	May 2011	Aug 2013	Data collection	
Funded systematic reviews						
Eczema Treatments Review	Systematic review of treatments for atopic eczema	NIHR Programme Grant for Applied Research	Jan 2009	Dec 2012	Ongoing	
Eczema prevention umbrella review	The prevention of eczema in children: An overview of Cochrane and non-Cochrane reviews	NIHR Programme Grant for Applied Research	Nov 2010	Sep 2011	Completed	www.ncbi.nlm.nih.gov/pubmed/22822349
Review treatment of SCC	Systematic review of observational studies of interventions for SCC of the skin	NIHR Programme Grant for Applied Research	Dec 2009	Dec 2012	Ongoing	
Other funded research						
HOME initiative	Harmonizing Outcome Measures for Eczema	NIHR Programme Grant for Applied Research	Sept 2008	Aug 2013	Ongoing	www.homeforeczema.org.uk
Eczema Prioritisation Partnership	Working with the James Lind Alliance to establish priority areas for research	NIHR Programme Grant for Applied Research	Jan 2011	Jan 2012	Completed	www.nottingham.ac.uk/dermatology
Raman imaging	Raman spectral imaging for automated Mohs micrographic surgery of high-risk basal cell carcinoma	NIHR i4i	May 2010	April 2013	Ongoing	

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 bringing 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.

NIHR Programme Grant Award

Our NIHR Programme Grant for Applied Research 'Setting Priorities and Reducing Uncertainty for the Treatment and Prevention of Skin Disease' has had a great impact on how the Centre of Evidence Based Dermatology functions as a research group. It has provided an excellent opportunity to develop and foster new collaborative links throughout the world, and has provided a platform for important, practice-changing research.

The work includes work packages in five disease areas: eczema treatment, eczema prevention, skin cancer (squamous cell carcinoma), vitiligo and pyoderma gangrenosum.

This programme of work is due to be completed in August 2013, but we are already working hard to ensure that all aspects of the research are disseminated widely and implemented appropriately.

Some highlights for 2011/2012 have been:

Harmonizing Outcome Measures for Eczema (HOME)

We are delighted that this International collaborative project to establish a core set of outcome measures for eczema trials has now been formally adopted as part of this programme grant (www.homeforeczema.org). The group have already agreed on the core "domains" to be included in the core outcome set (eczema signs, eczema symptoms, long-term disease control and quality of life), and work is now underway to establish how best to measure these aspects of the disease.

Work is well underway in establishing international working groups to tackle some of the important areas for debate prior to our next meeting in San Diego in April 2013.

The HOME initiative now has 130 members from all continents.

Success of our pilot trials

Two pilot randomised controlled trials (RCTs) have been conducted as part of this programme of work:

- Barrier Enhancement for the Prevention of Eczema (BEEP Trial) recruited 124 pregnant women and their babies in four UK centres and one centre in the United States. The study was designed to test the feasibility of conducting a future large-scale trial of barrier enhancement using moisturisers, applied daily from birth, for the prevention of eczema and other allergic diseases. Initial results of this trial are promising and we are currently applying for further funding to conduct the main trial.

- Home Intervention of Light therapy for vitiligo (HI-LIGHT Vitiligo Trial) has also been a great success. This small pilot trial recruited in two UK centres and was closed to recruitment early following an overwhelming response from vitiligo patients wishing to take part. Further funding is currently being sought to undertake a large, multi-centre national trial.

Re-launch of the GREAT Database

The GREAT Database of eczema trials has just been re-launched — and it's even bigger and better than before (www.greatdatabase.org.uk).

The new website allows vastly improved accessibility and search functioning, and the database now includes all systematic reviews published since 2000 as well as all randomised controlled trials. We've even expanded the search for randomised controlled trials to include trials published prior to 2000, making this the single most important database to use when looking for up-to-date, reliable information of eczema treatments. Please use this resource and let us know how and why you have used it.

Largest ever trial of pyoderma gangrenosum

Pyoderma gangrenosum is a rare, disfiguring and very painful skin condition that affects around 360 people each year in the UK. The condition results in large painful skin ulcers that can take many months to heal — often with scarring. People with rare skin conditions are often poorly served by the research community and many treatments may be used without a thorough understanding of their likely benefits and potential harms.

Our STOP GAP trial compares two commonly used oral treatments — prednisolone (a steroid) and ciclosporin (an immuno-suppressant), and is the largest study of its kind in the world. STOP GAP is recruiting patients from across the UK, in around 44 hospitals, in the hope that the results will help to change and inform clinical practice.

"Being told you have a rare skin condition and that very little evidence is out there to inform treatment because it is so uncommon is just not good enough in 2012. Many treatments have been tried, yet only one small clinical trial has ever been done on this condition." says Professor Williams, Director of the CEED.

For more information about the trial please see: www.stopgaptrial.co.uk

Current trials

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

Basal cell carcinoma is the most common form of cancer 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, avoiding surgery, possibly improving cosmetic outcome and cost. We are comparing the long-term success rate, cosmetic result, costs and side effects in this trial.

This study (SINS) compares the gold standard for treating basal cell carcinomas (BCCs) — simple excision surgery — against imiquimod 5% cream (an immune response modifier), in people with low-risk BCC. Patients were randomised to one of the two treatments, and followed up for three years (up to five years from medical notes). Imiquimod was applied once a day for six weeks for those with superficial BCC, and 12 weeks for nodular BCC. Since we started the study, imiquimod has become licensed for superficial BCC.

The trial is funded by Cancer Research UK. Five hundred and one participants were recruited between June 2003 and February 2007, with the help of three dedicated research nurses, and a number of network nurses. The three-year follow-up was completed in May 2010. Double data entry to the trial database was carried out, with data 100% checked and corrected. The study was formally closed in July 2012, after five year data collection from patient records was completed. The primary endpoint is success (no treatment failure or recurrence) at three years. The results are due to be published at the end of 2012.

If you are interested in further information, contact the Trial Coordinator: Mara.Ozolins@nottingham.ac.uk.

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¹University of Nottingham, ²Queen's Medical Centre, Nottingham, ³Chesterfield and North Derbyshire Royal Hospital, ⁴Solihull Hospital, ⁵Astra-Zeneca (previously at The University of Nottingham)

Data Monitoring Committee: Dr Nick Telfer⁽¹⁾, Prof Stephen Walters⁽²⁾, Prof Carol Jagger⁽³⁾
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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 Trial)

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.

The PATCH I trial evaluated the effectiveness of prophylactic antibiotics for the prevention of cellulitis of the leg in patients suffering from recurrent disease. It investigated the impact of giving a low dose of penicillin after an attack of cellulitis, to see if this simple and low cost intervention could prevent further attacks and further complications, such as swelling and ulceration. Participants received either penicillin (250mg bd) or placebo (bd) for a period of 12 months.

This trial is being run through the UK Dermatology Clinical Trials Network with 29 hospitals in the UK and Republic of Ireland recruiting into the study. The PATCH I study exceeded its recruitment target of 260 participants and was completed in early 2012.

PATCH I trial results

A total of 274 patients were recruited with similar baseline characteristics in both groups. The risk of recurrence in the penicillin group was reduced by 45% during the 12 month prophylaxis period ($p=0.01$). However, this protective effect was not sustained during the follow-up period once prophylaxis was stopped, suggesting that long-term prophylaxis is required for patients with recurrent disease. The study also indicated a 27% reduction in the overall number of episodes of cellulitis in the penicillin group compared to the placebo group during the trial (119 penicillin, 164 placebo; $p=0.02$). Twenty two per cent of participants in the penicillin group experienced a bout of cellulitis whilst on treatment implying other influences are also important. There were no significant differences in the use of health resources, or number of adverse events.

The PATCH I trial is one of two similar trials recently completed by the UK Dermatology Clinical Trials Network. The PATCH II trial was reported in last year's annual report and further details can be found in the impact section.

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Data Monitoring Committee: Robert Hills⁽¹⁾, Jane Daniels⁽²⁾, Beverley Adriaans⁽³⁾
¹Cardiff University, ²University of Birmingham, ³Retired – 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.

UK Dermatology Clinical Trials Network's PATCH Trial Team, Thomas K, Crook A, Foster K, Mason J, Chalmers J, Bourke J, Ferguson A, Level N, Nunn A and Williams H. Prophylactic antibiotics for the prevention of cellulitis (erysipelas) of the leg: results of the UK Dermatology Clinical Trials Network's PATCH II trial. *Br J Dermatol*. 2012;166:169-78.

Study of treatments for Pyoderma Gangrenosum Patients (STOP GAP)

Pyoderma gangrenosum (PG) is a mutilating, very painful skin disease that often affects people with an underlying internal disease (such as inflammatory bowel disease, monoclonal gammopathy and rheumatoid arthritis). It starts as a reddish purple bump in the skin that develops into a large, deep, spreading ulcer in a matter of days.

People with 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.

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 a period of up to six months. A parallel observational study is also being conducted in order to capture prospective outcomes for participants treated with topical therapies such as corticosteroids or immunosuppressant ointments.

This trial is being run through the UK Dermatology Clinical Trials Network and is being managed by the Nottingham Clinical Trials Unit. We aim to recruit 140 patients into this trial from 44 secondary-care dermatology departments around the UK.

Thanks to an excellent team of dedicated clinicians and trial staff, the study is going well. As of August 2012 we have recruited 113 participants into the randomised controlled trial and 67 participants into the observational study of topical treatments. Recruitment is currently at 81% of overall target. Recruitment into the RCT will close at the end of October 2012 and recruitment into the observational study was closed at the end of June 2012.

If you are interested in further information, please contact the Trial Manager: stopgap@nottingham.ac.uk or 0115 8844926. More information about the trial can be found at www.stopgaptrial.co.uk.

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

Craig F, Thomas KS, Mitchell E et al on behalf of the UK Dermatology Clinical Trials Network's STOP GAP Trial Team. A multicentre RCT of prednisolone versus ciclosporin for pyoderma gangrenosum: protocol for the UK Dermatology Clinical Trials Network's STOPGAP Trial. *Trials* 13(1), 51.

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)

Bullous pemphigoid is a serious blistering condition that affects both patients' morbidity and mortality. Widespread blisters, skin erosions and severe itching cause patients a great deal of distress and pain. The mortality rate in treated patients is estimated to range from 20%-40% at one year.

There is currently no high-quality evidence to determine whether this condition should be treated with oral steroids or tetracyclines, and it is possible that the use of oral steroids is contributing to the high mortality rates in these patients. The purpose of this study is to determine whether doxycycline is sufficiently effective and safe to be used as an alternative treatment for bullous pemphigoid.

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.

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. A total of 256 participants will be recruited to the study (approximately 210 in the UK). Participants will be recruited from approximately 45 hospitals in the UK and 5 hospitals in Germany. Each centre will need to recruit approximately seven participants over a three year recruitment period to meet the recruitment target.

After a slow period of recruitment an 18 month extension to the study has been accepted and now, thanks to an excellent team of dedicated clinicians and trial staff, we are recruiting well. As of end July 2012, we have recruited 204 participants into the study. Recruitment will close September 2013.

If you are interested in further information, please contact the Trial Manager: kath.foster@nottingham.ac.uk or 0115 8844925.

Trial Management Group: Hywel Williams⁽¹⁾, Andrew Nunn⁽²⁾, Daniel Bratton⁽²⁾, Fenella Wojnarowska⁽³⁾, Gudula Kirtschig⁽⁴⁾, Kath foster⁽¹⁾
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Data Monitoring Committee: Sallie Lamb⁽¹⁾, Robin Graham – Brown⁽²⁾ and Tracey Young⁽³⁾

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

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 into the skin, which increases the risk of the cancer spreading. Because of this risk, it is important that lentigo maligna is treated effectively at an early stage. The current treatment is surgery to remove all of the cancerous cells. Although surgery cures most cases (90-95% cure rate at five years) the procedure is invasive, patients often find it stressful and unpleasant and it can result in scarring.

The aim of this study was to establish the pathological complete regression rate for lentigo maligna, following topical treatment with imiquimod 5% cream. This proof of concept trial was designed to inform the need for a randomised controlled trial comparing imiquimod with surgery.

The treatment schedule involved patients applying imiquimod to their lesion for a duration of 12 weeks, followed by full surgical excision of the treated area plus a 5mm margin of clinically normal skin. Eight hospitals in England, Scotland and Wales contributed patients into the study between October 2010 and August 2011.

The trial closed in March 2012, and we are hoping to publish the results toward the end of the year. If you are interested in further information, please contact the Trial Manager: nafisa.boota@nottingham.ac.uk or 0115 8844924.

Trial Management Group: Dr Jerry Marsden⁽¹⁾, Keith Wheatley⁽²⁾, Richard Fox⁽²⁾, Dan Simpkins⁽³⁾, Nazia Boota⁽³⁾
¹University Hospitals of Birmingham, ²University of Birmingham, ³University of Nottingham

Trial Steering Group: Professor Chris Bunker⁽¹⁾, Mr Simon Wharton⁽²⁾, Mr Stephen Brothwell⁽³⁾
¹University College London Hospital, ²Russell Hall Hospital, ³Patient Representative

Data Monitoring Committee: Dr Catherine Harwood⁽¹⁾, Dr Helen Ramsay⁽²⁾, Natalie Ives⁽³⁾

¹Barts and the London School of Medicine and Dentistry, ²Royal Hallamshire Hospital, ³University 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 (moisturisers) are first line therapy for treating eczema, but we don't know whether they can prevent eczema from developing in the first place. A definitive randomised controlled trial (RCT) is required, but prior to undertaking such a large and expensive trial, we are conducting a pilot RCT to establish if the intervention is acceptable to parents and whether a large trial is feasible.

The BEEP pilot is a multi-centre, two-arm parallel group RCT taking place at four sites in the UK and one in the USA. Between April 2010 and March 2011 we recruited 124 (78 in the UK) newborn babies with a family history of asthma, eczema or hay-fever. They were randomised to either the intervention group (emollient applied to the baby's entire skin surface at least once a day for six months after birth) or the control group (no emollient). All families were given advice on best practice skin care. Parents had a choice of three emollients: Sunflower Seed Oil, Doublebase or 50:50 white soft paraffin / liquid paraffin. The primary outcome was willingness to participate. Secondary outcomes included adherence, acceptability, contamination, adverse events, and effectiveness of blinding and proportion that developed eczema by six-months of age.

All babies were examined at six-months for signs of eczema (and earlier if eczema was suspected). This examination was performed by investigators blinded to treatment allocation.

The results of this pilot study are encouraging. In the UK, where 78 pregnant mothers were recruited and consented prior to delivery and randomised after birth, 59% of eligible families agreed to be randomised and only six (8%) of the families recruited in the UK withdrew from the study or were lost to follow up. Other outcomes (looking at the 124 families from the UK and US) showed that parental reported adherence with the emollient was good; 80% reported applying it at least five-six days per week. Contamination of the control group was low; only eight (7%) reported using emollient on their child at more than one occasion for reasons other than cradle cap or nappy rash. The rate of skin infections was also low (and comparable between groups).

Although this pilot study was not powered to detect clinical outcomes, the cumulative incidence of investigator diagnosed eczema at six-months showed a statistically significant and clinically important reduction in the rate of eczema in the emollient group compared to the control group. The intention-to-treat (ITT) analysis showed the

odds ratio of developing eczema in the emollient group compared to the control group was 0.33 [95% CI 0.23-0.42, $P < 0.0001$].

Participants are now being assessed at one year by questionnaire and two years old by a further skin examination where possible to see if this benefit is maintained. We are also planning to assess the incidence of sensitisation by skin prick test (SPT) to common allergens: egg, milk, nuts, house dust mite, cats, grass pollen) at two years old. An Ethics application is currently being submitted.

For further information on this trial, please contact Joanne Chalmers, Research Fellow on 0115 8232435 or by email at joanne.chalmers@nottingham.ac.uk.

Trial Management Group: Joanne Chalmers⁽¹⁾, Hywel Williams⁽¹⁾, Eric Simpson⁽²⁾

¹University of Nottingham, ²Oregon Health and Science University, Portland, USA

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 represents a drain on NHS resources through patients requiring multiple clinical visits and potentially needing long-term, expensive medications. A Cochrane Systematic Review found no randomised controlled trial (RCT) evidence on which to base treatment. There is subsequently a need for high quality RCTs in this area which will provide guidance for clinicians.

To address deficiencies in the management of ELPV we are planning a multi-centre RCT that will test the effectiveness of systemic treatments in patients who have not responded adequately to initial topical therapy. Feasibility work includes surveys of national patient and expert groups, a national multi-centre case note audit and review of data from 172 patients, and interviews with 25 UK clinicians. The most commonly used systemic treatments in clinical practice have been identified and three have been selected by experts for use in a trial.

Methodologists from the Medical Research Council's Clinical Trials Unit have collaborated to develop a trial protocol that can incorporate the three selected medications into a single RCT. The next step will be to perform a pilot trial that tests the first stage of the trial design and to ascertain whether a full RCT will be possible. The International and British Societies for the Study of Vulvovaginal Disease, and the UK

Lichen Planus Support Group are supporting this work.

Rosalind Simpson has been awarded an NIHR Doctoral Research Fellowship to support her in completing this project. If you are interested in further information, or would like to be involved in the pilot trial, please contact: rosalind.simpson@nottingham.ac.uk or 0115 8468630.

Trial Development Group: Dr Rosalind Simpson⁽¹⁾, Dr Kim Thomas⁽¹⁾, Dr Ruth Murphy⁽²⁾, Dr Matthew Sydes⁽³⁾, Sandra Lawton⁽²⁾, Jo Clayton⁽⁴⁾

¹University of Nottingham, ²Nottingham University NHS Trust, ³MRC Clinical Trials Unit, ⁴Patient Representative, Nottingham.

Relevant publications

Simpson RC, Murphy R. Considerations for Disease Impact and Outcome Measures in Vulvar Disease. *J Low Genit Tract Dis.* 2012 May 31. [Epub ahead of print]

Simpson RC, Littlewood SM, Cooper SM, Cruickshank ME, Green CM, Derrick E, Yell J, Chiang N, Bell H, Owen C, Javed A, Wilson CL, McLelland J, Murphy R. Real-life experience of managing vulval erosive lichen planus: a case-based review and U.K. multicentre case note audit. *Br J Dermatol.* 2012 Jul; 167(1):85-91

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 have shown that patients are frightened and embarrassed by vitiligo and may experience discrimination; especially people with darker skin types or with vitiligo patches on visible sites such as face and hands.

Vitiligo is a chronic condition requiring long-term treatment, but little is known about the treatments used for the condition. A 2010 update of the Cochrane systematic review 'Interventions for vitiligo' included 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.

To address this lack of evidence, we have 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 our NIHR Programme Grant for Applied Research, 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 light therapy 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 HI-Light trial is now closed for recruitment. We have recruited more patients than was originally anticipated (29 participants) in Leicester and Nottingham in just 3 months. The preliminary results of the trial will be evaluated in November 2012.

Outcomes of the trial include assessment of 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.

Trial Management Group: Dr Viktoria Eleftheriadou⁽¹⁾, Dr Kim Thomas⁽¹⁾, Dr Jane Ravenscroft⁽²⁾, Dr Jonathan Batchelor⁽²⁾, Mrs Maxine Whitton⁽³⁾, Dr Robert Dawe⁽⁴⁾, Prof. Hywel Williams⁽¹⁾

¹University of Nottingham, ²Nottingham University NHS Trust.

Relevant publications

1. 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.

2. 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.

3. 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

4. Eleftheriadou V, Thomas KS, Whitton ME et al 2012. Which outcomes should we measure in vitiligo? results of a systematic review and a survey amongst patients and clinicians on outcomes in vitiligo trials. *Br J Dermatol* 2012; (epub ahead of publication).

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)

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. Once enrolled in the study, patients are followed up over a 5 year period and patients on both biologic drugs and conventional systemic therapies are eligible for inclusion. The study began in August 2008 and over 4,000 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 over 130 hospital sites across the UK and Eire recruiting into BADBIR. One of these sites is the dermatology department at Queens Medical Centre Nottingham, with CEBD based research nurses Jo Llewellyn and Sue Davies-Jones being responsible for recruitment and administrative assistance being provided by Johanna Perdue. The site has recruited over 170 patients so far and is in the top ten recruiting centres for the study.

BADBIR is based at the University of Manchester and further details can be found website: www.badbir.org or by contacting the study team on: badbir@manchester.ac.uk

Further studies

NIHR portfolio studies as outlined in the table have all recruited in the Trent region over the past year and as such

are eligible for support from our Trent CLRN funded nurses as outlined in the BADBIR study above. With regards to the acne genetics study (NIHR CRN portfolio number 5793) Nottingham is 6th place nationally out of 39 sites and has recruited 288 patients over the past 12 months. We hope to begin recruitment shortly into two additional portfolio studies, one looking at the identification of food allergy genes for food allergy and eczema in children (NIHR CRN portfolio number 10226) and the other biomarkers for systemic treatments of psoriasis (NIHR CRN portfolio number 10464).

Further details of these studies can be found on the NIHR CRN study database: http://tiny.cc/CRN_study

Study title/ acronym	NIHR CRN Portfolio Number	Skin condition
AVAST-M	1751	Melanoma
VENUS IV	7994	Leg ulcers
Melanoma Cohort Study	1381	Melanoma
Melanoma Lifestyle Study	3945	Melanoma
ESOS	8799	Systemic sclerosis
ACE	9087	Lymphoedema
PEST	8269	Psoriatic arthritis
Genetics of acne	5793	Acne

Cochrane systematic reviews



The Cochrane Skin Group have published 13 protocols and 9 full reviews this year. Details of reviews and protocols published for the period 1 August 2011 to 1 August 2012 are outlined over the following pages.

Reviews and Updates

Issue 11, 2011: Lasers or light sources for treating port-wine stains (Lansbury L, Leonardi-Bee J, Perkins W, Goodacre T, Tweed JA, Bath-Hextall FJ)

Summary findings: Five RCTs involving a total of 103 participants were included; all of the trials used a within-participant design. The interventions and outcomes were too varied to be combined statistically. All trials used the pulsed dye laser for comparisons. The pulsed dye laser leads to clinically relevant clearance of port-wine stains. A limited number of RCTs evaluated the efficacy from intense pulsed light and other laser types. High-quality RCTs are needed to assess individual efficacy from different lasers and light sources, as well as participant satisfaction.

Issue 12, 2011: Topical interventions for genital lichen sclerosis (Chi C-C, Kirtschig G, Baldo M, Brackenbury F, Lewis F, Wojnarowska F)

Summary findings: Seven RCTs, with a total of 249 participants, covering six treatments, were included. Six of these RCTs tested the efficacy of one active intervention against placebo or another active intervention, while the other trial tested three active interventions against placebo. The current limited evidence demonstrates the efficacy of clobetasol propionate, mometasone furoate, and pimecrolimus in treating genital lichen sclerosis. Further RCTs are needed to determine the optimal potency and regimen of topical corticosteroids, examine other topical interventions, assess the duration of remission or prevention of flares, evaluate the reduction in the risk of genital squamous cell carcinoma or genital intraepithelial neoplasia, and examine the efficacy in improving the quality of the sex lives of people with this condition.

Issue 1, 2012: Interventions for impetigo (Koning S, van der Sande R, Verhagen AP, van Suijlekom-Smit LWA, Morris AD, Butler CC, Berger M, van der Wouden JC)

Summary findings: Fifty seven trials were in the first version of this review. For this update, one of those trials was excluded and 12 new trials were added. The total number of included trials was 68, with 5,578 participants, reporting on 50 different treatments, including placebo. Most trials were in primary impetigo or did not specify this. There is good evidence that topical mupirocin and topical fusidic acid are equally, or more effective than oral treatment. Due to the lack of studies in people with extensive impetigo, it is unclear if oral antibiotics are superior to topical antibiotics in this group. Fusidic acid and mupirocin are of similar efficacy. Penicillin was not as effective as most other antibiotics. There is a lack of evidence to support disinfection measures to manage impetigo.

Issue 2, 2012: Dietary supplements for established atopic eczema (Bath-Hextall FJ, Jenkinson C, Humphreys R, Williams HC)

Summary findings: Eleven studies with a total of 596 participants were included in the review. Studies assessed fish oil versus olive oil or corn oil placebo. The following were all looked at in single studies: oral zinc sulphate compared to placebo, selenium versus selenium plus vitamin E versus placebo, vitamin D versus placebo, vitamin D versus vitamin E versus vitamins D plus vitamin E together versus placebo, pyridoxine versus placebo, sea buckthorn seed oil versus sea buckthorn pulp oil versus placebo, hempseed oil versus placebo, sunflower oil (linoleic acid) versus fish oil versus placebo, and DHA versus control (saturated fatty acids of the same energy value). Two small studies on fish oil suggest a possible modest benefit, but many outcomes were explored. A convincingly positive result from a much larger study with a publicly-registered protocol is needed before clinical practice can be influenced. There is no convincing evidence of the benefit of dietary supplements in eczema, and they cannot be recommended for the public or for clinical practice at present. Whilst some may argue that at least supplements do not do any harm, high doses of vitamin D may give rise to serious medical problems, and the cost of long-term supplements may also mount up.

Issue 2, 2012: Interventions for erosive lichen planus affecting mucosal sites (Cheng S, Kirtschig G, Cooper S, Thornhill M, Leonardi-Bee J, Murphy R)

Summary findings: Fifteen RCTs were included, giving a total of 473 participants with ELP (study sizes ranged between 8 to 94). All studies involved oral sites only. Six studies included participants with non-erosive lichen planus but only the erosive subgroup was included for intended subgroup analysis. We were unable to pool data from any of the nine studies with only ELP participants or any of the six studies with the ELP subgroup, due to small numbers and the heterogeneity of the interventions, design methods, and outcome variables between studies. This review suggests that there is only weak evidence for the effectiveness of any of the treatments for oral ELP, whilst no evidence was found for genital ELP. More RCTs on a larger scale are needed in the oral and genital ELP populations. We suggest that future studies should have standardised outcome variables that are clinically important to affected individuals. We recommend the measurement of a clinical severity score and a participant-rated symptom score using agreed and validated severity scoring tools. We also recommend the development of a validated combined severity scoring tool for both oral and genital populations.

Issue 3, 2012: Histamine H2-receptor antagonists for urticaria (Fedorowicz Z, van Zuuren EJ, Hu N)

Summary findings: Four studies of a relatively small size, involving 144 participants, were included in this review. A combination of ranitidine with diphenhydramine was more effective at improving the resolution of urticaria than diphenhydramine administered alone (risk ratio (RR) 1.59, 95% confidence interval (CI) 1.07 to 2.36). Although there was a similar improvement in itching, weal size, and intensity, cimetidine provided no statistically significant greater overall improvement in symptoms of urticaria when compared to diphenhydramine. However, a combination of these medications was more effective than diphenhydramine alone (RR 2.02, 95% CI 1.03 to 3.94). Adverse events were reported with several of the interventions, i.e. ranitidine and diphenhydramine, causing drowsiness and sedation, but there was no significant difference in the level of sedation from baseline with either famotidine or diphenhydramine. The very limited evidence provided by this review was based on a few old studies of a relatively small size, which we categorised as having high to unclear risk of bias. At present, the review does not allow confident decision-making about the use of H2-receptor antagonists for urticaria. Although some of these studies have reported a measure of relief of symptoms of urticaria and rather minimal clinical improvement in some of the participants, the evidence was weak and unreliable.

Issue 4, 2012: Interventions for ingrowing toenails (Eekhof JAH, Van Wijk B, Knuistingh Neven A, van der Wouden JC)

Summary findings: This is an update of the Cochrane review 'Surgical treatments for ingrowing toenails'. In this update we included 24 studies, with a total of 2,826 participants (of which seven were also included in the previous review). Five studies were on non-surgical interventions, and 19 were on surgical interventions. Surgical interventions are more effective than non-surgical interventions in preventing the recurrence of an ingrowing toenail. In the studies comparing a surgical intervention to a surgical intervention with the application of phenol, the addition of phenol is probably more effective in preventing recurrence and regrowth of the ingrowing toenail. Because there is only one study in which the surgical interventions in both study arms were equal, more studies have to be done to confirm these outcomes. Postoperative interventions do not decrease the risk of postoperative infection, postoperative pain or healing time.

Issue 5, 2012: Interventions for female pattern hair loss (van Zuuren EJ, Fedorowicz Z, Carter B, Andriolo RB, Schoones J)

Summary findings: Twenty two trials, comprising 2,349 participants, were included. A wide range of interventions were evaluated, with 10 studies investigating the different concentrations of minoxidil. Pooled data from 4 studies indicated that a greater proportion of participants (121/488) treated with minoxidil reported a moderate increase in their hair regrowth when compared with placebo (64/476) (risk ratio (RR)=1.86, 95% confidence interval (CI) 1.42 to 2.43). In seven studies, there was an important increase of 13.28 in total hair count per cm² in the minoxidil group compared to the placebo group (95% CI 10.89 to 15.68). There was no difference in the number of adverse events in the twice daily minoxidil and placebo intervention groups, with the exception of a reported increase of adverse events (additional hair growth on areas other than the scalp) with minoxidil (5%) twice daily. Most of the other comparisons consisted of single studies. These were assessed as high risk of bias — they did not address our prespecified outcomes and provided limited evidence of either the efficacy or safety of these interventions. Although more than half of the included studies were assessed as being at high risk of bias, and the rest at unclear, there was evidence to support the effectiveness and safety of topical minoxidil in the treatment of female pattern hair loss. Further direct comparison studies of minoxidil 5% applied once a day, which could improve adherence when compared to minoxidil 2% twice daily, are still required. Consideration should also be given to conducting additional well-designed, adequately-powered randomised controlled trials investigating several of the other treatment options.



Issue 8, 2012: Minocycline for acne vulgaris: efficacy and safety (Garner SE, Eady A, Bennett C, Newton JN, Thomas K, Popescu CM)

Summary findings: Twelve new RCTs were included for this update, giving a total of 39 RCTs (6,013 participants). These additional twelve RCTs have not changed the original conclusions about the clinical efficacy of minocycline. Minocycline is an effective treatment for moderate to moderately-severe inflammatory acne vulgaris, but there is still no evidence that it is superior to other commonly used therapies. This review found no reliable evidence to justify the reinstatement of its first-line use, even though the price differential is less than it was 10 years ago. Concerns remain about its safety compared to other tetracyclines.

Protocols

Issue 10, 2011: Interventions for treatment of herpes simplex labialis (cold sores on the lips) (Lee C, Chi C-C, Hsieh S-C, Chang C-J, Delamere FM, Peters MC, Kanjirath PP, Anderson PF)

Issue 10, 2011: Interventions for excessive sweating of unknown cause (Shams K, Rzany BJ, Prescott LE, Musekiwa A)

Issue 11, 2011: Oral isotretinoin for acne (Costa CS, Bagatin E, da Silva EMK, Lúcio MM, Magin P, Riera R)

Issue 11, 2011: Topical anti-inflammatory agents for seborrhoeic dermatitis of the face or scalp (Oksanen T, Kastarinen H, Kiviniemi V, Airola K, Peura P, Okokon EO, Verbeek JH)

Issue 11, 2011: Complementary therapies for acne vulgaris (Cao H, Liu JP, Luo H, Smith CA, Liu Y)

Issue 12, 2011: Narrow-band ultraviolet B phototherapy versus broad-band ultraviolet B or psoralen-ultraviolet A photochemotherapy for psoriasis (Chen X, Cheng Y, Yang M, Liu GJ, Zhang M)

Issue 12, 2011: Topical retinoids for the treatment of acne vulgaris (Tzellos T, Toulis KA, Dessinioti C, Zampeli V, Abdel-Naser MB, Katsambas A, Bauer A, Gollnick HPM, Thielitz A, Franke C, Zouboulis CC)

Issue 4, 2012: Topical treatments for scalp psoriasis (Jales RD, Nast A, Saconato H, Atallah AN, Hirata SH)

Issue 4, 2012: Interventions for the prevention of recurrent erysipelas and cellulitis (Dalal A, Eskin-Shwartz M, Mimouni D, Ray S, Days W, Hodak E, Leibovici L, Paul M)

Issue 5, 2012: Topical tacrolimus for atopic dermatitis (Cury Martins J, Martins C, Aoki V, Leonardi-Bee J, Gois AFT, Ishii HAKira, da Silva EMK)

Issue 8, 2012: Oral antifungal medication for toenail onychomycosis (Kreijkamp-Kaspers S, Bell-Syer SEM, Magin P, Bell-Syer SV, van Driel ML)

Issue 8, 2012: Topical antifungal treatments for tinea cruris and tinea corporis (El-Gohary M, Burgess H, Doney L, Johnson E, Stuart B, Moore M, Hearn P, Little P)

Issue 8, 2012: Anti-TNF agents for paediatric psoriasis (Sancllemente G, Murphy R, Contreras J, Rengifo-Pardo M, Garcia H, Bonfill Cosp X)

Other systematic reviews

Treatment of squamous cell carcinoma (cSCC) 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 cSCC are based largely on case series.

Following on from our original review, we are now undertaking a second systematic review of cSCC treatments, prompted by the lack of evidence from RCTs. This review will include observational studies of cSCC treatments and, although such studies are recognised to be more prone to bias, we believe that the results will be valuable to further 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 more than 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⁽¹⁾, Fiona Bath-Hextall⁽¹⁾, Jo Leonardi-Bee⁽¹⁾ Dr William Perkins⁽²⁾

¹Centre of Evidence Based Dermatology, University of Nottingham, ²School of Nursing, Midwifery and Physiotherapy, University of Nottingham, ³School of Community Health Sciences, University of Nottingham, ⁴Nottingham University Hospitals 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

Other research

Global Resource of Eczema Trials (GREAT database)

This freely accessible, comprehensive online database holds records for all randomised controlled trials on eczema 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 and systematic reviews of eczema treatments. Reducing the hours spent searching and filtering references will speed 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, CINHALL 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 trial including the interventions, duration, method of randomisation, blinding, withdrawals, outcomes and authors' conclusions. The search facility enables users to search across all fields or just one field for any term of interest. The database currently holds details of approximately 60 systematic reviews and 500 randomised controlled trials. The database is freely available at www.greatdatabase.org.uk.

This work is being carried out as part of our NIHR Programme Grant Award (RP-PG-0407-10177).

People involved: Helen Nankervis⁽¹⁾, Hywel Williams⁽¹⁾, Kim Thomas⁽¹⁾, Sherie Smith⁽¹⁾
¹University 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

Nankervis H, Baibergenova A, Williams HC and Thomas KS Prospective registration and outcome reporting bias in randomised controlled trials of eczema treatments. J Invest Dermatol 2012 doi: 10.1038/jid.2012.231.

Harmonising Outcome Measures for Eczema (HOME)

The HOME (Harmonising Outcome Measures for Eczema) initiative was founded in 2008 by Hywel Williams (UK) and Jochen Schmitt (Germany) in response to the use of multiple invalidated outcome measures in eczema trials. Far too many measures are currently in use making it impossible to compare results in a meaningful way.

The aim of HOME is to agree a set of core outcome measures for atopic eczema which should be included in ALL clinical trials and clinical recordkeeping to allow comparison of data across multiple trials.

Progress has been made towards this aim. An initial Delphi exercise was followed by two working meetings; HOME I and HOME II. The inclusion of four core outcome domains has been agreed by consensus. These are:

- clinical signs
- symptoms
- long term control
- quality of life

Including the core outcome measures in a trial does not preclude the use of any other outcomes necessary for any particular trial or recordkeeping.

Membership of HOME currently stands at over 130. Members are drawn from all over the world and represent all stakeholders; clinicians, nurses, patients, regulatory bodies, journal editors and the pharmaceutical industry. Anyone with an interest in outcome measures for eczema is welcome to join.

Management of HOME is by an executive group and a scientific committee. Research groups have been formed from within the membership of HOME to conduct a number of research projects to help inform which instruments should be included in the core outcome set. Deciding on which instruments should be recommended will be the focus of the next working meeting in San Diego, USA, 6-7th April 2013 (HOME III).

Research projects currently being carried out by groups around the world are:

Signs Working Group:

- updating the systematic review "What are the best outcome measurements for atopic eczema? A systematic review" published in 2007
- comparing the results of the detailed scales (SCORAD and EASI) from published studies with the more simple "Three Item Severity Score" (TISS)
- comparing four of the main outcome measures, in

eczema patients rather than using trial data, to assess responsiveness and possibly determine what is a clinically meaningful improvement on each scale.

Symptoms Working Group:

- systematic review of symptom scales and scores used in eczema trials
- a survey of patients and members of the HOME group to establish which symptoms are important (to patients in particular) and should be measured in future trials
- identify and validate the most appropriate adjectival markers for an itch VAS scale (including work to ensure that the wording is appropriate and translatable throughout the world)

Long-term Control Working Group:

- updating the systematic review "What is meant by a "flare" in atopic dermatitis? A systematic review and proposal" published in 2006
- validity, reliability and responsiveness to change of the Totally Controlled Week / Well Controlled Week and correlation with other measures such as POEM
- validation study of flares as captured using the definition of "step-up" in treatment

Quality of Life Working Group

- Systematic review of currently used QoL tools in eczema trials

For further information about the HOME initiative visit: www.homeforeczema.org or e: home@nottingham.ac.uk

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

Both Hywel Williams and Carsten Flohr have played a key role in ensuring adequate representation and analysis of eczema data in the International Study of Asthma and Allergies in Childhood — the largest study to date that documents the global prevalence of asthma, eczema and hay fever and how this has changed in over 100 countries worldwide over the last 10 years.

Sadly, after a 20 year-history, it is time to close down the ISAAC study as it has achieved its aims. The last aim of ISAAC is to liberate all its data into the public domain for future researchers to analyse and revisit. You can view a summary of the ISAAC story at <http://isaac.auckland.ac.nz/story/index.html>.

The impact of ISAAC has been huge:

- 1.96 million children
- 306 research centres
- 105 countries
- 53 languages
- more than 500 publications
- more than 20 years of research

Relevant publications

Hywel Williams and Carsten Flohr were involved in two key ISAAC publications in the last year:

Flohr C, Nagel G, Weinmayr G, Kleiner A, Williams HC, Ait-Khaled N, Strachan DP; ISAAC Phase Two Study Group. Tuberculosis, bacillus Calmette-Guérin vaccination, and allergic disease: findings from the International Study of Asthma and Allergies in Childhood Phase Two. *Pediatr Allergy Immunol.* 2012;23:324-31.

Ellwood P, Asher MI, Stewart AW, Ait-Khaled N, Mallol J, Strachan D; ISAAC Phase III Time Trends Study Group. The challenges of replicating the methodology between Phases I and III of the ISAAC programme. *Int J Tuberc Lung Dis.* 2012;16:687-93.

Popular pruritic eruption of HIV in Ugandan participants in the anti-retroviral therapy era

This project forms part of a PhD thesis for Dr Ser Ling Chua. It is examining factors associated with the popular pruritic eruption (PPE) of HIV, its natural history and its utility as a predictor for failure of antiretroviral therapy (ART) if present after ART has been established.

This project involves two studies based in Mbarara, Uganda. The first is a two-year prospective cohort study following participants with PPE from initiation of ART. The second is a nested case control study where participants were recruited from the Uganda Anti-Retroviral Therapy Outcomes (UARTO) cohort.

Oral administration of the Runyankore-version of Skindex-16 was studied prior to the commencement of these two studies.

Recruitment for these studies has been completed. Data analysis and writing up of the thesis is underway. Peer-reviewed publication to date is: Chua SL, Maurer T, Chren MM. Adaptation of a Runyankore version of Skindex-16 for oral administration in Mbarara, Uganda. *Int J Dermatol* 2011; 50: 1249-54.

Data from these studies have been presented at the following meetings:

5th International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention (2009)

A study examining active skin disease as a predictor for treatment failure in HIV-infected individuals established on anti-retroviral therapy

5th International Dermato-Epidemiology Association Congress (2008)

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

Regional Dermatology Training Centre Annual Continuing Medical Education Meeting, Moshi, Tanzania (2008) -

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

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

¹University Hospital Birmingham, UK, ²University of California San Francisco, USA, ³Mbarara National Referral Hospital, Uganda, ⁴Harvard School of Public Health and Harvard Initiative for Global Health, USA.

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

Mid-infrared-transmitting, novel-glass, fibre-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) and pending European funding (FP7 project in negotiation to be announced in November 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, and also the first mid-infrared fibre lasers. Additionally, sub-diffraction analysis using the mid-infrared beamline at the Diamond Light Synchrotron, Oxford, is investigating the limits of mid-infrared cell and tissue analysis.

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. Prof. Angela Seddon has given invited talks in 2012, interestingly, at the former home of Niels Bohr in

Copenhagen, Denmark, ('Mid-infrared light for cancer detection') and at the University of Cambridge, UK, ('The mid-infrared – a hot topic!'). She has had published the invited paper: "A prospective for new mid-infrared medical endoscopy using chalcogenide glasses", *Int. J. Appl. Glass Sci* 2 [3] 177–191 (2011).

For further details on this work please contact Prof Angela Seddon on angela.seddon@nottingham.ac.uk.

People Involved: Professor Angela B Seddon⁽¹⁾, Dr David Furniss⁽¹⁾, Professor Trevor Benson⁽¹⁾, Dr Slawek Sujecki⁽¹⁾, Dr Sandeep Varma⁽²⁾, Professor Hywel Williams⁽²⁾

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

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

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

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 skin 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: ioan.notingher@nottingham.ac.uk.

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

¹University of Nottingham, School of Physics and Astronomy, ²University of Nottingham. ³Queen'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

Research impact

We conduct 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.



Research highlights for 2011/2012

The following sections provide a snapshot of some of the highlights of our research over the last 12 to 18 months and the impact it may have on the way that we think about skin disease and its treatment. For further details of important Cochrane systematic reviews, please see the earlier Cochrane Skin Group section of our report.

Key clinical messages

Are prophylactic antibiotics useful for the prevention of recurrent cellulitis (erysipelas) of the leg?

Clinical recommendation: consider using prophylactic antibiotics for the prevention of cellulitis of the leg if a patient has had two or more episodes in the last three years. All such patients should be offered prophylaxis, not just those with known risk factors, such as lymphoedema and multiple previous episodes. Other measures should be considered alongside the prophylaxis, such as control of the lymphoedema using compression hosiery.

Study summary: a randomised controlled trial including 260 patients with recurrent cellulitis of the leg showed that low dose prophylactic penicillin V prescribed 250mg, twice a day for 12 months resulted in a substantial and clinically significant reduction in the risk of recurrence whilst patients were taking the prophylaxis. However, the beneficial effects were subsequently lost over the following two years, suggesting that long-term prophylaxis is required for patients with recurrent disease (patients with at least two previous episodes in the last three years). There was evidence to suggest that patients with lymphoedema, more than three previous episodes, and patients with a high BMI were less likely to benefit from the prophylaxis. This is of concern since these are the very patients who are currently most likely to receive prophylaxis. This trial was funded by Action Medical Research.

Key publication: Thomas KS and the UK Dermatology Clinical Trials Network's PATCH I Trial Team. UK Dermatology Clinical Trials Network's PATCH I trial: a randomized controlled trial of prophylactic antibiotics for the prevention of cellulitis (erysipelas) of the leg in patients with recurrent disease British Journal of Dermatology 2012; 167 (SI Supplement: 1):5 DOI: 10.1111/j.1365-2133.2012.10956.x

Are prophylactic antibiotics useful for the prevention of cellulitis of the leg after a single episode?

Clinical recommendation: these results provide further evidence in support of the notion that current practice in relation to prophylactic antibiotics for the prevention of cellulitis is targeting the wrong patients, and that prophylaxis should be introduced sooner, before irreparable damage to the lymphatic system is incurred. These findings require validation in a subsequent large-scale RCT.

Study summary: in a randomised controlled trial of 123 patients with largely first episode cellulitis, there was a suggestion that six months of prophylactic penicillin V could substantially reduce the risk of further episodes of cellulitis, and that the protective effect was maintained in the long term (3 years). This finding requires confirmation in a subsequent trial as the study was under powered and narrowly missed conventional statistical significance. This trial was funded by the BUPA Foundation.

Key publication: UK Dermatology Clinical Trials Network's PATCH Trial Team, Thomas K, Crook A, Foster K, Mason J, Chalmers J, Bourke J, Ferguson A, Level N, Nunn A, and Williams HC. Prophylactic antibiotics for the prevention of cellulitis (erysipelas) of the leg: results of the UK Dermatology Clinical Trials Network's PATCH II trial. Br J Dermatol. 2012; 166:169-78.

Is cryotherapy better than salicylic acid for the treatment of verrucae?

Clinical recommendation: do not use cryotherapy for the treatment of verrucae. Over-the-counter salicylic acid is just as good and much more cost-effective.

Study summary: an NIHR HTA-funded trial involving 240 children and adults aged 12 years and over showed convincing evidence that cryotherapy was no better than salicylic acid in the treatment of verrucae, but that cryotherapy was considerably more expensive. Indeed, only 14% of participants in both groups showed complete clearance of the verrucae at 12 weeks.

Key publication: 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.

Are water softeners helpful for the treatment of eczema?

Clinical recommendation: do not advise eczema patients to buy a water softener in the hope that it may improve the eczema.

Study summary: an NIHR HTA-funded randomised controlled trial involving 336 children with eczema showed convincing evidence of no benefit from the installation of an ion-exchange water softener for the treatment of eczema.

Key publication: Thomas KS, Dean T, O'Leary C, Sach TH, Koller K, Frost A, Williams HC and the SWET trial team, 2011. A Randomised Controlled Trial of Ion-Exchange Water Softeners for the Treatment of Eczema in Children. PLoS Med 8(2), e1000395

Does the use of daily emollients from birth reduce the incidence and severity of eczema in infants?

Clinical recommendation: whilst these results show great promise, it is too early as yet to recommend the routine use of emollients from birth in children at risk of eczema. Further research is needed in order to clarify the risks and benefits of such an approach.

Study summary: a multi-centre pilot trial involving 124 babies born to parents with a history of atopy were randomised to receive daily use of emollients compared to standard skin care. Whilst this pilot trial was primarily set-up to establish the feasibility of conducting a large-scale trial in the future, results showed a substantial reduction in the incidence of eczema at 6 months in babies that had used the emollient. These results show great promise and we are currently seeking funding to conduct a large national trial involving over 1,200 babies.

Key publication: Simpson EL, Chalmers JR; Hanifin JM; French ME, Lubianski T, Samrao A, Chen Y, Chen Z, Williams HC Barrier enhancement for eczema prevention-the BEEP feasibility study. Journal of Investigative Dermatology 2012; 132 (Supplement: 1): S90-S90 Meeting Abstract: 529

What role does autoimmunity play in driving eczema flares?

Clinical recommendation: treating the eczema with topical corticosteroids of an appropriate potency and liberal emollient use will help to reduce the need to scratch and thus help to minimise this autoimmune response.

Study summary: very little is known about why eczema persists in some people and not in others. One theory is that after a while, some people with eczema become

'allergic' to components of their own skin - a process called 'autoimmunity' which is well described in other human conditions such as thyroid disease or lupus. This systematic review suggested that there is some pretty convincing evidence that autoimmunity might be a key factor in keeping eczema active in some people. It is possible that the act of scratching exposes bits of skin cells to the body's immune system resulting in an immune reaction - a sort of "civil war". Whether this happens in children with milder disease is unsure, but it does open up new ways of thinking about treating eczema or preventing scratching in order to prevent it from developing a life of its own.

Key publication: Tang TS, Bieber T and Williams HC Does "autoreactivity" play a role in atopic dermatitis? J Allergy Clin Immunol 2012; 129 (5):1209-1215.e2.

Defining standards of care for vulval erosive lichen planus

Clinical recommendation: patient-reported assessment of disease severity needs to be prioritised when treating vulval disorders such as ELPV. Various systemic treatments may be used for patients with ELPV but formal assessment of their efficacy needs to be determined through well-designed RCTs. Work is now ongoing to identify suitable outcome measures for use in vulval disorders, to agree diagnostic criteria for ELPV and to run a pilot RCT.

Study summary: erosive lichen planus affecting the vulva (ELPV) is an uncommon, but chronic and distressing inflammatory dermatosis that is often resistant to first-line therapy. A recent Cochrane Review has shown there is no RCT evidence on which to base treatment for ELPV, even for very potent topical steroids which are commonly used as first-line therapy. Furthermore, due to lack of evidence, there are no guidelines for management of ELPV. To define current standards of care for this condition, we reviewed the notes of 172 patients from 10 UK specialist centres. The study demonstrated that assessment and management of ELPV in the UK is variable, particularly in terms of diagnostic criteria, outcome measures and second-line therapies. Patient-reported outcomes were only assessed in 3% of cases and when systemic treatment was required, there was no consistency in choice of agent. The most frequently used systemic agents were prednisolone, hydroxychloroquine, mycophenolate mofetil, methotrexate and minocycline.

Key publication: Simpson RC, Littlewood SM, Cooper SM, Cruikshank ME, Greon CM, Derrick E, Yell J, Chiang N, Bell H, Owen C, Javed A, Wilson CL, McLelland J and Murphy R. Real life experience of managing vulval erosive lichen planus: a case based review and U.K. multicentre case-note audit. Br J Dermatol 167(1):85-91 2012.

“What could I, as a frustrated patient with severe vitiligo, do?”
Maxine Whitton

Methodological issues

Harmonizing Outcome Measures for Eczema (HOME) initiative

Take home message: Sorting out an agreed set of core outcomes for use in future eczema research will be one of the single most important achievements for the eczema community this decade.

Study summary: this project is aiming to secure international consensus over the most appropriate outcomes to be used in measuring treatment response, so that an agreed set of core outcomes can be defined for use in all future clinical trials. This work will enable appropriate comparison across all treatment trials, and will facilitate meta-analysis of published results, thus enabling a much clearer picture of the comparative effectiveness of different treatments.

Key Publication: Schmitt, J.; Spuls, P.; Boers, M.; Thomas, K.; Chalmers, J.; Roekevisch, E. et al Towards global consensus on outcome measures for atopic eczema research: results of the HOME II meeting. *Allergy* 2012; 67 (9): 1111-1117

What outcome measures are used in vitiligo trials and do they reflect what patients think is important?

Take home message: international consensus over a core set of outcome measures for use in future trials is required. The Vitiligo European Task Force are now in the process of developing consensus in this area.

Study summary: out of 54 vitiligo RCTs included in the Cochrane review of interventions for vitiligo, 25 different outcomes were used. Although repigmentation was reported in the majority of the trials (96%), this was measured in 48 different ways, making it impossible to compare trials and treatments. Only 9% of trials assessed quality of life, 13% measured cessation of spreading of the disease and 17% reported patients' satisfaction with the treatment.

In contrast, out of 438 suggestions made by patients and clinicians, cosmetically acceptable repigmentation (rather than percentage of repigmentation) was the most desirable outcome, followed by cessation of spread of vitiligo, quality of life and maintenance of repigmentation.

Key publication: Eleftheriadou V, Thomas KS, Whitton ME, Batchelor JM, and Ravenscroft JC, 2012. Which outcomes should we measure in vitiligo? Results of a systematic review and a survey amongst patients and clinicians on outcomes in vitiligo trials. *Br J Dermatol*. epub ahead of publication Doi: 10.1111/j.1365-2133.2012.11056.x

Protocol registration prior to start of recruitment into trials is still poor in eczema research

Take home message: protocol registration is an important and mandatory process that is designed to reduce publication bias and outcome reporting bias.

Study summary: this study looked at all eczema randomised controlled trials published in the last five years and checked against the World Health Organization's Trials Registry Platform for evidence of trial registration prior to starting the trial. We found that only 18 of 109 RCTs had been registered prior to starting the trial, and only five provided sufficient detail in the trials registry to be able to ascertain whether or not outcome reporting bias was a problem.

Key publication: Nankervis H, Baibergenova A, Williams HC and Thomas KS. Prospective registration and outcome reporting bias in RCTs eczema treatments. *J Invest Dermatol* 2012 doi: 10.1038/jid.2012.231.

How should an incident case of atopic dermatitis be defined?

Take home message: there is a need for improved reporting and standardization of the definition used for an incident case in eczema prevention studies. Most prevention studies have used disease definitions that include disease chronicity, which is problematic when aiming to capture a precise measurement of disease onset.

Study summary: this systematic review looked at how other researchers have defined an incident case of eczema in previous prevention trials. Of 102 trials identified, 27 (26.5%) did not describe any criteria for defining an incident case. Of the remaining 75 studies with reported disease criteria, the Hanifin-Rajka criteria were the most commonly used (28 studies). A disease definition unique to that particular study (21 studies) was the second most commonly used disease definition, although the sources for such novel definitions were not cited.

Key publication: Simpson EL, Keck LE, Chalmers JR, Williams HC. How should an incident case of atopic dermatitis be defined? A systematic review of primary prevention studies. *J Allergy Clin Immunol* 2012; 130(1):137-44.

How to reply to referees' comments?

This paper is from back in 2004, but due to popular demand we thought it was worth sharing it with you again.

Key publication: Williams HC How to reply to referees' comments when submitting manuscripts for publication. *Am Acad Dermatol* 2004;51:79-83.



My involvement

“It was my involvement as a consumer member of the Cochrane Skin Group and encouragement from Professor Hywel Williams that inspired me to lead the Cochrane review of interventions for vitiligo, published in 2006.

I was appalled at the paucity and poor quality of the studies we found. The review highlighted a desperate need for at least one good trial on which to base clinical decisions, but there were many unanswered questions and basic scientific knowledge about the disease was lacking.

In 2002 I agreed to become the patient representative on the Steering and Executive Committees of the UK DCTN. I was encouraged to submit a study suggestion, but it was hard to decide on the most appropriate research question, and so the study stayed

on amber for some years. During this time there was an explosion of published studies and an increase in our understanding of the nature of vitiligo, including the discovery of genes from a genome wide project, which placed vitiligo firmly among the autoimmune group of diseases.

After five years of working with researchers at the Centre of Evidence Based Dermatology, my vision finally became a reality, when the opportunity arose for me to contribute to a programme grant from the NIHR for four skin diseases including vitiligo. This has resulted in a priority-setting partnership with patients and clinicians that has identified the top 10 most important questions to be addressed by research.

A small pilot trial has been conducted and plans are underway for a large, multi-centre randomised controlled trial. Finally vitiligo has come out of the shadows.”

Setting the Dermatology research agenda

Over recent years there has been growing appreciation of the importance of identifying the right questions for future research, in order to ensure that finite research funding is targeted appropriately.

The Centre of Evidence Based Dermatology has conducted two Priority Setting Partnerships in collaboration with the James Lind Alliance: one for the treatment of vitiligo and one for the treatment of eczema.

All major UK funding bodies have been sent details of the topics that were agreed as being a top priority for patients and clinicians, and these will no doubt inform the research agenda for many years to come.

We are always happy to help and advise other groups who may be conducting similar partnerships, and have been pleased to advise colleagues from the United States and Canada as well as researchers in the UK. We have also contributed sections to the James Lind Alliance handbook, in order to share our experiences and lessons learned.

Evidence-based dermatology

There is real enthusiasm throughout the dermatology community to engage in and learn about Evidence-Based Dermatology. Our popular Getting to Grips with Evidence-Based Dermatology course is always oversubscribed, and we are getting more and more high-quality applications for the UK DCTN Fellowships and awards each year. It is a real pleasure to work with all of these enthusiastic and dedicated clinicians.

This year is the 10th anniversary for the UK Dermatology Clinical Trials Network — a network that has achieved so much more than we dared to hope. This model is now providing inspiration for other disciplines and networks throughout the UK and internationally. The ability to learn from each other and to encourage high quality research will be facilitated by the newly formed International Federation of Dermatology Clinical Trial Networks (www.ifdctn.org.uk), which provides a platform for collaborative research throughout the world.



Dermatology has been the focus of many NIHR commissioned funding calls in the last 12 months including:

- silk therapeutic clothing for eczema
- bath emollients for eczema
- narrow band UVB and topical steroids for vitiligo
- interventions for the prevention of hand eczema in healthcare workers
- interventions for the treatment of hand eczema

The work of the NIHR Dermatology Specialty Group also means that dermatology is one of the most successful groups with regards to participation in NIHR portfolio studies, and has delivered year on year improvements in the number of trials delivering to time and target.

Tackling research waste

After a decade of eczema research, what do we know?

How useful is the evidence?

- over 260 randomised controlled trials and 115 systematic reviews have been published since 2000
- however, useful clinical messages are scant

Where are we going wrong?

- research often addresses questions of little relevance to patients or clinicians
- inappropriate design or analysis limits interpretation

- different outcome measures are used, making comparison of trial findings difficult

What can be done?

- achieve international consensus over outcome measures for eczema
- register protocols and share them openly
- do fewer, but better quality studies
- implement what we DO know

Developing core outcome measures

The Harmonizing Outcome Measures for Eczema (HOME) initiative is gathering momentum in developing international consensus over a core set of outcome measures for use in future eczema research. This work is being supported through our NIHR Programme Grant award, www.homeforeczema.org.

Similar work is now being developed by members of the Vitiligo European Task Force for the development of a core outcome set in vitiligo trials, and work is underway to establish consensus over diagnostic criteria and outcome measures for erosive lichen planus of the vulva.

Making evidence easily available

The GREAT database now provides a one-stop shop for all trial and systematic review evidence relating to the treatment of eczema, www.greatdatabase.org.uk.

This openly accessible resource goes a long way in preventing the duplication of effort in identifying relevant eczema research.

We already have collaborative projects underway including:

- systematic reviews
- methodological projects
- informing guideline writers & patient information resources
- informing commissioning and QIPP agenda

Reporting evidence clearly and without bias

Hywel Williams continues to be an active member of the EQUATOR Group, 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, www.equator-network.org.

As a department we are keen to support initiatives that encourage:

- early registration of trial protocols
- full reporting of ALL outcome measures
- pre-specification of the primary (main) outcome
- publication of trial results in on-line registries

Implementing what we know

Members of the Centre of Evidence Based Dermatology regularly contribute to clinical guidelines, care pathways and patient information resources. In the last year these include:

- map of Medicine: cellulitis and erysipelas care map
- map of Medicine referral pathways for cellulitis, urticaria and scabies
- NICE Skin Cancer: prevention using public information, sun protection resources and changes to the environment
- NICE Quality Standards for eczema and malignant melanoma
- American Academy of Dermatology eczema guidelines

Evidence synthesis and dissemination

Many in the dermatology community feel the loss of the NHS Evidence Skin Disorders Specialist Collection. While many aspects of the old service are now provided through the NHS Evidence search engine, the emphasis on evidence synthesis and training is no longer so prominent.

As a result, the Centre of Evidence Based Dermatology now provides maps of systematic reviews and evidence summaries for eczema and acne on its website, and the popular Annual Evidence Update Meetings are a great way to keep up-to-date with the latest evidence.

Other resources available on our website include:

- summaries of key research papers
- Global Resource of Eczema Trials (GREAT Database) – containing all systematic reviews and randomised controlled trials relating to the treatment of eczema
- outcome measures and diagnostic criteria (including translations)
- clinical tools and patient resources

For more information see www.nottingham.ac.uk/dermatology

Institutional exchanges and invited lectures

Visitors to CEBD

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

In 2012, we were delighted to welcome Professor Neil Shear to Nottingham as the Stiefel Visiting Lecturer. This is the third time that the Centre has hosted the Stiefel lecturer and it is a visit that we always look forward to. Professor Shear gave a fascinating lecture on Stevens-Johnson/Toxic Epidermal Necrolysis, followed by a tour of the department and discussion of our research activities.



Prof Neil Shear during his visit as Steifel Lecturer 2012

Dr Jerry Tan, consultant dermatologist from Canada, also joined us for a day in May prior to attending the Evidence Based Update meeting on acne. This was a great opportunity to foster new collaborative links with colleagues working in the field of acne research and we put Jerry to work straight away by asking him to join the expert panel for the Q&A session during the conference.

“Thank you so much for being such gracious hosts for me during my brief visit last week. You were all so kind and helpful — I learnt so much from our afternoon together.”

Dr Jerry Tan, Canada

One of our Cochrane authors, Dr Gloria Sanclemente, from Columbia also joined the Centre of Evidence Based Dermatology for a week in June in order to work on her Cochrane review Anti-TNF agents for paediatric psoriasis.

“My stay in Nottingham was wonderful and extremely significant for my academic work. I have advanced really fast in finishing our protocol...People are all very kind to assist you in any matter. I definitely have enjoyed”

Dr Gloria Sanclemente, Medellin, Columbia

Other visitors to the Centre include Dr Alison Layton and Dr Anne Eady, who came to discuss ideas for collaborative acne research, Professor Anne Schilder, who is working to establish an ENT research network modelled on the work of the UK Dermatology Clinical Trials Network, and our UK Dermatology Clinical Trials Network fellows all of whom came for a three-day taster visit as part of their fellowship award.

“Thank you so much for spending time with Helen and Natalie last week, they were truly inspired (like me) by your team and work.”

Prof Anne Schilder of Paediatric Otorhinolaryngology and Director of ENT Clinical Trials Programme



Prof Hywel Williams and visiting consultant, Dr Jerry Tan

We have been fortunate to have been joined for a year by Dr Masaki Futamura — a paediatrician from Japan with a particular interest in allergic disease.

Masaki has been working with us as a visiting Research Fellow since January 2011 and is working with members of the Centre of Evidence Based Dermatology on several projects about the treatment of eczema including:

- a project that maps and summarises the key clinical messages from all eczema systematic reviews published since 2000
- an annual evidence update for eczema that summarises the key clinical messages from systematic reviews published in 2010 and 2011
- a systematic review of how investigator global assessment (IGA) is assessed in clinical trials of eczema
- development of a trial protocol for a future randomised controlled trial to be conducted on his return to Japan.

We are also looking forward to welcoming Dr Sebastien Barbarot from France, who will be joining the centre as a visiting fellow for nine months in 2013.

“Being in the department has given me the chance to experience high-quality clinical research conducted by a warm-hearted team! I shall do my best to make and apply “evidence” when I return home to Japan. I have just started a never-ending journey into the world of research.”

Dr Masaki Futamura, Japan

Collaborative links

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



National Institute of Health Research (NIHR) Clinical Research Networks

Comprehensive Local Research Networks (CLRNs)

All trials run through the Centre are registered on the NIHR portfolio of trials http://tiny.cc/NIHR_portfoliotrials and, as such, are eligible for support from CLRNs. 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 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 CLRNs. Such additional support has made an enormous difference in our ability to successfully recruit into these studies.

Medicines for Children Research Network (MCRN)

Dr Kim Thomas represented the interests of dermatology on the Medicines for Children's Clinical Studies Group for general paediatrics until the end of 2011 and Dr Joanne Chalmers is the scientific member for their Methodology Clinical Studies Group. The MCRN have continued to support our work by providing assistance for the Barrier Enhancement for Eczema Prevention study (BEEP) Further information on the MCRN is at: 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 (PCRNs) (www.crncc.nihr.ac.uk/about_us/pcrn) to help deliver dermatology research in this setting. 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) and the Hi-light pilot study on vitiligo.

Health Technology Assessment Programme

Prof Hywel Williams, Director of Centre of Evidence Based Dermatology, continues in his role as Chair of the NIHR Health Technology Assessment (HTA) commissioning board. The 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. For more information about the HTA and funding opportunities visit: www.hta.ac.uk.

Programme Grant for Applied Research

Dr Kim Thomas is a sub-panel member for the NIHR Programme Grant for Applied Research funding stream. This is a national response mode programme that aims to provide evidence to improve health outcomes in England through promotion of health, prevention of ill health, and optimal disease management, with particular emphasis on conditions causing significant disease burden. For further information please see: http://tiny.cc/NIHR_pgfar.

Clinical trials units and academic institutions

The Nottingham Clinical Trials Unit (CTU)

Trials developed by Centre of Evidence Based Dermatology are increasingly developed in collaboration with the Nottingham Clinical Trials Unit including the eczema studies CLOTHES and BEEP and the HI-Light study on vitiligo. In addition, we are working jointly on the delivery and management of several of our trials including STOP GAP and BLISTER.

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 DCTN 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, are involved in the SPRUSD Programme Grant and are also providing support for the work on erosive lichen planus.

Higher Education Institutions and Related Groups

We have a history of successful collaborative links with other Higher Education Institutions as outlined in the table below:

Institution	Study	Skin disorder
Universities of Aberdeen, Durham and Glasgow	STOP GAP	Pyoderma Gangrenosum
University of Oxford	BLISTER	Bullous Pemphigoid
Universities of Durham and Aberdeen Paul Sabatier University, France Toulouse University Hospital, France	SPRUSD NIHR Programme Grant	Eczema, Vitiligo, Pyoderma Gangrenosum, SCC
University of Oxford	NIHR Fellowship	Erosive Lichen Planus
Universities of Southampton, Bristol and Cardiff	BATHE	Eczema
University of Portsmouth	CLOTHES	Eczema
Universities of Hull and York	HABITS	Eczema
University of Newcastle	MATE	Eczema
University of Southampton	HI-Light	Vitiligo
Oregon Health and Science University, Portland, USA	BEEP	Eczema

East Midlands Research Design Service (RDS)

The Centre works with the East Midlands Research Design Service on grant applications submitted to the local Research for Patient Benefit funding scheme and they have been particularly helpful in supporting Dr Rosalind Simpson with her erosive lichen planus project.

Birmingham Clinical Trials Unit

Two large pilot studies on different forms of skin cancer have been developed between the UK DCTN 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 start recruiting shortly.

Working with patients and carers

Dermatology Patient Panel

The Centre of Evidence Based Dermatology has a long history of Patient and Public Involvement (PPI) in all stages of the research process including 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

This activity has been formalised over the past two and a half years by establishing our Dermatology Patient Panel. Funded by the SPRUSD 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 our research as we have access to a trained cohort of individuals to assist us in this way. The panel has approximately 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 on their website www.lindalliance.org

We have carried out two priority setting partnerships with the James Lind Alliance to date, one on vitiligo and one on eczema treatments; further details about these can be found

in the On-going Research section of this report. All research questions identified through these processes are submitted into the Database of Uncertainties about the Effects of Treatment (DUETs): www.library.nhs.uk/duets

INVOLVE

All of our studies that have involved patients and carers in the trial development process are registered on the Involve database, www.invo.org.uk 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 our work 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
- The Vitiligo Society: www.vitigosociety.org.uk
- The Psoriasis Association: www.psoriasis-association.org.uk
- The Lymphoedema Support Network: www.lymphoedema.org
- Skcin: www.skcin.org
- DebRA: www.debra.org.uk

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

As part of our longstanding interest in atopic eczema, some members of CEBD staff along with colleagues from the clinical dermatology department at Queens Medical Centre, Nottingham (Sandra Lawton, Jane Ravenscroft, Ruth Murphy and Hywel Williams) have worked closely with volunteers who run the Nottingham Eczema Support Group for Carers of Children with Eczema (Colin Gibb and Amanda Roberts). They have done a fantastic job in setting up an award winning 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 at: www.nottinghameczema.org.uk.

Highlights of the past year:

- 3500th follower of our Twitter feed, with over 55,000 tweets to date
- over 30 patient information leaflets are now available, over half of which are in audio format
- involvement in the research priorities for eczema treatments uncertainties being run by Centre of Evidence Based Dermatology
- outreach at two events: the November 2011 meeting of the British Society of Paediatric Dermatology and the July 2012 Regional Child Health conference.
- giving support and advice to a Support Group for childhood eczema setting up in Singapore
- involvement in NHS Choices on line clinic for eczema (September 2011)
- contribution to the Department of Health Teledermatology standards

Looking to the future, we are planning to redesign our website and hoping to be able to contribute to the Eczema in Children Quality Standard.

Recent twitter accolades:

"If you suffer from eczema, please follow @eczemasupport for great tips & reassurance that you're not going through this alone."

"This is an excellent example of an interactive, engaging socmed account: @eczemasupport."

"Much appreciation for @eczemasupport. Caring for a child w/ severe allergies & eczema is really stressful & a listening ear really helps."

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 BAD for topic prioritisation through the HTA programme. We are extremely grateful to the BAD for providing funding for the post of the Senior Trials Development Manager for the UK Dermatology Clinical Trials Network from 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 activities in the journal Dermatological Nursing and liaising with members of the BDNG Scientific Committee who are represented on the Network's Steering Committee by Fiona Cowdell.

Society for Academic Primary Care (SAPC) Skin Research Special Interest Group

This group is lead by Dr Matthew Ridd, an NIHR lecturer in Primary Care at Bristol University. Dr Kim Thomas and Prof Hywel Williams are members of this newly formed group and their inaugural meeting was held in December 2011. We are now working together on our first grant application (BATHE) — Bath Emollients for Eczema in collaboration with the Universities of Southampton, Bristol and Cardiff and the group helped with the eczema treatments priority setting partnership. Dr Kim Thomas along with Dr Ridd and other group members are running a workshop together at the Royal College of General Practitioner's Annual Conference in Oct 2012 on childhood eczema.

UK Dermatology Translational Research Network

This is a new network established in the past year, which aims to develop translational/biomarker research in skin biology and skin disease and is chaired by Prof

Nick Reynolds of the University of Newcastle. The UK Dermatology Clinical Trials Network have been involved in helping to establish this network which will bring together scientists and clinicians to develop a UK strategy for translational research in dermatology. The two networks have worked together on a study comparing the use of methotrexate and azothioprine to treat adult eczema, which was submitted to the the NIHR and MRC Efficacy and Mechanism Evaluation programme in July 2012.

Nottingham University Hospitals NHS Trust

The Nottingham University Hospitals NHS Trust continues to recognise dermatology as one of its priority research topics. We are grateful to Research and Development for their continuing support of our work.

NHS Trusts

All of our 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 trials 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 produced by the Centre is disseminated through this channel and fed into relevant patient information.

National Institute for Health and Clinical Excellence

Members of the Centre are registered as stakeholders with NICE and regularly comment on relevant NICE guidelines and appraisals.

Map of Medicine

Dr Kim Thomas sits on the Board of Fellows for Map of Medicine and along with Prof Hywel Williams and clinical colleagues has commented on a number of care pathways including eczema and psoriasis.

Royal College of Physicians (RCP)

Prof Hywel Williams has worked with the RCP (in collaboration with the EQUATOR transparency of trial reporting group) to develop a statement on the clear reporting of research studies.



“Having worked at Nottingham University Hospitals NHS Trust for 25 years I have been in the privileged position of watching the Centre of Evidence Based Dermatology develop from its inauguration. Working with this evolving and professional team has meant I have witnessed the difference they have made to dermatology research, health professionals knowledge and patient care.”

[Sandra Lawton, Nurse Consultant at Nottingham University Hospitals NHS Trust](#)

Working closely with clinical colleagues

Researchers at the Centre of Evidence Based dermatology work closely with clinical colleagues at Nottingham University Hospitals NHS Trust, as well as with colleagues throughout the country.

In 2011, three Nottingham-based Consultant Dermatologists (Dr Ruth Murphy, Dr Jane Ravenscroft and Dr Sandeep Varma) were appointed as Honorary Consultant Lecturers at the University. This has allowed greater collaborative working between the University and the Trust.

In addition, NIHR Flexibility & Sustainability funds have been used to support two Clinical Research Fellow posts in the department. Consultant Dermatologist, Dr Jonathan Batchelor now works with us one day per week in order to develop research skills and to support future NIHR grant applications. Dr Rosalind Simpson joined the department on a full-time basis in 2011 and has recently been successful in securing an NIHR Fellowship award to complete her PhD on the management of erosive lichen planus of the vulva.

We host two NIHR Academic Clinical Fellows (ACFs) appointed in 2010 and 2011. Dr Kyle Tang is working on a project looking at the role of autoimmunity in eczema, and Dr Ketaki Bahte is working on a project looking at the role of diet in acne.

We also have several honorary members of the Centre of Evidence Based Dermatology for colleagues working external to the University. These include: Dr Julia Schofield, who led the Health Care Needs Assessment for Skin Conditions in the UK (www.nottingham.ac.uk); Dr Carolyn Charman, who continues to work with us in developing and refining the Patient Oriented Eczema Scale (POEM); and Dr Sarah Garner (Associate Director for Research and Development, Clinical and Public Health Directorate, NICE), who works closely with the Cochrane Skin Group.

Training

The Centre of Evidenced Based Dermatology are keen to support anyone with an interest in evidence-based dermatology through a variety of studentships, fellowships and awards.



PhD studentships

We have five 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. Further information on the individual projects can be found in the on-going research section of this report:

- Helen Nankervis: Reducing Uncertainties for People with Eczema
- Louise Lansbury: An Evidence Based Approach to Optimising the Management of Squamous Cell Carcinoma of the Skin
- Viktoria Eleftheriadou: Setting Priorities and Reducing Uncertainties for People with Vitiligo
- Ser-Ling Chua: The clinical response of skin disease to anti-retroviral therapy (ART) in Uganda
- Rosalind Simpson: Vulval Erosive Lichen Planus: Defining the Disease, Developing Outcome Measures and Designing a Randomised Controlled Trial

NIHR Academic Clinical Fellows (ACFs)

Centre of Evidence Based Dermatology have hosted a dermatology ACF position for the last two years. This allows dermatology trainees at an early stage of their career to experience a research environment and develop an academic career.

Dr Kyle Tang joined the centre in July 2010 and is currently developing a project investigating the early aggressive treatment and disease-modification strategies for eczema. His research on the role of autoimmunity in eczema activity has been published in the Journal of Allergy and Clinical Immunology and has been invited to present his research at international meetings such as International Dermato-Epidemiology Association Congress (IDEA) and the annual meeting of the European Society for Dermatological Research.

Dr Ketaki Bhate joined us in July 2011. Her main research interest is in acne and she is currently working up an epidemiological project in this. She has presented her work so far at the BAD annual meeting and also at the 2012 Annual Evidence Based Update Meeting on Acne and Rosacea. She will also be presenting at the International Dermato-Epidemiology Association Congress (IDEA).

Clinical Research Fellows

Based on Hywel Williams's status as an NIHR Senior Investigator, the Centre of Evidence Based Dermatology has 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. In addition, Dr Rosalind Simpson an ST5 Trainee, is working with us for four days a week to develop a fellowship application for a study on erosive lichen planus and is registered for a PhD. She has recently been conditionally awarded an NIHR Doctoral Research Fellowship to continue this work.

Joint BAD/NIHR Travel Award

Along with other NIHR Senior Investigators in the field of dermatology (Profs Frank Nestle and Chris Griffiths) Hywel Williams has joined forces with the British Association of Dermatologists (BAD) to offer a joint BAD/NIHR Travel Award. The aim of this annual award is to promote interest in developing a career in UK based dermatology research to clinicians at the early stages of their profession. The award includes a travel bursary to attend a large dermatology research meeting and/or a research taster/visit bursary to spend time in a relevant dermatology research department. Seven awards were made in 2011/12.

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 clinical appraisal to help cultivate the next generation of research active and aware dermatologists. The Fellowship involves:

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

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. In 2012, Fellowships were awarded to Dr Rachel Abbott (Cardiff) and Dr Fiona Meredith (Aberdeen), with the latter obtaining the Neil Cox award. Highlights for past and present UK DCTN SpR Fellows over the past 12 months include Dr Rubeta Matin being awarded the THESIS prize for her PhD, Dr Kave Shams being awarded a Wellcome Trust Fellowship to undertake a PhD and as mentioned above Dr Rosalind Simpson being awarded an NIHR Doctoral Research Fellowship.

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. The winner of the 2012 SAS Award was Dr Areti Makrygeorgou an Associate Specialist grade doctor based at Western Infirmary, Glasgow.

Nursing Prize Award

To strengthen links with the dermatology nursing community a UK DCTN nursing prize has also been set up. Following discussions with the dermatology nursing community we have redeveloped the Nursing Prize Award so that it now reflects those awards offered to clinicians so, from 2011 onwards a two year award of £1500 with activities mirroring those of the SpR Fellowship Award will be available. The winner of the 2011 Nursing Prize was Angela Steen, a dermatology nurse consultant based in Rhyl, North Wales.

GP Fellowship Award

The UK DCTN have launched a GP Fellowship in 2012 to encourage greater collaboration with primary care colleagues. It will offer the same opportunities as the other award over a 2-3 year period and will be open to GPST's and GPs with an interest in dermatology research.

Events

Each spring the Centre holds an Annual Evidence Based Update Meeting, chaired by 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 year's 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 topic of interest for the 2011 meeting was psoriasis and speakers included Chris Griffiths, Jonathan Barker, Peter Wolf and Anne Mason. The 2012 meeting focused on acne and rosacea, and also saw the launch of the UK Dermatology Clinical Trials Network themed research call, part of the UK Dermatology Clinical Trials Network 10th birthday celebrations. Additionally, the meeting was attended by a representative from the NIHR who is investigating the potential for such meetings to identify priority areas for future commissioned calls. At this event, Christos Zouboulis spoke about a better understanding of acne pathogenesis, Fabienne Forton about the role of Demodex in rosacea, while Anders Sundstrom spoke about his research looking at acne, isotretinoin and suicide risk. A full list of speakers and selected presentations from the meetings can be found at: www.ukdctn.org/meetings/evidence

Feedback from delegates indicates a very high overall satisfaction rating for the meeting, with the Questions & Answers session and the open, interactive nature of the day being 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 is extremely useful.

What the delegates said

"Brings the experts together in a tight, relevant, focussed and interactive meeting."

"A good mixture of presentations; research and reviews."

"I will have better patient management based on this evidence-based knowledge."

"A very good programme with clinical relevance."

We were delighted to see Dr Jerry Tan (Canada), an international expert on acne, at the 2012 meeting,

"I found the way you conducted the evidence-based meeting in acne and rosacea to be both extremely engaging and impactful as the content was continually refocused on the needs of patients and practitioners. Past EBM meetings I have attended without your focus and forethought often come off being extremely methodological and mechanical – with little useful information for patient care. I wonder if there is a way to develop your process of running the EBM update in a similar manner in Canada/USA?."

The next meeting will be held on Thursday 23 May 2013 and will cover vitiligo and other pigment disorders. For further details contact the UK Dermatology Clinical Trials Network Manager at: carron.layfield@nottingham.ac.uk

References

Eczema: an evidence based update. Report on the 9th Nottingham evidence based update meeting, 13th May 2010, Loughborough UK Flohr C and Powell AM British Journal of Dermatology 2012 163 (3): 456-457

Psoriasis: an evidence-based update. Report on the 9th evidence based update meeting 12th May 2011, Loughborough UK DeMozzi P, Johnston G and Alexandrov AB British Journal of Dermatology 2012 166 (2): 252-260

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

This three day course is taught by staff from the Centre of Evidence Based Dermatology along with colleagues from Primary Care and Rheumatology. 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. A one day BEES Summer School is also held every other year, which focuses on writing and publishing papers.

What the delegates said

"Very inspirational – now need to get on and do some work. Have not really enjoyed any course as much as this one (no bias!)."

"Very enjoyable course. The interactive sessions were very helpful, the learning atmosphere was safe and I felt confident to contribute."

"I thought that doing the practical group work after each session was excellent and learnt a lot from this. Found it very helpful to discuss what I didn't understand on a one to one basis."

"All sessions highly educational and thought provoking. The course as a whole is very well thought out. The best course I have been to!"

For further details of the next three day course (Wednesday 30 January – Friday 1 February 2013), contact: margaret.whittingham@nottingham.ac.uk or visit the BEES website at www.bees.org.uk

Patient Panel Training Events

The latest training event for members of our Patient Panel took place on Monday 21st May 2012 at Attenborough Nature Reserve in Nottingham. Eleven panel members attended and the programme for the day focussed on elements of clinical research that panel members had asked for further training on including the lifecycle of a clinical trial, terminology used in Cochrane systematic reviews, and applying research findings to clinical practice. The afternoon session of the meeting was taken up by workshops about current projects in development. These included a pilot study on squamous cell carcinoma and a number of eczema studies in development.

What the delegates said

"Fantastic pack of information with additional info sheets (especially on Cochrane) that I can take away and read."

"Hywel's session really hit a chord on how patient/doctor/evidence relationship should work."

"An excellent day, good team building and communication forum."

"It's great to meet up with everyone and learn from others."

Meet the team

Professor Hywel Williams, Director of CEBD

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

Hywel's main interests include the promotion of evidence-based dermatology and the epidemiology and treatment of childhood eczema. Hywel chairs the UK Dermatology Clinical Trials Network and is Coordinating Editor of the Cochrane Skin Group. He has been national chair of the NIHR Comprehensive Clinical Research Network Dermatology Specialty Group since it started in 2007.

Outside of dermatology, Hywel was Director of Research and Development at Queen's Medical Centre NHS Trust from 1998 to 2001, and then became Director of the Trent Institute for Health Services Research (TIHSR) from 2000 to 2004. Hywel chaired the National Research Development Support Unit network from 2004 to 2006. He founded and then directed the University of Nottingham Clinical Trials Support Unit from 2007 to 2010, which is now a flourishing and successful accredited CTU. Hywel chaired the Research for Patient Benefit Programme for East Midlands from 2007 to 2010.

In 2010, Hywel was appointed as chair of the NIHR Health Technology Assessment Commissioning Board and deputy director of the HTA Programme, a post he still holds to this day.

Hywel has published over 340 peer-reviewed articles, including papers in Nature, the NEJM, Lancet and BMJ, and three books. He has raised over £7m in non-commercial externally funded research into health technology assessment in relation to skin disease. Hywel was awarded an NIHR senior investigator award in the first competition round, an award which was renewed in 2012.

CEBD Deputy Director



Kim Thomas, Associate Professor (non-clinical)
Kim was appointed Associate Professor at the Centre of Evidence Based Dermatology in April 2005 and is Deputy Director. Her interests are in the design and conduct of dermatology clinical trials, and in

clinical trial methodology, especially outcomes research. She is a founder member of the UK Dermatology Clinical Trials Network, and is Programme Manager for an NIHR Programme Grant Award (PGfAR) — Setting Priorities and Reducing Uncertainties for people with Skin Disease (SPRUSD). Kim is Deputy of Research for the School of Clinical Sciences and Deputy Chair of the School's Research Committee. She is a panel member for the NIHR Programme Grants for Applied Research (PGfAR); an affiliate member of the Health Technology Assessment (HTA) Commissioning Board; a member of the Board of Fellows for Map of Medicine, and an adviser to the National Institute for Clinical Excellence (NICE). She is assistant section editor for Evidence-based Dermatology in the *Journal of the Spanish Academy of Dermatology and Venereology (Actas Dermosifiliograficas)*.

Academic and 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, researching 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 completed 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 did his dermatology specialist training at Addenbrooke's Hospital, Cambridge. During this time he was awarded one of the first UK DCTN 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.



Fiona Bath-Hextall, Associate Professor and reader

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

collaboration since 1995 and has authored more than 23 Cochrane reviews. For the last six years her main research area has been non-melanoma skin cancer (NMSC). Fiona leads the squamous cell carcinoma stream of work for the NIHR programme grant. She is the grant holder for the SINS study, funded by Cancer Research UK and PI for the SCENE study (a mixed methodology study looking at the needs/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 used primary care databases (THIN database) to look at the incidence of basal cell carcinoma (BCC) in primary care and to investigate the relationship of smoking with BCC.



Ketaki Bhate, NIHR Academic Clinical Fellow

Ketaki is an ST4 NIHR Academic Clinical Fellow (ACF). She trained at Imperial College London qualifying with a B.Sc degree in Paediatrics in 2005 and a medical degree in 2007. She worked in West London as part of the

Imperial College Healthcare NHS Trust as a junior doctor before coming to Nottingham. As an ACF in dermatology Ketaki undertakes research at the CEBD alongside her clinical training. Her main research interest is in acne vulgaris, and in particular the epidemiology of acne and how the disease can be modified by lifestyle changes.



Nafisa Boota, Clinical Trial Manager

With a degree in Biological Sciences, Nafisa was a clinical research assistant at the Oncology & Haematology Trials Unit (UHL NHS Trust) for three years, collecting data for patients mainly on early phase commercial trials. She coordinated paediatric leukaemia and

brain tumour trials for the Children's Cancer and Leukaemia Group (CCLG). Nafisa joined the CEBD in 2009 to manage the LIMIT-1 study, a multicentre, open-label, single-arm trial to establish the pathological complete regression rate of lentigo maligna following topical treatment with imiquimod. Nafisa is studying for an MSc in Oncology.



Dr Joanne Chalmers, Research Fellow
With 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 the 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 works 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. This is in addition to 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, Queen's Medical Centre, in December 2004 as a specialist registrar. She spent a year in Mbarara, Uganda studying skin disease in HIV-infected patients on anti-retroviral therapy. Dr Kim Thomas is her academic supervisor for her research degree based at Nottingham. She is working under the mentorship of Dr Toby Maurer at the Department of Dermatology, University of California.



Tessa Clarke, UK DCTN Senior Clinical Trial Development Manager

With 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
Sue qualified in 1995 and has worked in a variety of adult nursing specialities, including Endoscopy, Theatre Recovery, Rheumatology and Dermatology. Sue joined the CEBD in March 2007 as a research nurse working initially on the

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 Clinical Research Nurse on various other trials within the department, including the PATCH studies, BEEP, STOP GAP, BLISTER, BADBIR, Hi-light Vitiligo and the Genetics in Acne Vulgaris study.



Finola Delamere, Managing Editor, Cochrane Skin Group
Finola's biochemistry-based PhD involved investigating the forensic identification of human seminal plasma. She worked for the Forensic Science Service. In Nottingham, she undertook laboratory-based research in cystic

fibrosis and asthma. As Managing Editor of the Cochrane Skin Group, Finola works with Cochrane review authors to produce protocols and reviews. 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 the 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 degree in Information Studies, a Postgraduate Certificate in Public Services Management and is a Chartered Member of the Chartered Institute of Library and Information Professionals (MCLIP). Liz works with Cochrane authors to design highly-sensitive search strategies, and identify studies for their reviews. She builds and maintains the Skin Group's specialised register of skin-related clinical trials, and makes submissions to The Cochrane Library's CENTRAL database.



Viktoria Eleftheriadou MD, PhD Student and Research Associate

After completing her Medical degree and pre-registration jobs in Greece, Viktoria continued her medical career in the UK. She worked for the NHS in various hospitals, 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', which includes vitiligo priority setting partnership, outcomes measures for vitiligo trials and pilot trial on hand held NB-UVB home phototherapy. She is also studying for a PhD on vitiligo at The University of Nottingham (2009-2012).



Katharine Foster, Clinical Trials Manager
Kath worked as a research scientist in Atlanta (USA) and the Institute for Animal Health in the UK following her PhD in Salmonella pathogenesis. She moved into clinical trials in 2001, initially in oncology (colorectal cancer) for an academic trials unit in Oxford.

After a spell in industry in the field of medical devices (orthopaedics), she moved back to academic trials in stroke medicine. Kath 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 are available. Kath manages the BLISTER study, investigating treatments for Bullous pemphigoid.



Masaki Futamura,
Masaki worked as a paediatrician after graduating from Nagoya University, Japan, in 1998. He completed a PhD in paediatric allergy investigating skin irritation by volatile organic compounds. He is a consultant paediatrician and a consultant allergist in Japan. Masaki

has worked at the CEBD in 2012, mainly updating and summarising the Map of Systematic Reviews on atopic dermatitis and creating a manual to maintain the quality of future work. In addition to collecting published systematic reviews, he is conducting two systematic reviews in collaboration with international colleagues.



Louise Lansbury, PhD Student and Research Associate

After graduating in Medicine, Louise worked as a clinical microbiologist in hospitals around the UK. She 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*. 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 Leonardi-Bee, Statistical Editor, Cochrane Skin Group

Jo completed a MSc and PhD in Medical Statistics, and is an Associate Professor in Medical Statistics. Her areas of expertise focus on systematic review and meta-analysis of epidemiological studies and randomised controlled trials; and analysing large databases, such as the Health Improvement Network (THIN) Primary Care database. Her PhD thesis used several individual patient data meta-analyses in the area of stroke medicine to determine the benefits and limitations of using individual patient data meta-analyses as compared to analysing summary level meta-analyses. Her expertise has enabled her and other colleagues to secure more than £8m external funding for research. She has been the Statistical Editor of the Cochrane Collaboration Skin Group for more than eight years, and has published more than 50 peer-reviewed papers, including 30 systematic reviews and meta-analyses on various risk factors and interventions for a range of medical diseases, predominately in the areas of tobacco control, dermatology and respiratory medicine.



Jo Llewellyn, Trent CLRN Funded Clinical Research Nurse

With a BA (Hons) in Nursing Studies, Jo has worked as a team leader for a contract research organisation, on phase 1 and 2 clinical trials, as a Drug Surveillance Executive for Roche and as a Clinical Project Manager for ClinPhone,

Nottingham. Jo joined the CEBD in January 2003 and has been the research nurse on the SINS trial and recruiting into the PATCH studies. Jo has also obtained an MSc in Science from the Open University. She is a CLRN Research Nurse on the following dermatology trials: STOPGAP (Pyoderma gangrenosum), BLISTER (Bullous pemphigoid), BADBIR (psoriasis), Genetics in Acne, Hi-Light (vitiligo), Susceptibility Genes for Eczema and Food Allergy and B-STOP (psoriasis).



Eleanor Mitchell, Clinical Trial Manager

Eleanor is the Trial Manager for the STOPGAP Trial, which is a multi-centre trial (around 50 sites) investigating treatments for pyoderma gangrenosum, a rare, ulcerative skin condition. She is based in the Nottingham Clinical Trials Unit at the Queen's Medical Centre. She joined the CEBD in 2008 having previously worked in clinical research for eight years as Project Coordinator 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.



Ruth Murphy, Clinical Director for Dermatology at Nottingham University Hospitals NHS Trust

Ruth was appointed as Honorary Consultant Lecturer at The University of Nottingham in 2011 in acknowledgement of her work in supporting NIHR portfolio studies, in particular the BADBIR study

looking at the long-term safety of systemic treatments for psoriasis, for which Nottingham has been one of the top recruiting centres. Ruth has a special interest in paediatrics and chronic inflammatory skin diseases, including eczema and psoriasis. She carried out her PhD in the genetics of atopic dermatitis and how genetics influences eczema severity. She is clinical supervisor for Rosalind Simpson's work on erosive lichen planus of the vulva and internal assessor for Serling Chua's work on skin disease as a marker for response to anti-retroviral therapy in HIV infected patients.



Helen Nankervis, PhD Student and Research Associate

With a degree in Medical Microbiology from Leeds University, Helen designed A-Level Microbiology practical experiments for the Society for General Microbiology and worked on clinical trial data before joining the CEBD in 2005 as

the editorial assistant for the Cochrane Skin Group. She is as a research associate on the eczema treatments work stream of the SPRUSD programme grant, which involves undertaking a systematic review of all treatments for eczema and creating a database of RCTs of eczema treatment. She is also studying for a PhD.



Jane Ravenscroft, Consultant Dermatologist

Jane is based at Queen's Medical Centre in Nottingham, with a clinical workload divided between Nottingham and Mansfield. She specialises in paediatric dermatology, and is a faculty member of the British Society of Paediatric

Dermatology. As an SpR in Nottingham in 2003, Jane co-authored a Cochrane systematic review of anti-staphylococcal interventions for atopic eczema, and is involved in research with the CEBD. She was awarded an Honorary Consultant lecturer post at The University of Nottingham in June 2011, and has one dedicated research session per week funded by the NIHR Comprehensive Local Research Network. Jane is interested in clinician and patient involvement in research and has worked on Priority Setting Partnerships to determine joint priorities for research into vitiligo and eczema, in conjunction with the James Lind Alliance. She is a clinical PhD supervisor and Trust representative for the NIHR Programme Grant for Applied Research award – Setting Priorities and Reducing Uncertainties for people with Skin Disease (SPRUSD), and is Principal Investigator for the HI-LIGHT pilot trial of hand held UVB for vitiligo. She is local PI for a number of UK DTN trials, and is part of a research committee to increase research activity in Mansfield. Jane is a member of the NICE committee developing National Quality Standards for Eczema in Children.



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

treatments for mild to moderate acne. This trial ended in 2002, and was published in *The Lancet* (Dec 2004) and as an HTA monograph (Jan 2005). Mara has also delivered occasional lectures in trial management and statistical topics and in 2007 achieved associate teacher status. In 2002 Mara took over responsibility for the SINS trial — a randomised controlled trial of Surgery vs Imiquimod five per cent in Nodular and Superficial basal cell carcinoma. This multicentre, hospital-based trial completed three-year follow-up of 501 participants in May 2010, and five-year follow-up of hospital and GP notes in July 2012.



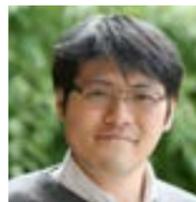
Rosalind Simpson, Dermatology Clinical Research Fellow
Rosalind studied at The University of Nottingham Medical School and completed a BMedSci degree in 2002 and BMBS degree in 2004. She has worked at Derby Hospitals NHS Foundation Trust, Nottingham University

Hospitals and University Hospitals Leicester 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 multicentre case note audit. In June 2011 Rosalind started a full-time Clinical Research Fellow Post at the CEBD to progress this work



Sherie Smith, Research Assistant
Sherie joined the CEBD in September 2011 as a research assistant. With a degree in Human Biological Sciences, she qualified as a nurse and worked in the NHS. She studied for a Master of Public Health and had a career in research. She has worked as an

information specialist at North Nottinghamshire Health Authority and came to the University in 2003. She has worked on research projects relating to injury prevention and hepatitis C. She helps maintain the GREAT database.



Ting Seng Tang (Kyle), NIHR Academic Clinical Fellow
Kyle graduated from Imperial College London with a BSc degree in Immunology and Pathology in 2006 and MBBS degree in 2008. He has worked as an academic foundation doctor and honorary clinical research

fellow at Swansea University on oxidative stress and genetic polymorphism epidemiology in patients with type II diabetes. With an interest in epidemiology, he joined the Department of Dermatology, Queen's Medical Centre, and CEBD in 2010 as an academic clinical fellow.



Sandeep Varma, Consultant Dermatologist
Sandeep is a consultant dermatologist and dermatological surgeon with an interest in Mohs micrographic surgery for skin cancer. For the past two years he has been Section Editor for the *British Journal of Dermatology* for

the skin cancer, skin surgery and lasers section and he was appointed as Honorary Consultant Lecturer at The University of Nottingham in 2011. His research interests are in photodynamic therapy (PDT) for basal cell carcinoma, intraepidermal carcinoma (Bowen's disease) and solar keratoses. He has been involved in multicentre international studies on PDT and has published over 100 abstracts and manuscripts. Sandeep co-founded the Karen Clifford Skin Cancer Charity (SKCIN) and as Chairman (2006-8) helped to raise over £33,000 for the charity.

Administrative, Professional and Managerial



Lisa Charlesworth, Trent CLRN Funded Clinical Trials Administrator
After working as an administrator at the Clinical Trials Unit, University of Nottingham, for three years, Lisa joined the CEBD in September 2009 to work as a trials administrator on projects funded by the UKCTN. Having a BA (Hons) degree in Communication Studies, prior to joining the University she worked in marketing and graphic design. Lisa is on secondment to the University of Manchester, working on the BADBIR (British Association of Dermatologists Biologics Interventions Register) as a Clinical Research Associate for the UK (Eastern region).



Bryony Elliott, Research Administrator
With a BA (Hons) Business Administration, Bryony was a security analyst for a global information solutions firm. She joined the CEBD in August 2009 providing administrative support. Her role involves purchasing, business management website maintenance.



Sally Kucyj, Trial Administrator
With a degree in BSc (Hons) Psychology in 2008 Sally worked as a research assistant for Nottinghamshire Healthcare NHS Trust and then the Data Management section of Nottingham Clinical Trials Unit. Sally joined the CEBD in September 2011. She provides

administrative support to the STOP GAP and BLISTER trials and the trial managers.



Carron Layfield, UK Dermatology Clinical Trials (UK DCTN) Network Manager
With a degree and a PhD in Biochemistry, Carron spent three years in academic scientific research at The University of Nottingham. She had a career in life science sales and marketing before joining the CEBD in November

2006. Carron is Network Manager for the UK DCTN and is responsible for developing and promoting the network. She is also the lead for the CEBD Patient Panel, organising the Annual Evidence Based Update Meeting and co-ordinating CEBD publicity. Carron also supports Prof Hywel Williams in his role as Chair of the NIHR Dermatology Specialty Group.



Johanna Perdue, Trent CLRN Funded Clinical Trials Administrator
Jo joined the CEBD as a temp in March 2009, offering administrative support to the Trial Manager of the PATCH study, helping to boost recruitment (PATCH eventually recruited above target). She became a more permanent member in

August 2009, and works as a clinical trial administrator on CLRN-funded studies adopted on to the NIHR portfolio. Jo had previously worked for over 20 years in textiles. During this time she achieved her ambition to return to study, graduating from the Open University in 2006 with a First-Class Honours degree in Literature.



Barbara Maston, Research Administration Assistant
Barbara joined the CEBD in December 2011 and provides administrative support for the SPRUSD programme grant. She monitors finances, plans meetings, prepares newsletters and tracks SPRUSD outputs and publications.



Margaret McPhee, UK DCTN Administrator
Margaret joined CEBD in January 2007. She provides administrative support to the UK DCTN Senior Clinical Trials Manager and Network Manager. She manages the membership database and the UK DCTN website, producing

publicity material and monitoring finances.



Laura Prescott, Editorial Assistant Cochrane Skin Group
Laura is editorial assistant for the Cochrane Skin Group (CSG), supporting the Managing Editor, Finola Delamere. She communicates with authors and contributors, ensures deadlines are met and edits copy. She also manages the

folders within the electronic and paper systems, maintains records of the group membership's contact details, 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 Professor Williams and is the departmental administrator for research, teaching and general business management. Her role also involves the

organisation of undergraduate and postgraduate teaching activities in the dermatology department. She also helps organise the BEES course and annual meeting, and other national and international meetings.

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Notes



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