



The University of
Nottingham

UNITED KINGDOM · CHINA · MALAYSIA



Annual Report

June 2011



**National Institute for
Health Research**

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WELCOME FROM THE CHAIR

What a wonderful year it has been for the UK Dermatology Clinical Trials Network, and all thanks to you - our supporters. The UK DCTN is now truly a mature network with its pipeline of new ideas and studies in development. Some of these studies then progress to national clinical trials that in turn are supported by the clinicians and research nurses belonging to the wonderful NIHR Comprehensive Clinical Research Network (CCRN).



What is special about this year is that we have completed two of our national clinical trials – in other words, the fruits of our labours are starting to emerge. The first UK DCTN trial to report is the PATCH II study which sought to explore whether low dose penicillin given to people with one or more episode of cellulitis of the leg can prevent recurrences – an idea that the late Neil Cox suggested to us when the network started. Recruitment was a struggle, but the findings were interesting in that those on penicillin had around half as many recurrences than those taking placebo – a result that almost reached the conventional level of significance. We are now eagerly awaiting the results of the larger PATCH I trial which explored a similar question but only in people with at least two previous episodes of cellulitis. Our adopted study, the Softened Water Eczema Trial (SWET) was designed to see if ion exchange water softeners help children with eczema, also reported this year. Despite our initial hopes that softened water would help children with eczema, the trial did not show any clear benefit. Sometimes “negative” results like this are really helpful when they are conclusive because they provide evidence to inform parents.

Our ongoing studies continue to keep us busy. Two of our national studies of less common skin conditions– bullous pemphigoid (BLISTER) and pyoderma gangrenosum (STOPGAP) are past their midway point in recruiting from over 50 centres throughout the UK. Such studies would never be completed without our network and the CCRN, and although recruitment is always challenging we are getting there in both studies. Other studies such as the LIMIT-1 study on lentigo maligna and the SINS study on topical imiquimod for basal cell carcinoma are reaching their final stages whilst others such as topical treatments to prevent squamous cell carcinoma in transplant patients are just starting.

Good people and process is at the heart of the UK DCTN. The addition of Tessa Clarke (Trial Development Manager) to our core staff, kindly funded by the British Association of Dermatology, means that we will now be able to give much more dedicated help to progressing the good ideas that our clinicians wish to develop. Our training activities are also flourishing with another very successful 2011 Annual Evidence Update on the topic of psoriasis, which was delivered in collaboration with UK leaders in the field. Another three outstanding UK DCTN Specialist Registrar Fellowships have joined our ranks, and we hope that these Fellows will become our leaders in the future. The time for conducting high quality clinical research that can help NHS patients has never been better, and the Network is flourishing in such a climate. Colleagues in the US are now thinking of developing a similar network based on the UK DCTN, and I am sure other countries will follow. What a compliment.

Professor Hywel Williams
Chair of the UK Dermatology Clinical Trials Network



About the UK DCTN

The UK Dermatology Clinical Trials Network (UK DCTN) is a national dermatology clinical trials network open to anyone with an interest in applied dermatological research. It was founded by Professor Hywel Williams and a group of other academic and clinical colleagues in 2002 in response to the growing need for high quality evidence to inform dermatology clinical practice.

The aim of the Network is to conduct high quality, independent, multi-centre, randomised controlled clinical trials for the treatment or prevention of skin disease.

The Network is a registered charity (no.1115745) and operates in accordance with a formal constitution as required by the Charity Commission. It is an affiliate group of the British Association of Dermatologists (BAD) and an affiliate group for topic prioritisation through the NIHR Health Technology Assessment Programme.

Co-ordinating Centre and Funding

The UK DCTN co-ordinating centre is composed of three members of staff based at the Centre of Evidence Based Dermatology, University of Nottingham. Funding for the main infrastructure is provided from a variety of sources including the National Institute of Health Research and the British Association of Dermatologists.

An organisational chart, provided in appendix 3, illustrates the structure of the co-ordinating centre and includes staff employed on each of our studies. A financial summary of our charitable funds is provided in appendix 2.



Pictured left to right Margaret McPhee (Network Administrator), Carron Layfield (Network Manager) and Tessa Clarke (Network Trials Development Manager)

UK DCTN Management Committees and Membership

Executive Committee

The regular business of the Network is run by an Executive Committee of nine members (including two patient representatives) with an independent chair person. Members are listed below:

UK DCTN Executive Committee			
Professor Andrew Finlay (Chair)	Cardiff	Amanda Roberts	Nottingham
Professor Hywel Williams	Nottingham	Joanne Clayton	Mansfield
Dr Nick Levell	Norwich	Dr Kim Thomas	Nottingham
Dr Hazel Bell	Liverpool	Dr Carron Layfield	Nottingham
Dr Ibrahim Nasr	Romford		

Steering Committee

The Executive Group is supported by the Steering Group which is responsible for evaluating trial proposals and advising the Executive Group on the suitability of trials for inclusion in the UK DCTN portfolio. It consists of approximately 30 members from the UK DCTN membership including dermatologists, dermatology nurses, patient representatives and statisticians. Members of the Steering Committee are listed in the table overleaf:

UK DCTN Steering Committee	
Sandra Lawton (Nottingham)	Girish Gupta (Airdrie)
Andrew Nunn (London)	Catherine Harwood (London)
Alison Layton (Harrogate)	Catherine Smith (London)
Anton Alexandroff (Leicester)	Simon Meggitt (Newcastle)
Chris Bower (Devon)	Debbie Shipley (Carmarthen)
Robert Dawe (Dundee)	Nick Taylor (Harrogate)
Adam Ferguson (Derby)	Shernaz Walton (Hull)
Saleem Taibjee (Birmingham)	Jonathan Batchelor (Nottingham)
Sarah Meredith (London)	Emma Smith (Swansea)
John Bourke (Cork)	All Executive Committee members

The following vignettes were presented to the Steering Group during 2010-11:

- Is oral 8 MOP PUVA or etanercept more effective for short to medium term suppression of chronic plaque psoriasis? (Dr Robert Dawe, Dundee)
- Using the PATCH studies: to what extent do RCT's impact on everyday clinical practice? (Dr Kim Thomas, Nottingham)
- Early intervention for acne: a pilot study. (Dr Alison Layton, Harrogate /Dr Emma Smith, South Wales)
- Is topical pimecrolimus equally efficient as topical hydrocortisone1% in treating mild/moderate eczema? (Dr Ibrahim Nasr, Romford)
- Is topical azelaic acid alone equally effective as oral tetracycline in treating rosacea? (Dr Ibrahim Nasr, Romford)

Membership

Our members are the backbone of the UK DCTN, as without their time, research questions and expertise we would not achieve our goals. Membership continues to grow, with just under 650 members as at June 2011. Most members are Consultant and Specialist Registrar Dermatologists but we actively encourage more nurses, G.P's and service users to join and get involved in our work.

Clinical Trial Development

The fundamental aim of the UK DCTN is to develop clinical trials of high quality and relevance to the dermatology community. The Network is open to trial suggestions from any of its members within the UK. Suggestions are submitted via a vignette form which is then reviewed by experts from the Trial Generation and Prioritisation Panel. If approved, the study is then presented to the UK DCTN Steering Group. Trials that have been identified as urgent research gaps in Cochrane Systematic Reviews are often given priority for development.

All submitted study ideas go through a 'traffic light system' and each will be at one of the three stages as outlined below:



- RED** Not suitable or ready to be developed through the Network or Lead Investigator not identified.
- AMBER** Approved by Steering Committee and currently being developed.
- GREEN** Ready for peer review and submission to funding bodies.

The UK DCTN is able to assist study leads in the following ways to help facilitate the trial development process:

- *Co-ordinate trial development groups.*
- *Conduct surveys to assist with trial development.*
- *Identify sources of funding and write funding applications.*
- *Apply for regulatory and ethical approvals on funded studies.*
- *Supervise trial managers employed on specific research grants.*
- *Promote the benefits of collective effort within the Network.*
- *Encourage and develop the involvement of service users/consumers.*

Trial Generation and Prioritisation Panel

The UK DCTN Trial Generation and Prioritisation Panel (TGPP) were set up in 2008 to identify and prioritise dermatology research topics for development through the Network. The role of the Panel is two-fold. First, it aims to proactively identify research gaps and source new research questions. Secondly, it reviews new research ideas submitted to the UK DCTN and recommends whether or not they are suitable and ready to be developed through the Network. The Panel is chaired by Dr Ibrahim Nasr, based at Queens Hospital, Romford. Full membership of the group is listed below:

Dr Mary Glover (London)	Dr John Lear (Manchester)
Dr Gudula Kirtschig (Germany)	Dr Robert Dawe (Dundee)
Dr Girish Gupta (Airdrie)	Dr Zohra Zaidi (Retired)
Sandra Lawton RN (Nottm)	Dr Carsten Flohr (London)
Dr Susannah Baron (Canterbury)	Dr Emma Smith (South Wales)
Dr Alison Layton (Harrogate)	Dr Ben Walker (Harrogate)
Dr Ruth Murphy (Nottingham)	Dr Liz Hare (Wirral)
Dr Thomas Poyner (Stockton)	Dr Alison Devine (North Wales)
Dr Fiona Craig (Aberdeen)	Dr Abby Macbeth (Norwich)

The vignettes listed below, were reviewed by the panel during 2010/2011:

- Is oral-8 MOP PUVA light therapy more effective than etanercept for chronic plaque psoriasis?
- Is topical pimecrolimus equally efficient as topical hydrocortisone1% in treating mild/moderate eczema?
- Is topical azelaic acid alone equally effective as oral tetracycline in treating rosacea?
- For infants at increased risk of developing eczema, does maternal ingestion of Lactobacillus Rhamnosus (from 34 weeks gestation through to the end of breastfeeding) and/or emollient applied to all infant skin daily from birth to 1 year of age, reduce the risk of developing eczema?
- Is teledermatology a safe and economic means by which patients referred from primary care to secondary care with suspected serious skin cancer (malignant melanoma (MM), squamous cell carcinoma (SCC)) can be triaged to the most appropriate dermatology setting?
- Is imiquimod more effective than topical clobetasol propionate in treating early stage Cutaneous T-cell lymphomas (CTCLs) (patches or plaques)?

Trials in Development

Pilot Studies

A number of pilot studies have taken place during 2010/11. These pilot studies are an important part of the development work in preparation for the main randomised controlled trials to follow (subject to funding).

1. Study of trimethoprim for wound healing of patients with epidermolysis bullosa: a feasibility study (TREBL)

Lead Investigator: **Dr Jemima Mellerio, St Thomas Hospital, London**

Funding: **UK DCTN pump priming award**



Epidermolysis bullosa (EB) is an inherited disorder of extreme fragility of the skin resulting in multiple blisters occurring after minor skin friction. The blisters become open wounds and eventually heal with scarring. The UK DCTN awarded this study £2,000 from its pump priming funds so that a feasibility study for an RCT could be carried out. The emphasis was on patient feedback on the study design and testing outcome measures. Three focus groups were held during July 2010 involving a total of 18 patients. A blister count manual and question booklet were developed and tested. A report of the findings has been drafted and a funding application for the main RCT will be submitted shortly.

2. Treatments for erosive lichen planus of the vulva.

Lead Investigator: **Dr Ruth Murphy, Queens Medical Centre, Nottingham**

Research Fellow: **Dr Rosalind Simpson, University of Nottingham**

Funding: **Nottingham University Hospitals NHS Trust pump priming fund**

Therapeutic interventions for erosive lichen planus are a poorly researched area, so this study received full support from the UK DCTN Steering Group in 2008.



The project title has deviated from the original submission 'Is clobetasol propionate ointment or tacrolimus ointment most effective as first line therapy for erosive lichen planus affecting the vulva (ELPV)' as we want to consider which systemic treatments are best for this condition. The reason for this is that some patients respond well to topical treatments, but those who are resistant to topical treatment have the most debilitating disease and greatest reduction in quality of life. We therefore want to find the best treatment for this subset of patients.

A Cochrane Review: 'Interventions for erosive lichen planus affecting mucosal sites' is due to be published in Summer 2011. Both the International Society and British Society for the Study of Vulvovaginal Disease have been involved in pilot work for this study, and 11 UK centres are currently participating in an audit of ELPV management. Patient members of the UK Lichen Planus Support Group have completed a quality of life centred survey about living with the disease. The results of these preliminary studies will be used to provide evidence towards the development of a full RCT.

Dr Rosalind Simpson (*pictured above*) has taken time out of Speciality Registrar Training to work as Dermatology Clinical Research Fellow to progress this project.

Other Trials in Development

Status: Amber	Does early intervention for acne effect severity in later life?	Lead: Dr Alison Layton, Harrogate
After initial feasibility work in 2009/2010 there has been good progress with this idea and development work continues. Dr Smith and Dr Layton are working on the final design of the study.		
Status: Red	Is oral 8 MOP PUVA or etanercept more effective for short to medium term suppression of chronic plaque psoriasis?	Lead: Dr Robert Dawe, Dundee
A survey was circulated to the UK DCTN membership to gauge the feasibility for this idea. It found there was some variation in practise in the use of biologics and phototherapy for psoriasis. The Steering Group are continuing discussions.		
Status: Amber	Does wearing specialist clothing reduce the severity of disease in children with atopic eczema?	Lead: Dr Kim Thomas, Nottingham
This study has been on hold but developments have re-started this year to find the most valuable question and which garments to compare.		
Status: Red	Can statins be used to treat psoriasis?	Lead: Dr K Finucane, Bristol
This study remains on hold but the Steering Group are open to further discussion about the development of this trial idea.		

Prioritisation Exercises

Vitiligo Priority Setting Partnership

Lead Investigator: **Maxine Whitton, Vitiligo Society**
Research Fellow: **Dr Viktoria Eleftheriadou**
Website: www.vitiligostudy.org.uk



Vitiligo is an autoimmune condition that results in loss of pigment. Although not life-threatening, loss of pigment can have major psychosocial effects, especially for people with dark skin.

A trial idea on treatments for vitiligo was originally proposed to the UK DCTN by Maxine Whitton. The development of this subject area by the UK DCTN led to its inclusion in the NIHR Programme Grant award. This project is now coordinated by the Centre of Evidence Based Dermatology, University of Nottingham as part of the 'SPRUSD' programme (see page 21). A prioritisation exercise was conducted in collaboration with the James Lind Alliance and the Vitiligo Society during 2010. A 'top 10' list of the research topics was identified and published. Two feasibility studies have emerged as a result of this exercise which the Centre of Evidence Based Dermatology are taking forward.

Publication:

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

Eczema Priority Setting Partnership

Lead Investigator: **Kim Thomas, Centre of Evidence Based Dermatology**
Research Support: **Tessa Clarke/ Margaret McPhee**
Website: www.homeforeczema.com



Following the success of the vitiligo research prioritisation a similar exercise has been set up for eczema treatments. A partnership has been created with the James Lind Alliance, the National Eczema Society and the Centre of Evidence Based Dermatology to identify uncertainties in the treatment of eczema. Patients, carers and health professionals will be asked to submit their research questions during summer 2011. These will be ranked in order of importance later this year, then a 'top ten' of research topics for eczema treatments will be shortlisted by 2012.



Ongoing Trials

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

Chief Investigator and Lead Clinician: Professor Hywel Williams and Professor Neil Cox (sadly deceased 2009)



Trial Manager: **Katharine Foster**
Email: patch@nottingham.ac.uk
Website: www.patchtrial.co.uk



PATCH I **Start date:** 01 July 2006 **End date:** 30 June 2009
Funded by: Action Medical Research
Recruitment status: Closed to recruitment

PATCH II **Start date:** 01 Jan 2007 **End date:** 31 Dec 2010
Funded by: BUPA Foundation
Recruitment status: Closed to recruitment

PATCH I and PATCH II are two closely related trials looking at the impact of prophylactic antibiotics on subsequent episodes of cellulitis of the leg. These two studies will establish whether low dose penicillin given after an attack of cellulitis can prevent further attacks and complications, such as swelling and ulceration. People with cellulitis of the leg are randomly allocated to receive either penicillin or a placebo tablet for 12 months (PATCH I) or six months (PATCH II). We will monitor patients for up to two and a half years, to see whether penicillin reduces the frequency of attacks of cellulitis. The 29 recruiting centres enrolled a fantastic 274 participants for PATCH I (exceeding the 260 target). Follow up will continue until July and study results are expected by the end of 2011.

PATCH II Results: 123 participants were recruited to PATCH II which closed early in December 2009. The primary point of comparison between the two groups in this study was the time to recurrence of cellulitis. In the penicillin group 12/60 (20%) had a repeat episode compared with 21/63 (33%) in the placebo control group. The hazard ratio showed a 47%, non-significant, reduction in the risk of further episodes (HR 0.53, 95% CI 0.26 – 1.07, $p = 0.08$). Whilst this trial was limited due to slow recruitment, and the results did not achieve conventional statistical significance (where $p \leq 0.05$), the study provides some evidence of a potentially large effect. We eagerly await the results of PATCH I.

Publications arising from the study:

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

Prophylactic antibiotics for the prevention of cellulitis of the leg – Results of the UK Dermatology Clinical Trials Network's PATCH II trial
Authors: Thomas KT and the UK Dermatology Clinical Trials Network's PATCH Trial Team (UKDCTN). (submitted to the British Journal of Dermatology).

2. Study of treatments for pyoderma gangrenosum patients (STOP GAP)

Chief Investigators and Lead Clinician: Professor Hywel Williams and Professor Anthony Ormerod



Trial Manager: **Eleanor Mitchell**
Email: stopgap@nottingham.ac.uk
Website: www.stopgaptrial.co.uk



Start date: January 2009 **End date:** August 2013
Funded by: NIHR - Programme Grant Award
Recruitment status: Open from April 2009

This is a randomised controlled trial to compare the two most commonly used treatments for pyoderma gangrenosum (PG), prednisolone and ciclosporin.

We have 50 recruiting centres in the UK and aim to recruit a total of 140 patients over a four year period.

As of May 2011, a total of 76 patients have been recruited into the randomised controlled trial, with a further 44 patients having been recruited into the parallel observational study, which is studying patients who are being treated with topical therapy. Recruitment is due to close in April 2012.



Map showing recruiting centres for the STOP GAP study.

Publications arising from the study:

- Mitchell E et al. RCT of treatment for pyoderma gangrenosum: time to get involved. *Wounds UK*, 2010, Vol 6, No 4: 27-32.
- Mitchell E. Do you see patients with pyoderma gangrenosum? If so, consider referral to STOP GAP trial. *Leg Ulcer Forum journal*, Issue 24—Autumn 2010: 46-48

3. A randomised controlled trial to compare the safety and effectiveness of doxycycline with prednisolone for initial treatment of bullous pemphigoid (BLISTER)

Chief Investigator and Lead Clinician: Professor Hywel Williams and Professor Fenella Wojnarowska



Trial Manager: **Anna Sandell/ Caroline Onions**
Email: blister@nottingham.ac.uk
Website: www.blistertrial.co.uk



Start date: October 2008 **End date:** February 2013
Funded by: NIHR Health Technology Assessment Programme
Recruitment status: Open to recruitment from March 2009

This study aims to compare the safety and effectiveness of doxycycline (200 mg/day) with prednisolone (0.5 mg/kg/day) for treating bullous pemphigoid.

Patients will be randomised to receive either prednisolone or doxycycline. Adults with bullous pemphigoid who have received no treatment for this condition in the past year are eligible to enrol into the study. We have 50 active recruiting centres in the UK and Germany and aim to recruit a total of 256 patients over a three year period. The study opened to recruitment in seven centres in Germany in 2010, led by Dr Gudula Kirtschig. As of June 2011, 129 patients were recruited to the study.



Map showing recruiting sites for the Blister Study.

4. Effect of topical imiquimod on lentigo maligna (LIMIT I)

Chief Investigator: Dr Jerry Marsden



Trial Manager: **Nazia Boota**

Email: Nazia.boota@nottingham.ac.uk



Start date: April 2010 **End date:** Sept 2011
Funded by: NIHR - Research for Patient Benefit
Recruitment status: Open from April 2010

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

We aim to recruit 40 patients from 13 treatment centres. It is anticipated that each centre will recruit 3-4 patients with lentigo maligna in an 8 month recruitment period. As of June 2011, a total of 23 patients were recruited to the study.



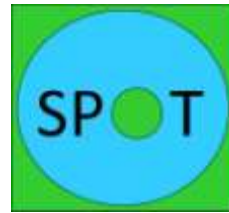
Map showing recruiting sites for LIMIT I

5. SCC Prevention in Organ Transplant recipients with Topical Treatment (SPOT Study)

Lead Investigator: Dr Catherine Harwood, Barts and the London Cancer Centre

Dr C Proby, Ninewells Hospital, Dundee

Funding: NIHR Research for Patient Benefit



This study was presented to the UK DCTN in February 2010 by Dr Catherine Harwood. It will look at two topical therapies for actinic keratoses in organ transplant patients (who are at increased risk of developing SCC). It will compare topical 5-fluouracil and topical imiquimod with a control arm using sunscreen only for prevention of SCC. This study received funding from the NIHR in March 2011. It aims to recruit 60 patients at three recruiting centres (two in Manchester one in London).

Adopted Studies

The UK DCTN established an adoption process for non-commercial dermatology trials that have been developed by other groups. 'Adoption' means that the UK DCTN will assist with publicity, help identify additional recruiting centres, and take an active role in dissemination of the study results. The same adoption criteria as those used by the NIHR Clinical Research Network (CRN) are used in order to ensure that all UK DCTN trials are eligible for inclusion in the NIHR CRN portfolio. We support the following studies in this way:

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

Lead Investigators: Dr Fiona Bath-Hextall and Professor Hywel Williams



Trial Manager: Mara Ozolins, University of Nottingham.

Start date: September 2002 **End date:** August 2012

Funded by: Cancer Research UK (with funding for imiquimod and genetic markers addendum provided by 3M).

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

Recruitment (501 participants) was completed in February 2007. The study team will continue to capture five year outcomes from patient notes until 2012. The team have published a summary of the protocol, and hope to soon publish the conjoint data analysis and three year follow up data.

Ozolins, Mara, Williams, Hywel C, Armstrong, Sarah J and Bath-Hextall, Fiona J. The SINS trial: A randomised controlled trial of excisional surgery versus imiquimod 5% cream for nodular and superficial basal cell carcinoma. Trials, 2010, 11(1), 42

SWET Study: Softened Water Eczema Trial (ion-exchange water softeners for the treatment of eczema in children) RESULTS



The Softened Water Eczema Trial was completed and published last year and was the first study of its kind in the world. It involved 336 children and showed that installing a water softener for 3 months brought no additional relief for eczema sufferers. Anecdotal reports from patients had suggested that hard water may worsen atopic eczema. Population surveys also suggested a possible link between atopic eczema prevalence and the degree of water hardness. It had been hoped that water softeners would provide simple but effective relief for eczema sufferers. However, the trial showed no objective difference in outcomes between the children whose homes were fitted with water softeners and those without.

Thomas Kim S, Dean Tara, O'Leary Caroline, Sach Tracey H, Koller Karin, Frost Anthony, Williams Hywel C and the SWET TRIAL TEAM, 2011. A Randomised Controlled Trial of Ion-Exchange Water Softeners for the Treatment of Eczema in Children. PLoS medicine, 8(2), e1000395
(Won 'Best Paper' at the BAD Conference 2011)

Education and Training

Annual Evidence Based Update Meetings

Each spring the Centre of Evidence Based Dermatology holds an Annual Evidence Based Update Meeting which is hosted by the UK DCTN Chair, Professor Hywel Williams. The day is aimed mainly at dermatologists and specialist dermatology nurses, although anyone with an interest in the topic is welcome. Subject topics are chosen following suggestions given by the previous year's delegates. This popular annual meeting focuses on a different topic each year and seeks to summarise the most recent evidence in the form of systematic reviews and recently completed trials for the treatment and management of skin diseases. The programme includes a popular Q&A session where delegates submit clinical questions to an expert panel composed of the speakers from the day. We seek to include presentations from European experts in the field, as feedback indicates that gaining a European perspective on a subject is extremely useful for clinical practice. The meeting is written up for the 'Conference Reports Section' of the British Journal of Dermatology (BJD). Presentations from previous meetings can be found on our website www.ukdctn.org/meetings/evidence.

The 2010 Evidence Based Update Meeting focused on eczema. Speakers included: Dr Jochen Schmitt and Dr Doris Staab from Germany, Professor Alain Taieb from France, Dr Marie-Louise Schuttelaar from the Netherlands and Dr Robert Boyle from the UK. The 2011 Evidence Based Update looked at Psoriasis with speakers including Professors Chris Griffiths, Jonathan Barker, Peter Wolf and Adrian Tanew. The full programmes for both these events can be found in appendix 1.

Sponsors for the 2010 meeting were:



UK DCTN Awards

Specialist Registrar (SpR) Fellowships

A two year fellowship of £1500 is awarded each year, for two outstanding dermatology trainees. The aim of this award is to develop skills in clinical trials and clinical appraisal by:

- attending the BEES (British Epidermo-Epidemiology Society) course
- spending three days at the UK DCTN co-ordinating centre in Nottingham
- developing critical appraisal skills by working closely with Professor Hywel Williams
- joining the UK DCTN Steering Committee to review research proposals.
- joining a trial development team or a Cochrane systematic review team
- attending the CEBD Annual Evidence Based Update Meeting.

The UK DCTN Neil Cox SpR Fellowship Award is awarded each year to the highest scoring applicant for the Fellowship, (in memory of the late Professor Neil Cox – lead clinician of the PATCH trials).

Successful applicants for the 2010 awards were:



Pictured left to right Dr Abby Macbeth (Norwich), Dr Roz Simpson (Nottingham) and Dr Kave Shams (Lanarkshire).

Successful applicants for the 2011 awards were:



Pictured left to right Dr Donna Torley (Lanarkshire), Dr Suyin Ong (Oxford) and Dr Rubeta Matin (Bucks) winner of the first Neil Cox award.

SAS Award

The winner of the 2011 UK DCTN SAS Award was Dr Penny Thomson from Hertfordshire. This training programme is very similar to the SpR award but run over a three year period.



Dissemination and Publications

Meetings and Conferences

The Chair of the Network (Hywel Williams), the Network Manager (Carron Layfield), and Advisor to the Network (Kim Thomas), have ensured the work of the Network is publicised and highlighted to national and international audiences over the past year.

The UK DCTN has been represented at the following events:

- Tissue Viability Annual Meeting, April 2010
- Annual Evidence Based Update Meeting (Eczema) May 2010
- Psoriasis Association AGM, May 2010
- Primary Care Dermatology Society, June 2010
- BAD Annual Meeting Manchester, July 2010
- International symposium on Atopic Dermatitis, Munich July 2010
- SAS Annual Meeting Manchester October 2010
- First Eastern Asia Dermatology Congress, Japan October 2010
- Talk at Duke University, Raleigh, USA October 2010
- Cochrane Colloquium, Keystone, Colorado, USA October 2010
- Wounds UK Annual Meeting November 2010
- British Hair and Nails Research Day January 2011
- 'Getting to Grips with Evidence Based Dermatology' University of Nottingham, Feb 2011
- Medical Dermatology Annual Meeting March 2011

Newsletters

'Network News' is the UK DCTN quarterly newsletter sent to all members, providing a regular update of our activities. It is available on the UK DCTN website and electronic copies are emailed to our associate members outside the UK.

Website

Our website continues to be an excellent portal of UK DCTN activities for members and non-members alike (www.ukdctn.org). It provides details of ongoing studies, trials in development and guidance on how to submit a trial idea. There is a separate 'members' area' which provides access to study protocols and meeting minutes. Each ongoing trial has its own dedicated website.



Publications and Articles

- THOMAS, KS and UK DERMATOLOGY CLINICAL TRIALS NETWORK'S PATCH STUDY TEAM, 2010. Studying a disease with no home--lessons in trial recruitment from the PATCH II study. *Trials*, 11, 22
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Networking and Collaborative Partnerships

Centre of Evidence Based Dermatology

We work closely with the Centre of Evidence Based Dermatology, University of Nottingham (home to the UK DCTN co-ordinating centre).



In 2008 CEBD started work on a five-year NIHR Programme Grant award, 'Setting research Priorities and Reducing Uncertainties in the prevention and treatment of patients with Skin Diseases' (SPRUSD). This NIHR flagship award aims to set priorities for skin research and develop clinical trials to answer the research questions generated.

The UK DCTN is contributing to this work via the STOP GAP trial, the eczema prioritisation exercise, the vitiligo prioritisation exercise, and the development of pilot studies through surveys and discussion with the Network membership.

National Institute for Health Research: Comprehensive Local Research Networks



Due to their funding sources, all UK DCTN trials are registered on the NIHR portfolio and as such are eligible for support from Comprehensive Local Research Networks (CLRNs). On a local (to the UK DCTN co-ordinating centre) basis we continue to receive support from Trent CLRN in the form of research nurse time, clinical trials administrators and PA sessions for clinicians. Support has also been made available to many investigators across England involved in our multi-centre trials from their relevant CLRN. In the past year, over £1.5 million pounds was allocated in this way specifically to support dermatology research across England, with additional assistance being provided in some areas in the form of generic research nurses. This is making an enormous difference to our ability to successfully recruit into our multi-centre trials.

Professor Hywel Williams is Chair of the NIHR Dermatology Specialty Group (DSG). The Dermatology Specialty Group (DSG) is comprised of local leads from each CLRN region where dermatology has been identified as a local priority (17 out of the 25 CLRN's across England have identified dermatology as a local research priority along with Scotland and Wales). All of the local leads are members of the UK DCTN and a number are members of our Steering Committee. The primary role of the group is the successful delivery of the NIHR portfolio of dermatology studies, and providing advice regarding the adoption of industry studies into the portfolio. Further information on the group can be found at http://www.ccrn.nihr.ac.uk/about_us/ccrn/specialty/derm

The synergy between the UK DCTN and DSG is illustrated in the diagram below.



NIHR Health Technology Assessment Programme

In addition to suggesting study proposals to the HTA programme through the HTA affiliate scheme, the UK DCTN has strong links with the HTA programme through its Chair, Hywel Williams. Professor Williams was appointed Chair of the HTA Commissioning Board and Deputy Director of the HTA programme in 2010 for a five year period. This does not mean that UK DCTN proposals are more likely to get HTA funding as the HTA abides by strict conflict of interest rules, but general knowledge of the commissioning process run by the NIHR is useful to the UK DCTN.



British Association of Dermatologists (BAD)

The UK DCTN is a Special Interest Group of the BAD and we act as an affiliate group for the BAD for topic prioritisation through the HTA programme. The UK DCTN was successful in securing three years of funding from the BAD for a Senior Trial Development Manager post. The successful applicant was Tessa Clarke who joined the team in February 2010. In the short time she has been here Tessa has worked on the funding applications for the TREBL RCT and Eczema Clothing study. She has been instrumental in the set up of the Eczema Priority Setting Partnership, and has worked closely with vignette authors Anton Alexandroff, Robert Dawe, Alison Layton and Roz Simpson.



Clinical Trial Units (CTUs)

The UK DCTN continues its partnership with a number of UKCRC registered Clinical Trial Units to develop and implement studies.

Patient and Carer Involvement

The UK DCTN strongly supports the involvement of patients and carers in all aspects of the design and conduct of clinical trials. Involvement at an early stage of trial design is encouraged. In particular, we have close links with the National Eczema Society, Vitiligo Society, Psoriasis Association, and DEBRA.



Both the UK DCTN Steering and Executive Groups have patient representatives to ensure the needs of patients and carers are considered by the Network.

The UK DCTN is registered with the James Lind Alliance, and "People in Research", which provides opportunities for public involvement in clinical research. Studies which have involved patients in the trial development process are registered on the 'Involve database'.

Future Challenges

Sustainability

The key challenge for the UK DCTN is sustainability. Whilst it might appear to be a robust network that could survive indefinitely, its' success critically depends on three things: (i) core staff to run the network and help develop new ideas into fundable proposals (ii) funding for individual clinical trials and (iii) continuing support from a network of enthusiastic individuals.

At present, we are lucky to have identified financial backing from a variety of sources to support our core staff, but some of those funding sources could dry up in the future. Infrastructure funding is always the most difficult to obtain, and in the absence of any national funding for disease-specific study development groups, we will always be on the lookout for ways of ensuring that our core staff remain. The advent of our Network Senior Trial Development Manager (Tessa Clarke) kindly supported by the British Association of Dermatology is a particularly welcome development that will provide dedicated help to colleagues across the country wishing to develop new ideas into fundable proposals.

The climate for funding for individual trials from sources such as the NIHR HTA Programme, the NIHR Research for Patient Benefit Programme and charities such as CR-UK, the British Skin Foundation, BUPA and Action Medical Research has never been better. But things could change in the future, and it is crucial that our Network's applications remain competitive by addressing important questions for UK patients, in a way that incorporates the latest developments in clinical trial design and management.

Continuing support from individuals is also crucial to the future success of the UK DCTN. Bringing in new blood through the UK DCTN Specialist Registrar Fellowship scheme has been a brilliant idea which is now already producing research active new consultants as evidenced by John Ingram and Jonathan Batchelor, who were the first two Fellows appointed to our Network. The hands-on support in recruiting patients and following up patients provided by the Comprehensive Clinical Research Network Dermatology Speciality Group has been a wonderful concept, but there is no guarantee that such support will be there forever. Avoiding trial fatigue in our clinicians is another challenge – recruiting into studies of rare diseases when one or two eligible cases are seen each year (like BLISTER and STOP GAP) can be particularly challenging, and we could not support more than one or two such studies at a time. It is good that other groups with special interest such as dermatological surgeons, those interested in inherited blistering disorders and vulval skin diseases are now coming forward to develop and participate in trials. Such diversity is essential to the health and appeal of our Network.

Working more with basic scientists

Whilst it is not essential to undertake basic science research in a trial that asks a simple clinical question about whether a drug works in a pragmatic setting, there is much scope for learning more about why some people respond well to treatment and why some develop adverse effects by more collaboration in exploring biomarkers with basic scientists. We also need a pipeline of new medicines and technologies to test in the future, and UK academic dermatologists are well placed to identify promising new therapies. To this end, it is exciting that Professor Nick Reynolds and colleagues are developing a UK Translational Research Network which the UK DCTN will seek to work with actively. It is our hope that this translational network will achieve more by the nature of a national collaboration as opposed to the previous model of individual departments competing against each other in a relatively small funding pool. We wish them every success.

International collaboration

There is nothing quite like the UK DCTN anywhere else in the world, yet there is nothing stopping other colleagues in other countries from developing similar national networks. It has always been our aspiration to facilitate the development of other national groups by developing a Federation of Dermatology Clinical Trial Networks in order to allow collaboration on processes and methods, as well as occasional direct collaboration on clinical trials of very rare skin conditions such as toxic epidermal necrolysis which can only be undertaken on an international basis. To this end, it is encouraging that colleagues in the American Dermato-Epidemiology Network (ADEN) are now starting to mirror many of the ideas developed by the UK DCTN. We wish them every success and we will offer them our experience in helping them to set up. It is our hope that other countries will follow, and if you are aware of key individuals in other countries who might be interested in starting or leading such a network in their own country, then please get in touch with Tessa Clarke. It is a great credit to those who have developed and worked for the UK DCTN to know that the concept is a world-leader - long may it prosper.

Appendices

Eczema Evidence Based Update

Holywell Park, Loughborough

13 May 2010

9.45am		Welcome and Introduction	Hywel Williams
10am	Review 1	Eczema Treatments Update	Helen Nankervis UK
10.30am	RCT 1	Ciclosporin vs Prednisolone for Severe Atopic Eczema	Jochen Schmitt Germany
11.00am	Coffee		
11.20am	Evidence 1	When and How to Perform Allergy Tests in Eczema	Alain Taieb France
11.50am	Evidence 2	Education Schools to Support Atopic Eczema Management	Doris Staab Germany
12.20pm	Lunch		
1.30pm		Question & Answer Session: Ask the Experts	Panel
3.10pm	RCT 2	Nurse Practitioner vs Dermatologist in the Treatment of Childhood Eczema	Marie-Louise Schuttelaar Netherlands
3.40pm	Review 2	Probiotics for Treating Atopic Eczema- a Systematic Review	Robert Boyle UK
4.10pm		Closing Remarks	Hywel Williams UK

Appendix 1a

Psoriasis Evidence Based Update

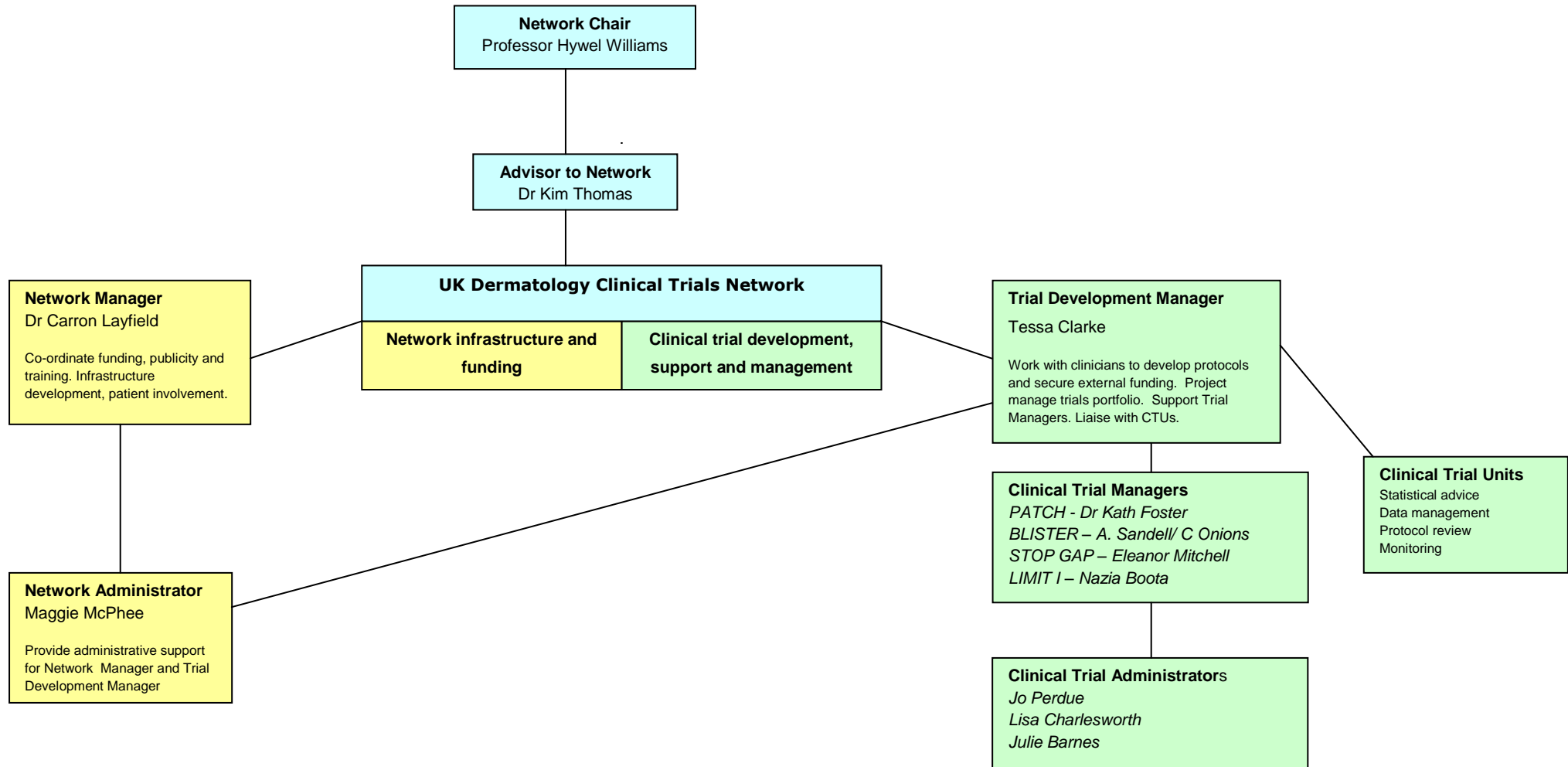
Holywell Park, Loughborough

12 May 2011

9.45am		Welcome and Introduction	Hywel Williams
10am	Review 1	Topical treatments for psoriasis update	Dr Anne Mason UK
10.40am	RCT 1	An overview of 3 recent studies investigating the use of UV311nm and biologics for the treatment of psoriasis	Prof Peter Wolf Austria
11.10am	Coffee		
11.30am	Review 2	Interventions for nail psoriasis	Dr Anna-Christa de Vries & Dr Phyllis Spuls Netherlands
12 noon	RCT 2	A direct comparison of two combination regimens for the treatment of pustular palmoplantar psoriasis: acitretin-PUVA vs fumaric acid esters-PUVA	Prof Adrian Tanew Austria
12.30pm	Lunch		
1.45pm	Q & A Panel	Question & Answer Session: Ask the Experts	Expert Panel
3.10pm	Evidence 1	Genotyping psoriasis – Implications for personalised medicine	Prof Jonathan Barker UK
3.40pm	Evidence 2	How to stop biologics	Prof Chris Griffiths UK
4.10pm		Closing Remarks	Hywel Williams UK

[Appendix 1b](#)

Structure of the UK DCTN co-ordinating centre



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