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# skin 'n' bones connection

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## Dear Reader

It can sometimes feel that we are alone and helpless when living with conditions such as psoriasis and psoriatic arthritis. The frustration of waiting for the result of a test, wondering when a flare is going to happen or what will happen if a treatment fails, can be as big a burden as the conditions themselves.

Learning more about what happens when you have psoriasis and or psoriatic arthritis can help alleviate the anxiety, so being actively engaged with those who provide your care is important. What the NHS is doing to involve people in their own health and care is outlined on page 4.

If you would like to be more active and help give insight into your experiences of living with a chronic condition, either imputing into the decisions, as is described on page 5, or being a trial participant (pages 6-7), might be more rewarding than you think.

Remember, when you see new therapies becoming available or in the research pipeline described on pages 14-15, someone like you would have been involved. Without those participants new therapies would not become available. So you could turn what you may see as a negative experience into a positive outcome, not only for you, but others in a similar situation.

**Managing editor**


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The Psoriasis and Psoriatic Arthritis Alliance (PAPAA) is the new single identity of the Psoriatic Arthropathy Alliance and Psoriasis Support Trust. The organisation is independently funded and aims to be a definitive source of information and educational material for people with psoriasis and psoriatic arthritis in the UK. To be a support to both patients and professionals by providing material that can be trusted (evidence based), which has been approved and contains no bias or agendas. We will be looking to provide positive advice that enables people to be involved as they move through their healthcare journey in an informed way, which is appropriate for their needs and any changing circumstances.


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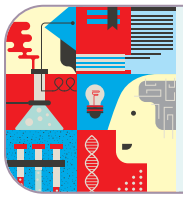

**COVER PHOTO:**

Science and research

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**In a year when the NHS reaches a milestone of 70 years, it is hard to believe that for much of that time the people (patients) who use the service often had little say in its work and areas of research.**

In the past, research was very much 'to', 'about' or 'for' them, whereas in a now more enlightened time it is 'with' or 'by' people or members of the public.

It is also a curious point that this approach has seen patients becoming people, with the view that you are no longer defined by your condition. For most of us we are only a patient for brief periods of time, when seeing a doctor at a consultation (out-patient) or when in a hospital bed (in-patient).

The term 'public' is also an all-encompassing term to include patients, potential patients, carers and people who use health and social care services, as well as people from organisations that represent people who use services.

This recognition of a life beyond the treatment may be an obvious point, although it is sometimes not that obvious to those who research and design treatments and care.

When health secretary Aneurin Bevan launched the NHS at Park Hospital in Manchester (today known as Trafford General Hospital) on 5 July 1948, it was the climax of a hugely ambitious plan to bring good healthcare to all.

For the first time, hospitals, doctors, nurses, pharmacists, opticians and dentists were brought together under one umbrella organisation to provide services that would be free for all at the point of delivery. Although, a curious point, doctors at the time were not in favour, with 10 to 1 voting against it.

The central principles were clear: the health service would be available to all and financed entirely from taxation, which means that people pay into it according to their means. The principle remains the same, although with an ageing, sicker population it remains to be seen whether that principle can be sustained for another 70 years.

Aneurin Bevan statue in Cardiff

**References:**
**https://www.nhs.uk/NHSEngland/thenhs/nhshistory/Pages/NHShistory1948.aspx**

# Involving people


**As the NHS belongs to us, we have a vested interest, we fund it and use it, so it is not a huge leap for us (the public) to have a say in how it operates, particularly around research and innovation. This work often falls under the term 'patient and public involvement' (PPI).**

The insight members of the public can provide is invaluable to making advancements in medical care and how the service works effectively.

In 2017 the publication ***Involving people in their own health and care: statutory guidance for clinical commissioning groups and NHS England*** was produced.

In a summary it was expressed that:

"Clinical Commissioning Groups (CCGs) and NHS England have a key role to play in ensuring that providers make individuals' personal involvement in their health and care a reality. This guidance supports CCGs and NHS England to fulfil their legal duties to involve people in their health and care, so that people experience better quality care and improved health and wellbeing, and the system makes more efficient use of resources."

The guidance sets out 10 key actions for CCGs and NHS England on how to involve people in their own health and care. These include:

**1.** Support patients, carers and representatives

**2.** Publicise and promote personal health budgets

**3.** Publicise and promote the choices available to patients

**4.** Commission for involvement

**5.** Promote and publicise the involvement of individuals

**6.** Assure them that providers are involving people in their own health and care to an acceptable standard

**7.** Use and promote tools and resources

**8.** Assure them that they are commissioning services that match the needs and preferences of their population

**9.** Implement a workforce strategy to support health and care professionals to involve people in their own health and care

**10.** Advance equality and reduce health inequalities.

In the introduction of the report Professor Alf Collins, doctor, commissioner, researcher and national policy advisor in person-centred care, says:

*"National surveys tell us that over 40% of people want to be more involved in decisions about their care; this situation has hardly changed in a decade. Similarly 40% of people living with long-term conditions want more support to manage their health and wellbeing on a day to day basis. Indeed, the Five Year Forward View states that more could be done to involve people in their own health and care, to involve communities and the voluntary sector in improving health and wellbeing and to coordinate and personalise care and support including through personal health budgets.*

*By involving people in decisions about their health and care we will improve health and wellbeing, improve the quality of care and ensure people make informed use of available healthcare resources. Involving people in their own health and care not only adds value to people's lives, it creates value for the taxpayer. The challenge now is to shift the focus of care and support services from 'what is the matter with you?' towards 'what matters to you?"*


The document can be accessed at:

**www.england.nhs.uk/wp-content/uploads/2017/04/ppp-involving-people-health-care-guidance.pdf**

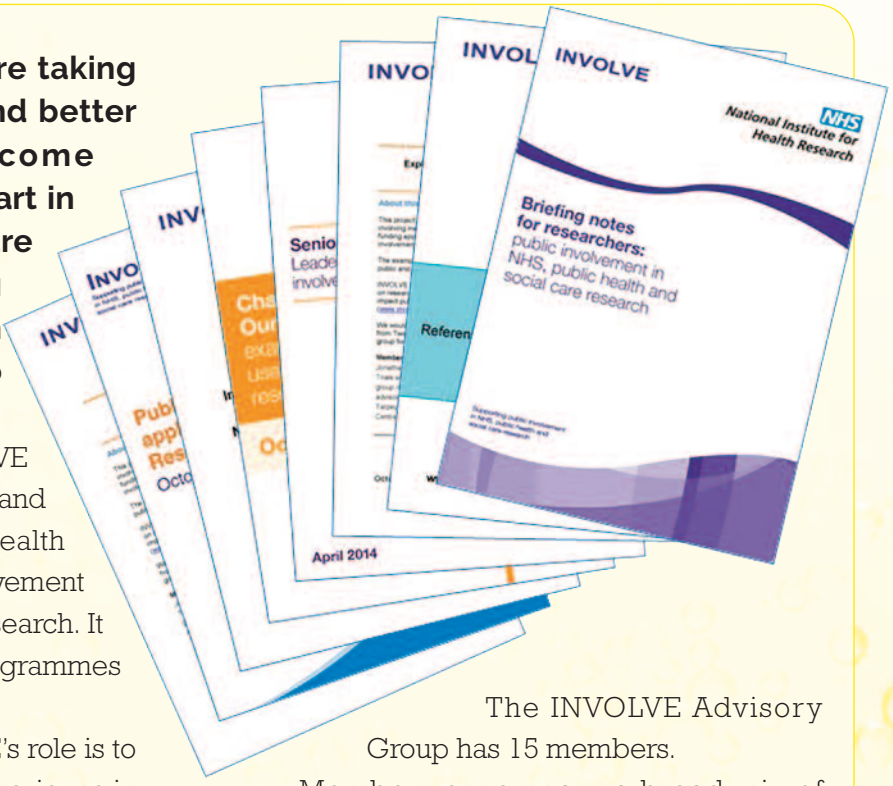
**More people than ever before are taking part in research studies. New and better treatments and services become available because people take part in research. Members of the public are also getting involved in advising INVOLVE about what research should be funded and helping to design research studies.**

To coordinate research studies, INVOLVE was established in 1996 and is part of, and funded by, the National Institute for Health Research, to support active public involvement in NHS, public health and social care research. It is one of the few government-funded programmes of its kind in the world.

As a national advisory group INVOLVE's role is to bring together expertise, insight and experience in the field of public involvement in research, with the aim of advancing it as an essential part of the process by which research is identified, prioritised, designed, conducted and disseminated.

Whilst all of us are actual, former or indeed potential users of health and social care services, there is an important distinction to be made between the perspectives of the public and the perspectives of people who have a professional role in health and social care services.

INVOLVE places equality and diversity at the centre of its work, actively seeks and values involvement from a variety of cultures, experiences and perspectives, and is guided by the principles of the Equality Act 2010.


The INVOLVE Advisory Group has 15 members.

Members encompass a broad mix of individuals who use health and social care services, carers, people from voluntary organisations, and health service and social care practitioners, managers and researchers.

There is a series of publications available from INVOLVE and included in the Public Information Pack (PIP):

**PIP 1:** A quick guide – a brief introduction to involvement

**PIP 2:** Getting started – explaining involvement and what to expect

**PIP 3:** Finding out more – the different organisations involved in research

**PIP 4**: Jargon buster – explaining common research terms

**To get copies visit www.involve.nihr.ac.uk**

**Contact: INVOLVE, Alpha House**
**University of Southampton Science Park**
**Southampton, Hampshire SO16 7NS**
**Email involve@nihr.ac.uk**
**Telephone: 023 8059 5628**

# Take part in a clinical trial

**Most research in the National Health Service (NHS) involves people, often patients, and is usually referred to as clinical research or medical research.**

Clinical trials may compare a new medical approach to one that is already available or to a placebo (a substance that has no therapeutic effect) or to no intervention at all. Some clinical trials compare interventions that are already available to each other.

A clinical trial may be researching a particular IMP, and may therefore be called a Clinical Trial of an Investigational Medicinal Product (CTIMP). However, the clinical trial may also be looking at medical devices, procedures, or changes to participants' behaviour, such as their diet.

When a new product or approach is being studied, it is not usually known whether it will be helpful, harmful, or no different from available alternatives (including no intervention). The investigators try to work out the safety and efficacy (effectiveness) of the intervention by measuring certain outcomes. For example, they can measure how psoriasis or psoriatic arthritis improves by using a scoring system.


Clinical trials used in drug development are sometimes described by phase. This highly controlled process is regulated by the Medicines and Healthcare products Regulatory Authority (MHRA), which is the government agency responsible for making sure medicines and medical devices work and are acceptably safe.

## How is a clinical trial planned?

A CTIMP of a potential new medicine for psoriasis or psoriatic arthritis may involve a large number of people or groups, including:

- pharmaceutical company: The company which owns and has developed the IMP in the laboratory will organise the clinical trials necessary to develop the IMP for humans
- a contract research organisation: Clinical trials are sometimes conducted by a contract research organisation, which is an independent company with specific scientific expertise
- specialist doctors from the relevant specialty, such as dermatology for psoriasis or rheumatology for psoriatic arthritis
- specialists in the relevant medical speciality will be consulted and/or directly involved in the application for and running of a clinical trial.

These people or groups will decide the best way to investigate the IMP. The first stage involves writing a very detailed document containing all relevant information about the IMP and a plan that describes how the clinical trial will be conducted, where and by whom. This is called the clinical trial protocol. Once a clinical trial protocol is in place, a request for clinical trial approval is made.

## Getting involved in a clinical trial

Many people where there current treatment has not worked or where they have exhausted therapies, often look at volunteering to be part of a clinical trial.

Getting involved doesn't always mean that you would be offered the new treatment as most trials will have another product (comparator) with which the new product is compared. This is usually offered randomly to participants and sometimes may be a placebo (dummy drug).

## What questions should volunteers ask?

- What is the aim of the research? Clinical research should be done with a specific aim of improvements and these should be clearly explained by the researcher asking you to take part.
- Who qualifies? Many research projects have specific lists of the types of patients, such as their age when psoriasis first developed, which treatments they currently use, etc.
- What is the point of the trial and how will it help people? Participants should feel satisfied that the trial is worthwhile and that it is asking a useful question.
- How long will the clinical trial last? This varies greatly but must be practical for the volunteer. Considerations to take into account include the venue, frequency of visits and any impact on work or family life. If attendance involves travelling, travel expenses can be reimbursed.

## Can trial participants withdraw at any time?

Yes. All ethics committees require this for all trials. Patients have the right to withdraw at any time; they do not have to give a reason if they prefer not to.

If you would like to know more about clinical trials in psoriasis and psoriatic arthritis, we have a free booklet available called ***Clinical Trials: An overview***, which can be ordered by contacting us (see page 2) or is available to view and download at www.papaa.org/research/clinical-trials-psoriasis

## Funding of research

New drug and treatment trials are usually funded by commercial organisations, mostly the pharmaceutical industry. But charities also fund research and **PAPAA** considers that part of its role is to encourage, support and fund well-run medical research. **PAPAA** does this via the following activities:

- supporting research by providing research grants
- promoting research programmes
- publicising results of research
- helping to recruit into research.

### PAPAA funding of research

**PAPAA** is open to applications for funds via a grant-giving process. More information can be found at:

**www.papaa.org/research/grants**

## NIHR Partner Organisation status

**PAPAA** also meets the criteria for NIHR (National Institute for Health Research) Partner Organisation status for its research grants funding stream. Therefore is an NIHR Partner Organisation in respect of its research grants funding stream. Studies funded through this funding stream are eligible for inclusion in the NIHR Clinical Research Network Portfolio and therefore able to access NHS support via the NIHR Clinical Research Network infrastructure.


### Useful links:

**NHS Choices www.nhs.uk/conditions/clinical-trials/**

**UK Clinical Trials Gateway: www.ukctg.nihr.ac.uk**

**NIHR Clinical Research Network Portfolio: www.crn.nihr.ac.uk**

**PAPAA funded research: www.papaa.org/research/grants-awarded**

# UK research priorities

**As described in the articles on pages 3, 4 and 5, the shift towards participation and a patient-centred approach to research has also led to asking people what is important to them.**

The insight of people living with conditions is vital to gaining the correct outcome when deciding on what to research. The only way to fully understand these needs is to ask those most likely to benefit, which is ultimately the recipients, which means you.

In April 2014 we launched our patient-led research (PLR) priorities for psoriasis and psoriatic arthritis survey. The survey was online and asked the following questions:

- Do you have psoriasis and or psoriatic arthritis?
- Would you like to help with research?
- Do you want to have your say about what is important to you?

For those who answered 'yes', we gave them the opportunity to complete up to ten free text boxes with issues, worries, questions, concerns or anything they thought would help you cope, manage or understand the conditions they live with.

This could include therapies, treatments, doctors, appointments, hospitals etc. Our aims are to provide an insight into what is important to people with psoriasis and psoriatic arthritis and where they feel there is an unmet need. We hope that researchers will identify these as priority outcomes and include those within research study design, outcomes and end points.


The survey is ongoing and so far we have received 395 completed surveys with many completing all ten boxes, giving us close to 4,000 suggestions.

Who completed the survey?

- 69% of the submissions were from women and 31% from men.
- the average age was 47 (18-87),
- Location of respondents: England 75%, Scotland 12%, Northern Ireland 8% and Wales 5%.

We have periodically reviewed the suggestions and will continue to monitor future submissions. The mostly commonly appearing issues are listed below:

1. **Pain cause and management**
2. **Fatigue**
3. **Diet**
4. **Genetics**
5. **Adverse drug side-effects**
6. **Depression**
7. **Employment and work issues**
8. **Primary Care education**
9. **Physiotherapy**
10. **Patient support meetings**
11. **Emotional/psychological support**
12. **Itch**
13. **Alternative/complementary therapies**
14. **Occupational therapy**
15. **Pregnancy and children**
16. **Awareness**
17. **Continuity of care & follow-up appointments**
18. **Enthesitis**
19. **Flares**
20. **Cardiovascular disease.**

These suggestions have directly influenced our work, with the development of:

- primary care training (Psoriasis in Practice)
- information booklets on fatigue diet, lifestyle, and nutrition
- funding of research into parent/child and the association of sound and itch trigger and monitoring of psoriatic arthritis by pharmacists.

We also held patient education events, and used the data gathered in responses to NICE (National Institute for Health and Care Excellence) and SMC (Scottish Medicines Consortium) technical appraisals.

We are very grateful to those who have completed the survey. For anyone who wishes to provide their views, you can submit your comments anonymously. The survey can be accessed at: **www.papaa.org/surveys/uk-research-priorities**

By helping us with this survey, you will be directly influencing our work, the research agenda and raising issues that are important to people with psoriasis and psoriatic arthritis.


## We need your help

**As part of The Information Standard scheme we have developed a patient user group to review all written material. We are grateful to those members of PAPAA who have already agreed to carry out this role.**

**If you would like to get involved in reviewing our material then please get in touch.**

**For more information about the role and specification contact:**
**Caroline Marven on 01923 672837 or email cjm@papaa.org**

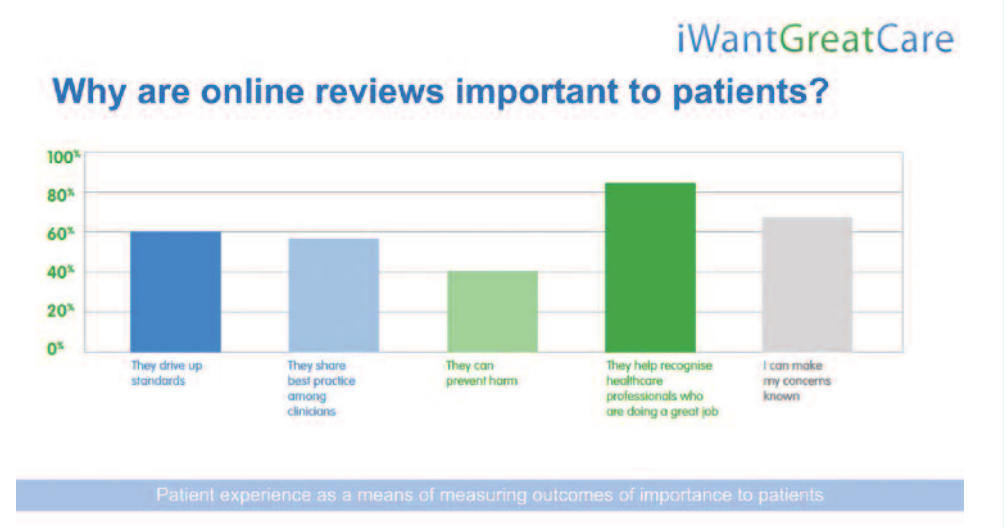
## Rate your food, hotel, holiday and now your health services


Dr Neil Bacon

In the mid-1990s, Dr Neil Bacon spent a year at Harvard in the US, when he first encountered the Internet. He said, "I saw what the Internet was going to do and thought this has the potential to change everything, including healthcare."

A seed was planted, and although he went on to complete his PhD and work in the NHS, he later resigned to set up doctors.net.uk with the aim of improving communication, collaboration and education for doctors. Launched in 1998, it grew into the world's largest online network of doctors and pioneered online learning for the medical profession.

Having achieved his aim, Dr Bacon wanted to tackle what he calls "the shocking variance in care across healthcare services, and make care quality transparent with patients and professionals able to see what is going on in the services that they use and the places they work." In 2008 he set up iWantGreatCare to help solve the problem.



Patient experience as a means of measuring outcomes of importance to patients

Today, iWantGreatCare is the world's largest independent patient data and insights platform - think TripAdvisor for health and you are on the right track.

It operates in 23 countries and 20 languages and has more than 5 million patient reviews covering clinicians, treatments, healthcare providers and medicines. Organisations, primarily within the NHS, but also some private healthcare and pharma/life science providers, can then use the patient insights generated to support improved quality, safety and outcomes in healthcare.

There are innumerable examples of where patient feedback has helped improve healthcare for all. Be it within the NHS providing insights that drive staff morale and identify risk to patients - or international pharmaceutical companies sharing data that improves effectiveness of medicines - iWantGreatCare is transforming patient healthcare for all.

Importantly, a key aspect of the service is that it is creating a place for patients to share experiences and outcomes, from feedback about how specific medicines impact patient lives, to new treatments and reviews about which doctors and hospitals offer the best services, and which you might want to think twice about using. Of course, even after 10 years, not every drug has been reviewed or every GP commented on. As Dr Bacon says,"

> Humira is fantastic for psoriasis and has changed my life.
>
> iwantgreatcare.org via "pullquote"

> As a sufferer of scalp psoriasis for a very long time I understood from my doctors that the condition could not be cured, only managed. I saw an item on BBC Breakfast last year which made me think that more could be done so an online search led me to Dr Clayton. An appointment was made and Dr Clayton was able to prescribe a programme of treatment which has transformed my condition in 7 weeks. Further weekly applications might be required for the foreseeable future but on the whole I feel so much better and the stress has gone. I was so glad Dr Clayton was able to deal with the condition. I have no regrets whatsoever that I contacted him for help...one of the best decisions I've made recently.
>
> iwantgreatcare.org via "pullquote"

"iWantGreatCare is still developing. As organisations such as the Psoriasis and Psoriatic Arthritis Alliance **(PAPAA)** get involved and more patients start to find out that they can share experiences online, the impact that we can all have and the way in which patients can help shape the future of healthcare just gets greater and greater"..

**How to leave a healthcare review**

1. Go to iwantgreatcare.org
2. Click on the area that you want to review, e.g. hospitals, doctors, medicines, etc
3. Click on the 'Write a Review' tab on the top left of the page
4. Type in the specific name you want to review and select it
5. Answer a few set questions and then fill in the free-text box. This is where you can really leave detailed information to help inform the next patient and provide information for healthcare providers to learn from
6. Submit the review
7. Click the link in the email sent to you.

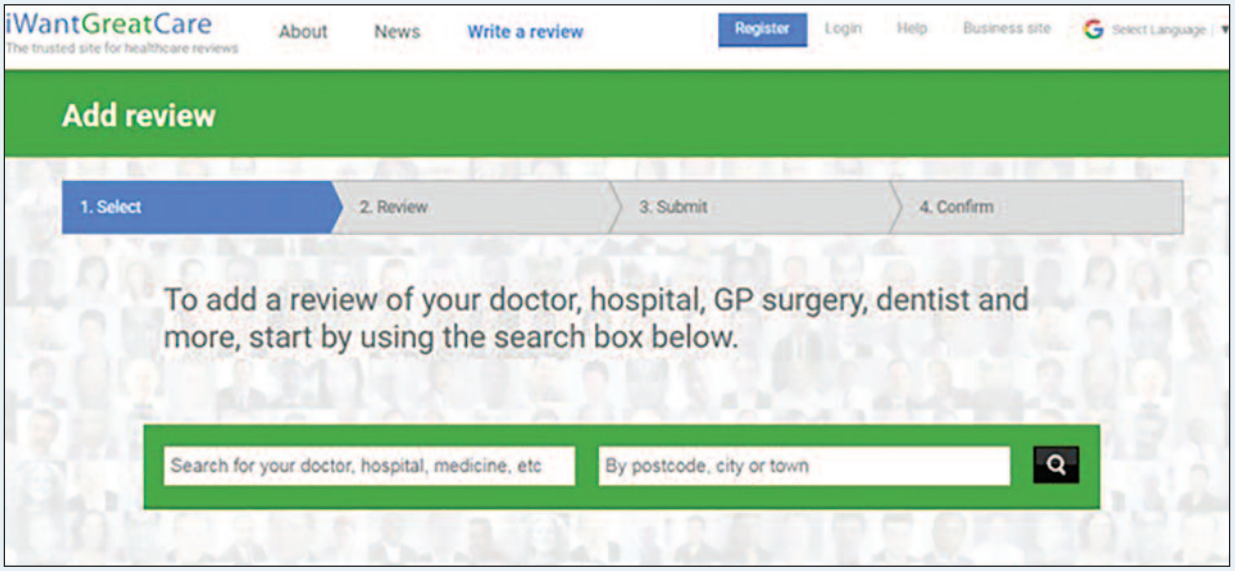
**To find out more please contact support@iwantgreatcare.org**

PAPAA is working with iWantGreatCare and, to assist you, we have provided links from the psoriasis and psoriatic arthritis treatments pages at www.papaa.org to the iWantGreatCare website.

To provide a review, visit the links below and click the link to the treatment you wish to review and click the link to the iWantGreatCare website.

PAPAA pages: Psoriasis - www.papaa.org/resources/psoriasis-treatments

Psoriatic arthritis - www.papaa.org/resources/treatments-psoriatic-arthritis



# Prevalence of psoriasis

**While psoriasis affects around 3% of all people worldwide, there is a good deal of variation in the prevalence of the disease between different ethnic groups. It affects approximately 2.5% of people of European descent, but psoriasis is rare among Africans and fewer than 1:1000 Asians have the condition. More specifically, rates among Caucasians are at least ten times higher than ethnic Chinese individuals. Why should that be?**

Some recent research has addressed exactly this question. In a unique collaborative project, researchers from Asia, North America and Europe compared DNA samples from Caucasian and Chinese individuals in a large cohort of subjects, comprising 15,000 people with psoriasis and 20,000 without.

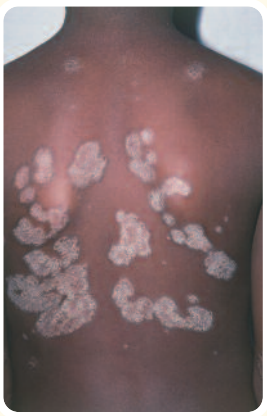
It turns out that of the many genetic markers for psoriasis, about 10 specific genes have an important role in the development of the condition in Caucasians. What the researchers found was that the same 10 genes did not appear to have any influence on the development of psoriasis in the Chinese subjects. In other words, genes that increase the risk of psoriasis in Caucasians have no effect in Chinese individuals.

These findings strongly suggest that variations in ethnic susceptibility to psoriasis have a genetic basis.

**Reference: Yin X, Low HQ, Liu J. Genome-wide meta-analysis identifies multiple novel associations and ethnic heterogeneity of psoriasis susceptibility. 2015. Nature Communications 6: Article 6916.**

## Ethnicity affects the severity of psoriasis at presentation

Although there are well-known variations in the prevalence of psoriasis in different ethnic populations, little is known regarding differences in the severity of psoriasis between these groups. In this recent study from the US, researchers looked at this question in a group of 848 patients with psoriasis between 2006-2016, 62% of whom were white, 26% Asian, 8% Hispanic, 2% African American and 2% Middle Eastern. The groups were assessed according to the severity of the disease (mild to moderate vs severe to very severe) at the time of presentation.



Results showed that Asian patients had significantly more severe psoriasis than the white group. Similarly, Hispanics were also found to have more severe psoriasis than Caucasians. The numbers of African Americans and Middle Eastern groups were too small to reveal any significant differences.

In summary, these findings suggest that Asians and Hispanics present with more serious psoriasis than Caucasians.

There are obvious limitations to this study in that the analysis was retrospective, the collection of data was at a single time point rather than continuous and the classification of severity was crude. Nevertheless, these observations point the way to further research which, in future, may result in ethnicity-specific approaches to treatment.

**Ref: Abrouk M, Lee K, Brodsky M et al. Ethnicity affects the presenting severity of psoriasis. J Am Acad Dermatol 2017; 77: 180-181**

**There is a well-recognized genetic contribution to psoriasis. Although a person who has no relatives with psoriasis may develop the disease, it is much more common within families.**

However, the precise significance of having a close family member who has psoriasis can be confusing, simply because different studies give different results. For example, in one study those individuals who have a sibling with psoriasis have about a 12-18% chance of getting the disease, whereas another study showed an 8% risk.

Some research studies have found that over 90% of participants with psoriasis had a close relative with it, but other studies have found that only 8-23% of those diagnosed with psoriasis had a close relative with the disease.

The strongest evidence that genes are involved in psoriasis comes from twin studies. In these studies, scientists compare each twin in identical and fraternal twin pairs. Remember that identical twins share the same DNA, whereas fraternal twins share only as much DNA as any two siblings. Thus, if an identical twin has psoriasis, his or her twin has a 35-72% chance of developing psoriasis, whereas among fraternal twins the likelihood decreases to between 15 and 23%.

The problem with all these studies of different populations – called epidemiological studies - is that there are very many factors which might bias the findings in one way or another. What is needed is a specific genetic test for psoriasis, so that we can identify individuals who are most at risk. Now scientists at Washington University School of Medicine in St. Louis have taken a big step in this direction by identifying the first gene directly linked to plaque psoriasis – the most common form. This type of psoriasis, which is characterised by itchy, dry, red patches and silvery scales, accounts for about 80% of all cases.

Researchers were able to show that when activated by an environmental trigger, such as infection, rare mutations in a gene called CARD14 can lead to plaque psoriasis. Interestingly, although psoriasis has long been thought to be caused by an overactive immune system, the CARD14 genetic pathway uncovered in this study points to defects in the skin itself as the main culprit of the condition and to immune cells as secondary players.

The new findings also indicate that mutations in CARD14 can be involved in the pustular form of psoriasis and in a debilitating arthritis linked to the psoriasis.

This research heralds a new era in therapeutics. In future, the ability to identify high-risk individuals through specific genetic markers should lead to more effective, targeted treatments for plaque psoriasis and other forms of the disease.

Dr David Ashton MD PhD

## References

Jordan CT, Bowcock AM et al. Rare and common variants in CARD14, an epidermal regulator of NF-kappaB, in psoriasis. The American Journal of Human Genetics. May 4, 2012.

Jordan CT, Bowcock AM et al. PSORS2 is due to mutations in CARD14. The American Journal of Human Genetics. May 4, 2012.

**Dr David Ashton MD PhD May 2018**

# New treatments approved

**Brodalumab has been recommended for use by both NICE (National Institute for Health and Care Excellence) and SMC (Scottish Medicines Consortium) for treating moderate to severe plaque psoriasis. The decision means that brodalumab can be offered IF the psoriasis has not improved with other treatments, for example ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet radiation), or these can't be taken.**


If you are not eligible for brodalumab but are already taking it, you should be able to continue until you and your doctor decide when best to stop.

Brodalumab is a biologic medicine for the systemic treatment of psoriasis. It is a human monoclonal antibody which selectively binds to and blocks interleukin 17 receptor A (IL-17RA), which inhibits IL-17 cytokine-induced responses resulting in normalisation of inflammation in the skin. The drug prescription-only medication (POM) prescribed in secondary care and is self-administered as a subcutaneous injection every two weeks after an initial loading dose. The drug is manufactured by LEO Pharma UK under the brand name of Kyntheum®.

Guselkumab for treating moderate to severe plaque psoriasis has also been recommended by NICE. Guselkumab is prescription-only medication (POM) prescribed in secondary care and also self-administered by subcutaneous injection at weeks 0 and 4, followed by a maintenance dose every 8 weeks. The treatment should be stopped after 16 weeks of treatment in people whose disease has shown no response. Guselkumab targets the IL-23 subunit alpha (p19 subunit), which offers a choice for patients where other similar but different targeted agents have failed. The product is branded as Tremfya® and manufactured by Janssen.

NICE National Institute for Health and Care Excellence

Healthcare Improvement Scotland | Scottish Medicines Consortium

These drugs join the growing list of biologic therapies which are now approved for psoriasis, including: adalimumab, etanercept, infliximab, ixekizumab, secukinumab and ustekinumab.

There are a number of other agents for both psoriasis and psoriatic arthritis in the process of being licensed or awaiting appraisals for use in the NHS. As these become available we will add them to our website.

For more information visit:
**www.nice.org.uk**
**www.scottishmedicines.org.uk**
Psoriasis biologics: **www.papaa.org/psoriasis-treatments/biologic-agents**
Psoriatic arthritis biologics: **www.papaa.org / psoriatic-arthritis-treatments/biologics**


## Update:

In the last issue of *Skin 'n' Bones Connection* (issue 46) we reported that topical psoriasis therapy calcipotriol (Dovonex Psoriasis 50 microgram/g ointment) had been approved to be sold as a pharmacy product (P), which meant that those with a diagnosis of psoriasis could buy the product without a prescription. We now understand that the manufacturer LEO Pharma UK has decided not to pursue this new classification and the product will remain as a prescription-only medication (POM).

**UCB recently announced that the Phase 2b BE ACTIVE study met the primary objective of establishing dose response for bimekizumab with statistical significance. The study also demonstrated robust efficacy in psoriatic arthritis signs and symptoms, as well as skin clearance measured by the PASI90 response, compared to placebo, at Week 12.**

"The results observed with bimekizumab are impressive, especially because the study included ACR50 and PASI90, rigorous and meaningful efficacy endpoints. Even at 12 weeks, the results showed strong joint and skin responses, giving psoriatic arthritis patients the possibility of significant disease improvement in two major affected areas where they seek relief," said Christopher T. Ritchlin, MD, MPH, University of Rochester Medical Centre.

"A complete and specific blockade of inflammation is key to achieving these compelling results. Preclinical research has shown that dual neutralization of IL-17A and IL-17F inhibits joint and skin inflammation to a greater extent than blocking IL-17A alone. Bimekizumab has the potential to be an important treatment option for psoriatic arthritis patients, many of whom do not respond to or tolerate current therapies."

## About bimekizumab

Bimekizumab is a novel humanised monoclonal IgG1 antibody that potently and selectively neutralises both IL-17A and IL-17F, two key cytokines driving inflammatory processes. IL-17A and IL-17F have overlapping pro-inflammatory functions and independently cooperate with other inflammatory mediators to drive chronic inflammation and damage across multiple tissues.

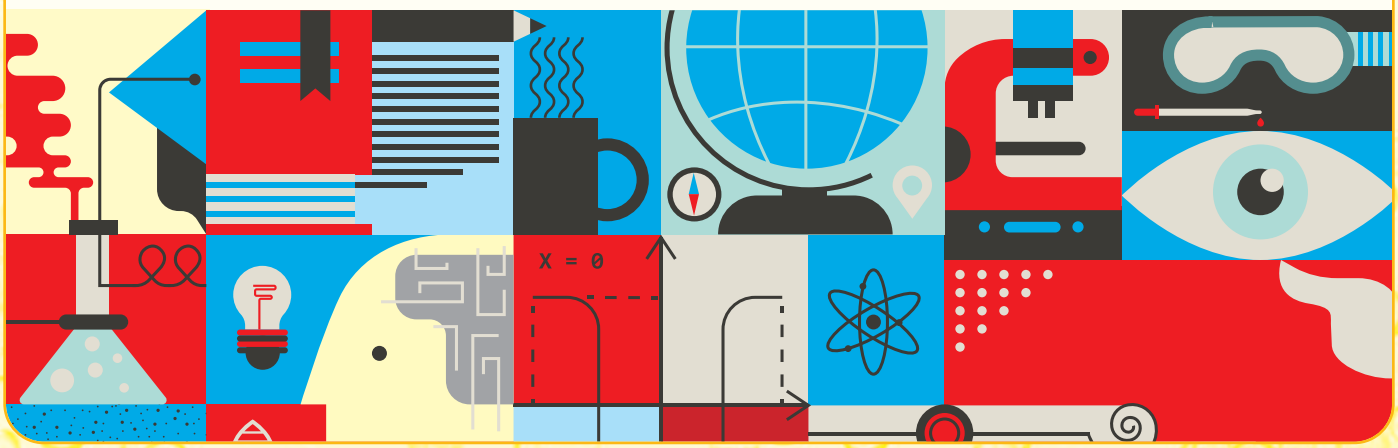
Previous early-phase clinical studies in psoriasis and psoriatic arthritis have suggested that dual neutralisation of both IL-17A and IL-17F with bimekizumab may provide a new targeted approach for the treatment of immune-mediated inflammatory diseases. Preclinical results in disease-relevant cells have shown that dual neutralisation of both IL-17A and IL-17F reduces skin and joint inflammation, as well as pathological bone formation to an extent greater than inhibition of IL-17A or IL-17F alone.

UCB is also studying bimekizumab in other disease areas, including psoriasis and ankylosing spondylitis. Bimekizumab is not approved by any regulatory authority worldwide.

### Glossary of terms:

- ACR50 - 50% improvement under American College of Rheumatology scoring
- IL (Interleukin)-17A is a protein that in humans is encoded by the IL17A gene
- Immune-mediated inflammatory diseases (IMID) is a concept used to collectively describe a group of ostensibly unrelated conditions that share common inflammatory pathways.
- PASI90 - 90% improvement of psoriasis as scored by Psoriasis Area and Severity Index
- Statistical significance - the quality of being worthy of attention
- Humanised monoclonal IgG1 antibody - A type of antibody made in the laboratory by combining a human antibody with a small part of a mouse or rat monoclonal antibody.

**Source: UCB media release**



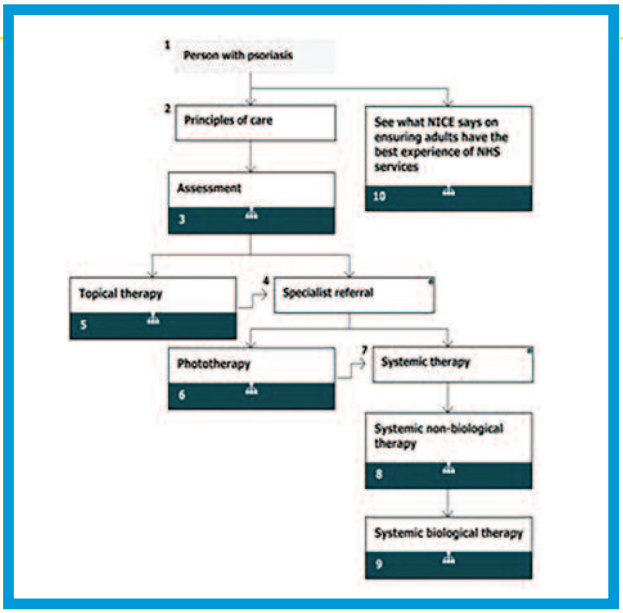
**The comments we receive in our surveys often have a common theme, which is the lack of awareness of psoriasis and, in particular, psoriatic arthritis at primary care.**

The problem appears to be widespread and many people tell us that they are often not even offered treatments or advice as recommended with the NHS pathway of care:

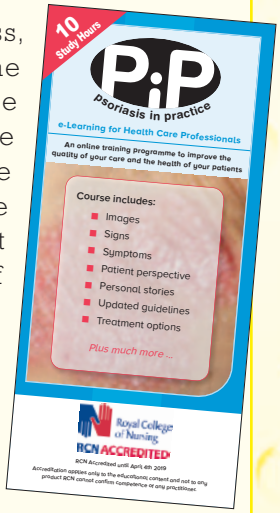
The principles of care: (https://pathways.nice.org.uk / pathways/psoriasis)

Offer people with any type of psoriasis support and information tailored to suit their individual needs and circumstances, in a range of different formats, so they can confidently understand:

- **their diagnosis and treatment options**
- **relevant lifestyle risk factors**
- **when and how to treat their condition**
- **how to use prescribed treatments safely and effectively (for example, how to apply topical treatments and how to minimise the risk of side effects through monitoring for safety of medicines)**




- **when and how to seek further general or specialist review**
- **strategies to deal with the impact on their physical, psychological and social wellbeing.**




To tackle this lack of awareness, PAPAA has developed an online distance learning programme specifically aimed at healthcare professionals working at primary care level. The programme provides those working within that non-specialist setting a complete understanding of the condition, what people want and the treatments. The course is accredited by the Royal College of Nursing. To promote the course we recently attended the Primary and Public Health event at the NEC in Birmingham. Many of those who visited our stand signed up to the course and took away our information leaflets, so hopefully people will start to see the benefit of this awareness and training activity.



**The Medicines and Healthcare products Regulatory Agency is warning people who may have purchased a "natural" Chinese herbal medicine, Yiganerjing cream, as a treatment for skin conditions to stop using it immediately as it has been found to contain an undisclosed steroid and two antifungal ingredients.**

MHRA officials have been acting to stop the sale of this cream and have had it withdrawn from many websites and online marketplaces but people may have purchased it in the past and still be using it.

Yiganerjing cream is not a licensed medicine and has been marketed in the UK as a "natural" Chinese herbal medicine for the treatment of a range of skin conditions, most commonly eczema, psoriasis and rosacea.

**The MHRA said:**

"Our analysis found the presence of the steroid clobetasol propionate. This steroid is the active ingredient in prescription-only medicines used for the treatment of a range skin conditions such as psoriasis and eczema. Creams containing steroids should be used sparingly and as directed by the prescriber. It is contraindicated in children under 1 year of age.

"We are also aware of the use, via a herbal clinic, of a product called Penny Orange Cream which has also been found to contain clobetasol propionate. While this product is no longer available, and we are not aware of its widespread use, it did contain an undisclosed steroid and should not be used."

If you are unsure about the safety of a medicine



claiming to be "natural" or "herbal" you should check for a marketing authorisation (MA) or Product Licence (PL) number or traditional herbal registration (THR) number/the THR logo. This means the product has been assessed by MHRA for safety and has been manufactured correctly. For more information, visit NHS Choices.

Dr Chris Jones, manager of the medicines borderline section at MHRA, said:

*"The sale of potent steroid creams directly to the public is illegal for good reason. If used without medical supervision these medicines can be dangerous.*

*Steroids must be prescribed by healthcare professionals who follow strict criteria when prescribing them and monitoring patients using them. They can suppress the skin's response to infection, can cause long-term thinning of the skin, and if applied long-term over a wide area, particularly in babies and children, can cause other medical problems.*

*"Our advice to anyone who is using Yiganerjing cream, particularly on young children and babies, is to discontinue use immediately. If you have any questions, please contact your healthcare professional."*

If you are aware of Yiganerjing cream being sold, please report it to MHRA at:
**Borderline_medicine@mhra.gov.uk.**

# Chinese medicine alert

**The Health Services Authority (HSA) in Singapore issued an alert on 2 November 2017 about two traditional Chinese medicinal products found to contain undeclared Western medicinal ingredients. The products have caused serious adverse reactions.**

The products are called: **WAN LING REN SEM CHIN KUO PILL** and **CHONG CAO DAN**.

The sale of these products may be confined to the area where the alert has been issued, but given the access to products over the internet, these may have been made available elsewhere. Anyone who has purchased these products is advised to contact their doctor.

We would encourage anyone to use the Medicines and Healthcare products Regulatory Agency (MHRA) Yellow Card scheme to report any possible reactions providing as much information as possible, including the brand name (if it has one), the list of ingredients, a copy of package labelling, and details of the manufacturer.

Further advice on using herbal medicines can be obtained by visiting the MHRA website or to report adverse events go to The Yellow Card scheme.

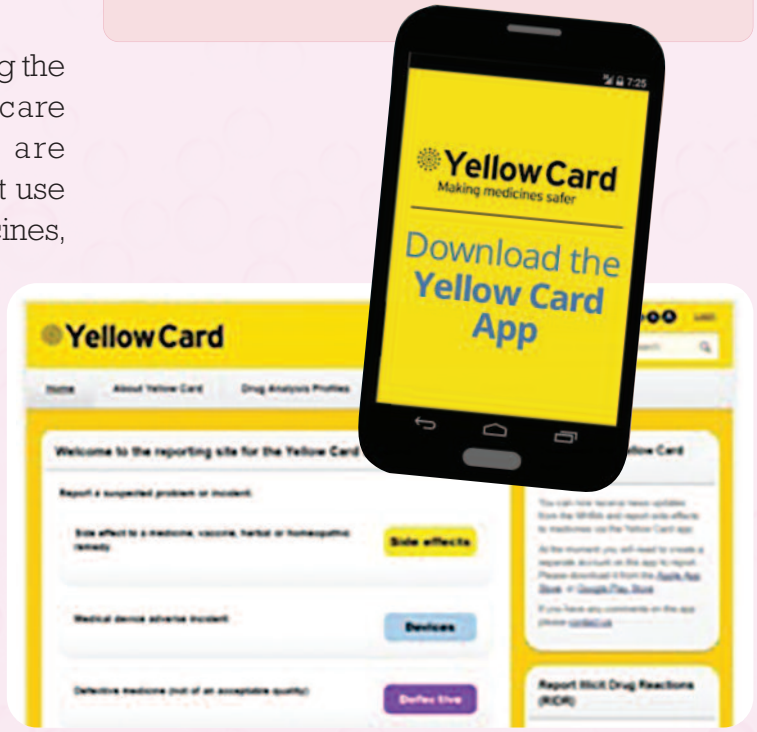
The Yellow Card Scheme is vital in helping the MHRA monitor the safety of all healthcare products in the UK to ensure they are acceptably safe for patients and those that use them. Reports can be made for all medicines, including vaccines, blood factors and immunoglobulins, herbal medicines and homeopathic remedies, and all medical devices available on the UK market. From the 20th of May 2016, the MHRA is also collecting reports of safety concerns associated with e-cigarette products through the Yellow Card Scheme.

The scheme collects information on suspected problems or incidents involving:

- **side effects (also known as adverse drug reactions or ADRs)**
- **medical device adverse incidents**
- **defective medicines (those that are not of an acceptable quality)**
- **counterfeit or fake medicines or medical devices**
- **safety concerns for e-cigarettes or their refill containers (e-liquids).**

It is important for people to report problems experienced with medicines or medical devices. This information is used to identify issues which might not have been previously known about. The MHRA will review the product if necessary, and take action to minimise risk and maximise benefit to the patients. The MHRA is also able to investigate counterfeit or fake medicines or devices and if necessary take action to protect public health.

**To find out more about the Yellow Card go to: https://yellowcard.mhra.gov.uk**





**By now you would have been inundated by the need for those who keep data on you, to provide you with an updated privacy notice and to give you options to how your data can be used. The law was made in 2016 and came in force on 25 May 2018, so most organisations have had plenty of time to get ready for the change.**

There has been some confusion and also some 'game playing', where some organisations have used the law change as an opportunity to increase their databases by contacting everyone whose details they have to get them to opt in, regardless of whether or not they needed to.

PAPAA's approach to the law change started a year ago, with a review of the law and what we as an organisation did with any data that we hold and whether we needed to make any changes.

Where an organisation has a legitimate reason (lawful basis) for contacting an individual the law is straightforward, and they can continue to do so.

The lawful basis for processing are set out in Article 6 of the GDPR (General Data Protection Regulation). At least one of these must apply whenever you process personal data and are as follows:

**(a) Consent:** the individual has given clear consent for the data holder to process their personal data for a specific purpose.

**(b) Contract:** the processing is necessary for a contract the data holder has with the individual, or because they have asked the data holder to take specific steps before entering into a contract.

**(c) Legal obligation:** the processing is necessary for the data holder to comply with the law (not including contractual obligations).

**(d) Vital interests:** the processing is necessary to protect someone's life.

**(e) Public task:** the processing is necessary for the data holder to perform a task in the public interest or for their official functions, and the task or function has a clear basis in law.

**(f) Legitimate interests:** the processing is necessary for the data holder's legitimate interests or the legitimate interests of a third party unless there is a good reason to protect the individual's personal data which overrides those legitimate interests. (This cannot apply if the data holder is a public authority processing data to perform their official tasks.)

So to be clear, as an ethical charity, PAPAA takes your privacy seriously. The following is what PAPAA does with data willingly provided by you:

We only use data when consent has been provided, so that means that we have been contacted by an individual who has willingly provided us with their data for a specific purpose, such as providing free information. The data provided, such as an individual's name, address and other personal information, is kept only for record keeping, internal audit (6 years) and is stored securely. After that time records are deleted or destroyed securely. We do not share or transfer data to any third-party organisation, except where legally required to do so, such as if someone has made a Gift Aid donation, we have to provide the name and postcode of the donor to Her Majesty's Revenue and Customs (HMRC), in order to provide proof that the donor is a UK tax payer.

Our full privacy statement can be viewed at:

**www.papaa.org/about-us/gdpr**

# Marketplace

## Visit the PAPAA shop

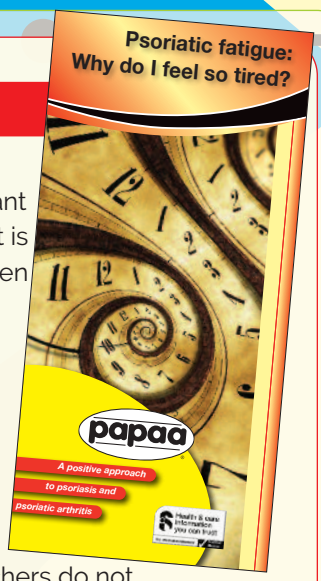
**www.psoriasis-shop.org**

- Order free information
- Join and pay for your subscription
- Renew your subscription
- Make a donation
- Purchase from a selection of books
- Informative training programmes.


## PAPAA's position on pharmaceutical funding

PAPAA does not receive funds (either directly or in kind) from the pharmaceutical industry or commercial sector. All activities are funded via donations, subscriptions, charitable grants, legacies or other income generation. We believe that this allows us to act in an open, non-biased way and free from any perceived influence or agendas that may arise. We do not link our activities to commercial marketing or public relations campaigns and will only link our name or logo to an activity if we believe it is beneficial to our constituent group.

## New booklet




For many people with psoriatic arthritis the constant tiredness is a symptom that is often not recognised or taken seriously. For some this constant weariness can be more debilitating than the recognised symptoms.

The cause appears to be the inflammation process associated with the condition, although researchers do not know exactly what the link is between inflammation and fatigue.

To help people understand what fatigue is, PAPAA has produced a new booklet called ***Psoriatic fatigue: Why do I feel so tired?*** The 12-page booklet covers the background of fatigue, the myths, what can be done, dietary advice, plus much more.

**The booklet is available free as hard copy or as a download from the PAPAA shop at www.psoriasis-shop.org**

The material was written by PAPAA and peer-reviewed by Dominique Raut-Roy, rheumatology research nurse at Cambridge University Hospital NHS Foundation Trust. A lay group of people with or affected by psoriasis and or psoriatic arthritis also reviewed and provide key input into the material. The booklet was produced under the NHS England Information Standard scheme.

## Join the conversations

If you have a social media presence, then why not follow us and join the conversation to see what others have to say?

The following are the links to our pages:

| | |
|---|---|
| Facebook: | **www.facebook.com/papaa.org** |
| Twitter: | **@PsoriasisInfo** |
| Pinterest: | **www.pinterest.co.uk/psoriasisuk** |
| Instagram: | **www.instagram.com/the_papaa_eye** |
| LinkedIn: | **www.linkedin.com/company/papaa/** |