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skin 'n' bones connection

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Dear Reader

Modern technology has the power and convenience to make every aspect of our lives better. Whether it is to buy goods online or watch TV on demand, it is seen by many as an essential right and provides choice. Although we are only selecting from goods and services that someone else has decided to make available. Which could be argued was always the case, so is there really a choice at all?

Part of the power of the virtual revolution is the ability to get information quickly, but this may also be part of the problem. News is often seen first on social media before being verified as accurate. "Shouting fire in a crowded theatre" is a phrase often used as a metaphor for inciting panic when there is no such event. This was emphasised by Professor Dame Sally Davies, chief medical officer for England, who recently, and ironically via her Twitter page, said "Measles is entirely preventable through the effective and safe MMR vaccine. Please take the opportunity to vaccinate your children against this terrible disease". Whatever your views on this topic, part of the idea of making this statement" is to try to provide an authoritative voice on the subject.

The problem may be that with so much misinformation being made available instantly and then repeated without any evidence, it is unsurprising that even when an authoritative figure makes an announcement, with supporting evidence, it can still be viewed with a level of scepticism.

In a recent enquiry to our information line, we were asked about psoriasis and the flu jab (see page opposite). The prompt for this call was following the issues in the media about MMR, so the knock-on effect of information in one area, can be very wide-ranging.

The evidence that supports claims either against or for an action is often dependent on interpretation and whether we trust that interpretation. On pages 10-12 we look at some of the work championed by Dr Ben Goldacre, who is best known for his Bad Science column in *The Guardian* newspaper. His desire is to see all data available, so we can make an interpretation without a pre-selected bias of what the supplier wishes us to choose.

Managing editor

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:

TRUTH hidden in a field of anti-honest text by Balefire

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This is the time of year when many GP practices are actively encouraging eligible patients to attend for flu vaccination, including those who may be immune-suppressed. For psoriasis patients this is especially important, given that their treatment may involve taking a variety of immuno-suppressant medications, such as ciclosporine and methotrexate, which may make them more susceptible to catching influenza.

Evidence suggests that only a minority of patients with psoriasis take advantage of a flu vaccination. Part of the reason for this may be the fear that the vaccination itself may make their psoriasis worse. In fact, there is very little evidence to suggest that this is the case. Only two studies have looked at the association between psoriasis and flu vaccination.

In the first, investigators sent a questionnaire to nearly 3,000 French dermatologists, requesting information in any case in which there was a flare of psoriasis after flu vaccination. They received feedback from six dermatologists concerning only ten patients reporting either new psoriasis, or a worsening of their existing condition following vaccination. Unfortunately, we have no information regarding the total number of psoriasis patients who received the vaccination, so we cannot estimate the actual rate. But it seems reasonable to assume that, in this study, the risk of psoriasis being made worse by vaccination was very low.

A more recent study found a total of 43 patients in whom the first onset of psoriasis was reported soon after flu vaccination was given in the 2009-2010 season. As with the previous study, however, we are told nothing about the total number of patients vaccinated, so the level of the risk cannot be stated with certainty. The other problem with studies of this kind is that it is difficult to be sure that other factors were not involved and that the vaccination caused the psoriasis.

Taken together, these studies suggest that although there may be an increased risk of a worsening of psoriasis following flu vaccination, this additional risk is very small. Furthermore, the benefits of protection against influenza – which can be a serious condition in older and immune-compromised patients – far outweigh the risks of psoriasis being made worse.

Conclusion

Individuals with psoriasis may be immune-compromised and at an increased risk of infections – including influenza. Scientific evidence suggests that the benefits of flu vaccination far exceed the small risk of a worsening of psoriasis.

Therefore we recommend that those with psoriasis should discuss the possibility of a flu vaccination with their GP, or least ask questions to alleviate any anxiety they may have.

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- Gunes AT, Fetil E, Akarsu S et al. Possible Triggering Effect of Influenza Vaccination on Psoriasis Journal of Immunology Research. Volume 2015, Article ID 258430, 4 pages. http://dx.doi.org/10.1155/2015/258430.

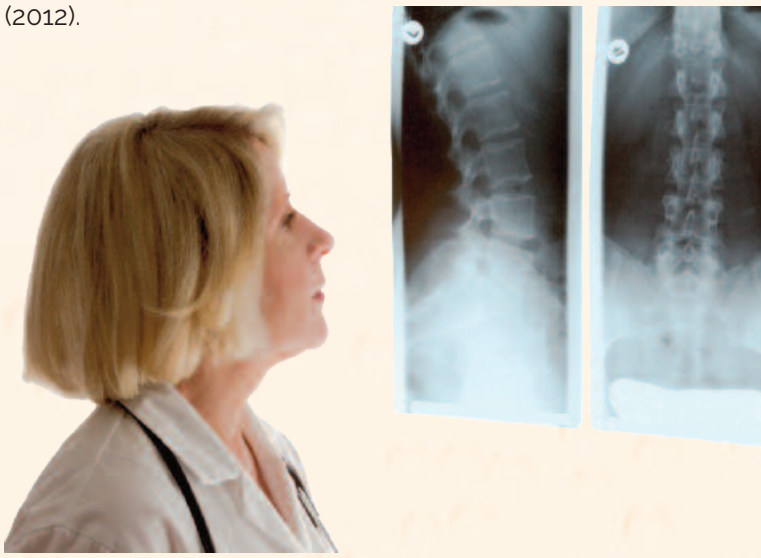
NICE Quality Standards

Following the publication of the guideline 'Spondyloarthritis in over 16s: diagnosis and management' by the National Institute for Health Care and Excellence (NICE) in February 2017, which saw recommendations under the following headings:

- **recognition and referral in non-specialist care settings**
- **diagnosing spondyloarthritis in specialist care settings**
- **information and support**
- **pharmacological management of spondyloarthritis**
- **non-pharmacological management of spondyloarthritis**
- **surgery for spondyloarthritis**
- **managing flares**
- **long-term complications**
- **organisation of care**

The institute has taken a further step to embed these under a process called NICE quality standards.

The NICE Quality Standards Programme was established in 2009 to manage the development of quality standards, and sits within NICE's Health and Social Care Directorate. NICE quality standards are central to supporting the government's vision for an NHS and social care system focused on delivering the best possible outcomes for people who use its services, as detailed in the Health and Social Care Act (2012).



What is a NICE quality standard?

NICE quality standards describe high-priority areas for quality improvement in a defined care or service area. Each standard consists of a set of specific, concise statements and related measures that are:

- derived from evidence-based guidance, such as NICE guidance or NICE-accredited guidance
- produced collaboratively with the NHS, social care or public health organisations, along with their partner organisations, people using services and carers.

Evidence from the underpinning guidance relating to people's experience of care or services, safety issues, equality and resource impact is considered during the development process.

NICE quality standards do not provide a comprehensive service specification. They define priority areas for quality improvement based on consideration of the topic area.

The key to developing standards is to produce meaningful statements that can be measured and improve outcomes. On the following page are quality statements produced for spondyloarthritis and published in June 2018

Statement 1 Adults with suspected axial or peripheral spondyloarthritis are referred to a rheumatologist.

Statement 2 Adults with suspected axial spondyloarthritis and an x-ray that does not show sacroiliitis have an MRI using an inflammatory back pain protocol.

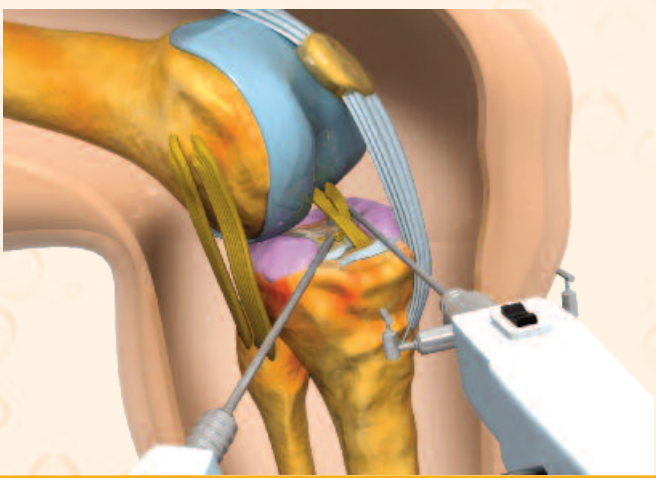
Statement 3 Adults with axial spondyloarthritis are referred to a specialist physiotherapist for a structured exercise programme.

Statement 4 Adults with spondyloarthritis are given information about their condition, which healthcare professionals will be involved with their care, and how and when to get in touch with them.

Improving outcomes

This quality standard is expected to contribute to improvements in the following outcomes:

- **functional capacity**
- **mobility**
- **work productivity**
- **health-related quality of life**
- **pain**
- **fatigue**
- **mortality rates from cardiovascular disease**
- **joint replacement surgery**
- **disease activity.**



It is also expected to support delivery of the Department of Health's outcome frameworks.

Expected levels of achievement for quality measures are not specified. Quality standards are intended to drive up the quality of care, and so achievement levels of 100% should be aspired to (or 0% if the quality statement states that something should not be done). However, this may not always be appropriate in practice. Taking account of safety, shared decision-making, choice and professional judgement, desired levels of achievement should be defined locally.

As a supporting organisation PAPAA recognises the benefit of this quality standard in improving care. We will help with promotion of the standard where possible and, through our work, promoting it to commissioners and service providers.

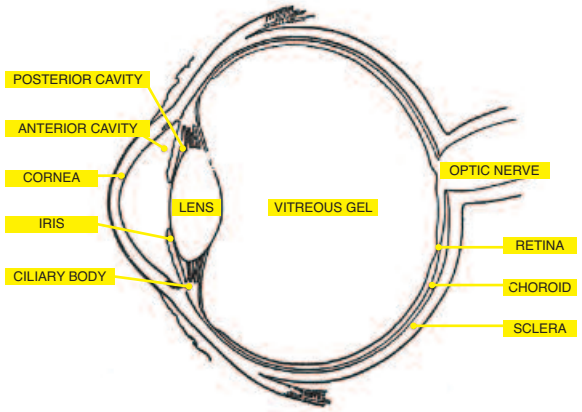
Source:

www.nice.org.uk

www.nice.org.uk/guidance/qs170

Uveitis and psoriatic arthritis

Developing psoriatic arthritis following psoriasis can be shocking news, often promoting disbelief that a skin condition could be in some way connected to a condition that affects the joints too. Developing a problem with your eyes may appear be just bad luck, but there is a link between a condition called uveitis and psoriatic arthritis.



What is uveitis?

Uveitis means inflammation of the uvea. This can affect the iris (iritis), ciliary body (cyclitis) or the choroid (choroiditis). Symptoms depend on whether all or just part of the uvea is affected, but may include:

- dull, aching pain in the eye
- redness
- risk is higher if HLA-B27 (human leukocyte antigen) is present, common in spondylitis sub-groups
- it can occur whether arthritis is currently active or not
- blurred or misty vision
- a muddy appearance to the coloured iris in the affected eye
- a pupil that may be smaller than on the other side and irregular in outline.

Symptoms can affect one or both eyes. Inflammation is thought to result from the immune system attacking the cells of the uvea. Treatment of uveitis is urgent to stop the inflamed iris from sticking to the lens behind. This would cause permanent damage to the eye and can also trigger glaucoma (a rise in fluid pressure in the eye due to blocked drainage channels). Uveitis often returns from time to time.

Note: Children with psoriatic arthritis should have regular screening tests for uveitis as they may not develop symptoms until their eyesight has been damaged and irreversible visual impairment takes place.

Treatment

Inflammation is damped down with eye-drops containing corticosteroid drugs. In severe cases, you may also need to take steroid tablets by mouth to boost the effect of the drops. Eye-drops that relax the iris and ciliary body are also used. These make the pupil dilate and ensure that an inflamed iris does not stick to the eye lens (posterior synechia). The inflammation is monitored by regular examination of the eye using a slit-lamp. If steroid eye drops are used for prolonged periods, the fluid pressure in the eye will also need to be checked regularly. This is because long-term use of steroid drops can cause a form of glaucoma.

The advice from the NHS is:
"Contact your GP as soon as possible if you have persistent eye pain or an unusual change in your vision, particularly if you've had previous episodes of uveitis. The sooner uveitis is treated, the more successful treatment is likely to be."

Remember: Uveitis is just one condition that can affect the eyes. Other conditions of the eye include blepharitis, cataracts, conjunctivitis, cysts, detached retinas, glaucoma, keratitis and styes. If you have any concerns about your eye health, talk to your healthcare provider.

Useful information
NHS website:
www.nhs.uk/conditions/uveitis/

The Royal College of Ophthalmologists
(eye specialists)
can provide a list of practising ophthalmologists.
www.rcophth.ac.uk

Dietary changes can improve psoriasis

According to a recently published report, dietary changes, in conjunction with standard medical treatment, can help adults with psoriasis or psoriatic arthritis reduce the severity of their disease. The report was based on a comprehensive review of scientific literature from the Medical Board of the National Psoriasis Foundation in the USA. The researchers took into account a total of 55 studies, representing 77,557 subjects, of whom 4,534 have psoriasis. There were three key findings and recommendations relating to (1) weight loss, (2) a gluten-free diet and (3) dietary supplements.

Weight loss

The board found very good evidence to suggest that weight loss in those who are overweight has a major positive impact on disease severity and quality of life. This is best achieved by a structured low-calorie diet combined with increased physical activity. There is nothing especially surprising about this and I have already covered the relationship between overweight and psoriasis, including psoriatic arthritis, in detail at www.papaa.org/resources/overweight-and-psoriasis

A gluten free diet

Psoriasis is linked to a more than twofold increased frequency of coeliac disease. The review concluded that in patients with psoriasis who tested positive for gluten sensitivity, a gluten-free diet led to significant improvements in clinical severity and in skin biopsy findings after 3 months.

Accordingly, the board recommends a gluten-free diet trial for 3 months, but only in patients with a positive blood test for gluten sensitivity. This is very important, because many people believe themselves to be gluten-sensitive, when in fact they are nothing of the sort. A physician diagnosis of gluten sensitivity is essential before embarking upon a gluten-free diet, which is not without its own hazards.

However, the board does not recommend universal screening for gluten sensitivity in adults with psoriatic disease because of the high rate of false positives. Potential screening candidates include those with a first-degree relative with coeliac disease or patients with gastrointestinal symptoms, typical of gluten (a protein found in wheat, barley and rye) sensitivity.

Dietary supplements

I have covered the question of supplements and psoriasis in the leaflet **Psoriatic Lifestyle and Nutrition** (available from PAPAA).

The review board did not recommend oral fish oil supplementation because they did not regard it as effective at the doses and durations studied. My own view, however, is that fish oils have important anti-inflammatory properties and health benefits which are independent of – and in addition to – their potentially positive impact on psoriasis. Moreover, regular consumption of oily fish is a general dietary recommendation from all expert groups.

The review did not recommend either vitamin D or B12 supplements for prevention or treatment of psoriasis. This seems reasonable given the lack of scientific evidence in this regard, though it is important to note that the UK Department of Health advises everyone to consider taking a vitamin D supplement (10mcg) for bone health, during the autumn/winter period.

Author: Dr David Ashton MD PhD

Reference:

Adam R. Ford, Michael Siegel, Jerry Bagel, et al. Dietary Recommendations for Adults with Psoriasis or Psoriatic Arthritis: from the Medical Board of the National Psoriasis Foundation. A Systematic Review. JAMA Dermatol. Published online June 20, 2018. doi:10.1001/jamadermatol.2018.1412

Strep throat, psoriasis and tonsillectomy

Getting a streptococcal throat infection - known as strep throat – can trigger a flare or, in some cases, lead to the onset of new psoriasis. In a recent study of 275 patients, among those with plaque psoriasis 42% reported flares associated with throat infections. In those where it was a confirmed streptococcal infection, 72% reported an exacerbation of their psoriasis. So, the interesting question is whether removing the tonsils (tonsillectomy) could be a way to reduce the risk of psoriasis flares.

The theory is that episodes of streptococcal throat infection can lead to movement of immune cells (T cells) from the tonsils into the skin, where they can initiate or exacerbate skin problems, including psoriasis. It is suggested that removing the infected tonsils should bring about a reduction in psoriasis. Well, that's the theory, but is there any evidence that tonsillectomy works?

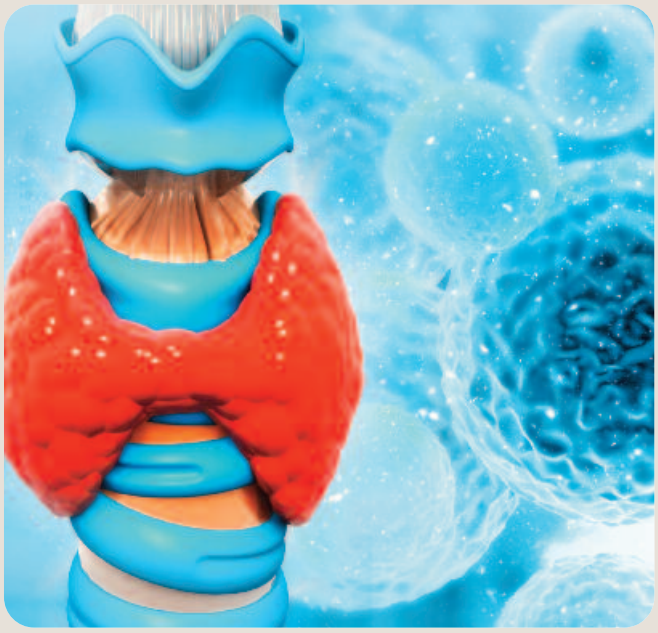
A recent comprehensive review looked at exactly this question. Researchers examined studies of tonsillectomy as a treatment for psoriasis published between 1960 and 2012. Of note is the fact that only 13 articles met the strict inclusion criteria and only one of the studies was of the "gold-standard" randomised trial design. Moreover, this study involved just 29 patients with plaque psoriasis. Of the 15 patients undergoing tonsillectomy, 86% showed a significant improvement in their psoriasis, whereas no improvement was seen in the controls. In most patients, this improvement was maintained at two years into follow-up.

Whilst other studies in the review also showed improvements, they generally included small numbers, making definitive recommendations difficult to make. Overall, the researchers feel that tonsillectomy may have a role to play in the management of psoriasis, but identifying which patients will benefit remains the main challenge for future research.

Finally, a Cochrane Review concluded that, whilst the overall evidence is weak, tonsillectomy should be considered a valid treatment option, though limited to cases where repeated streptococcal throat infections are associated with an exacerbation of psoriasis.

Conclusion

Currently there is no convincing evidence to justify the routine use of tonsillectomy in the management of psoriasis. The exception to this generalisation is where repeated streptococcal throat infections are clearly associated with a worsening of the skin symptoms.



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Owen CM, Chalmers R, O'Sullivan T et al. Antistreptococcal interventions for guttate and chronic plaque psoriasis. Cochrane Database Syst Rev 2013; (10):CD001976

Nail psoriasis (nail dystrophy) has been estimated to occur in up to 80-90% of people with psoriasis and is even more common in those with psoriatic arthritis. It may also occur as an isolated finding without any skin manifestations of the condition. Not only do people find it cosmetically unattractive, it may also cause significant functional impairment and pain. One survey found that in 1,728 patients, 52% suffered with pain from their disease and many of the subjects experienced impairment in both their private and professional lives.

The signs of nail psoriasis are non-specific and can be found in several other nail conditions. In general, however, the main signs are pitting, leukonychia (white spots), transverse grooves and crumbling of the nail plate (onycholysis).

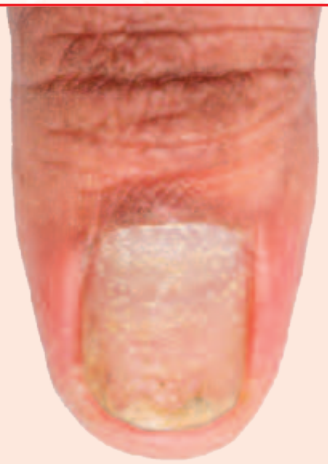
A number of different treatments have been proposed, though nail psoriasis can be difficult to treat. Currently, treatment options include various drugs such as methotrexate and cyclosporine, as well as non-pharmacological options such as phototherapy and laser treatment, though none is especially effective. Moreover, drug therapy obviously has the potential downside of a various side-effects. A recently published study has investigated a relatively simple topical treatment for nail psoriasis.

The study

Researchers investigated a topical treatment, K101-3 (Emtrix), which contained propylene glycol, glycerol urea and lactic acid, in the treatment of patients with nail psoriasis or onychomycosis (fungal infection) for a period of 8 weeks. In total, 72 subjects had onychomycosis, 34 had nail psoriasis and 1 subject had both. During and after treatment, patients were asked to rate the overall appearance of the affected nail(s) on a 4-point scale: No improvement, Some improvement, Clear improvement and Very good improvement.

Results

At the end of the 8 week period, 92% of patients reported at least some improvement in their nail problems – which was almost the same for both onychomycosis and nail psoriasis. There were no treatment-associated side-effects.



There are obvious problems with the design of the study. The first, as readily acknowledged by the researchers themselves, is that there was no control group (i.e. patients given a placebo in the form of a non-active substance). This makes it difficult to conclude that the treatment with K101-3 caused the reported nail improvements. The other difficulty is the self-reported 4 point improvement scale. It's quite difficult to interpret the difference between "some improvement and "clear improvement", but this makes a big difference to the results.

One could say that what we are really looking for is evidence of clear improvement, rather than some improvement. And if we adopt this as the standard, then the benefit falls from 92% of subjects to around 50%. This may be a more realistic interpretation. Even so, an improvement in 50% of sufferers without any significant side-effects is very interesting.

Summary

This is an interesting study which, despite some methodological limitations, suggests that the substance K101-03 (Emtrix) is a well-tolerated and moderately effective treatment for nail psoriasis and onychomycosis. More research is needed and is planned.

Author: Dr David Ashton MD PhD

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Dermatology. 2017 Oct; 233(2-3): 178–183. Published online 2017 Aug 5. doi: 10.1159/000478257

Where is the truth?

There is a well-known phrase often quoted which is "lies, damned lies and statistics" it is often widely attributed to Benjamin Disraeli, Earl of Beaconsfield and UK prime minister in the latter part of the 19th century. Although, its origin has been questioned, with the Department of Mathematics at the University of York suggesting that it may have been American writer Mark Twain who came up with the phrase. Which makes the quote even more interesting; if a poll was taken amongst the general public about who originated the quote, and the results were reported, what would that tell us?

The same could be said about any piece of data which is presented and, in particular, the benefits of a new therapy or treatment. Can we believe the results if we do not see full disclosure of all the results?

Dr Ben Goldacre GP, who is known for his Bad Science column in *The Guardian* and author of books such as *Bad Science* and *Bad Pharma*, has long maintained that the published trials do not always represent the truth, in his second book, *Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients,* he says:

"Drugs are tested by the people who manufacture them, in poorly designed trials, on hopelessly small numbers of weird, unrepresentative patients, and analysed using techniques which are flawed by design, in such a way that they exaggerate the benefits of treatments. Unsurprisingly, these trials tend to produce results that favour the manufacturer. When trials throw up results that companies don't like, they are perfectly entitled to hide them from doctors and patients, so we only ever see a distorted picture of any drug's true effects . . . "

Dr Goldacre is also a founder member of the campaign called All Trials, which wants to see all trials published regardless of the results.

According to the data they have gathered, nearly half of trials run by major trial sponsors in the last decade are missing results. Their trial tracker reports:

- 45.2% of trials conducted by major sponsors during the last decade are missing results
- since January 2006, major trial sponsors completed 25,927 eligible trials and haven't published results for 11,714 of them.
- one trial sponsor has published no results at all for any of the 35 trials it has run in the last 10 years
- one trial sponsor has published results for all of the 96 trials it has run in the last 10 years

- the top twenty trial sponsors as ranked by the tracker – those with the lowest proportion of trials that haven't published results – are all pharmaceutical companies.

This view is also the impetus for the charity Sense about Science, whose aim is to:

"Advocate openness and honesty about research, and ensure the public interest in sound science and evidence is recognised in public debates and policymaking."

In a recent British Medical Journal editorial entitled 'Transparency in clinical trial reporting', by Rochon et al, the authors report:

"Since the 1990s, most clinical trials have had industry funders who collaborate with academics for clinical and methodological expertise, recruitment of study participants, and access to scholarly publications. More recently, industry has increasingly turned to contract research organisations for efficient oversight of clinical trials. These for-profit entities employ physician-scientists, pharmacists, biostatisticians, managers, and medical writers who take control of the design, conduct, analysis, and reporting of trials. This commercialisation of the oversight of clinical trials has seen academic physicians shifted to comparatively minor roles."

The highlighting of this trend, along with the pressure of campaigns, has begun to get a reaction. The House of Commons Science and Technology Select Committee report on 'Research integrity: clinical trials transparency' published in October 2018 says:

"Selective non-publication of the results of research distorts the published evidence base and is a threat to research integrity. In the case of clinical trials, non-publication of results means that information on the efficacy of new drugs or other medical interventions cannot be used. Falling short on 'clinical trials transparency' in this way presents risks to human health, contributes to research wastage and means that clinical decisions are made without access to all the available evidence."

To improve transparency in the conclusion of the report, the committee said:

"We recommend that the government consult further with the Health Research Authority (HRA) on whether it is capable of delivering the improvements to clinical trials transparency needed within its current remit. If necessary its remit should be extended through introducing legislation which amends the provisions of the Care Act 2014."

The Rt Hon Norman Lamb MP, chair of the science and technology committee, said:

Where is the truth?

"An astounding amount of information from clinical trials is going unreported. The HRA (Health Research Authority), must act now to ensure current regulations are enforced and impose tough sanctions on those who seem to think it is acceptable to disregard valuable research, threaten research integrity and, in some cases, endanger human life. Many of these trials are funded with public money and the tax payer has a right to expect those who benefit from public funding to follow the rules and publish in full.

"People take part in these trials in good faith, hoping to help inform doctors and decision makers on vital issues affecting many of us every day. Their efforts are betrayed if the results are not made available at the end."

It is good to see that at least there is some recognition of the problem with a plan to rectify the situation, but only time will tell if this makes any difference. So, what can you do as a patient when seeing the latest breakthrough, miracle cure or statistics which make claims about the condition you have? Behind the Headlines is a section of the NHS website which aims to help people cut through the information by providing straightforward sections under the headings:

- **Where did the story come from?**
- **What kind of research was this?**
- **What did the research involve?**
- **What were the basic results?**
- **How did the researchers interpret the results?**
- **Conclusion.**

This simple approach helps the reader to take a measured view with any commercial bias removed, which has to be welcomed. In a world where we are bombarded with information that may have no basis in evidence or which is missing vital data, it is refreshing to see that there maybe some sense emerging from the plethora of lies, damn lies and statistics which form the daily fodder of our news-hungry media.

So, a final cynical piece of advice might be, "Believe nothing you hear, and only one half that you see," a quote attributed to American writer Edgar Allan Poe, although, if you take that advice, who knows what you will think of this article?

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Dr Ben Goldarce
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www.alltrials.net

Sense about Science
www.senseaboutscience.org

British Medical Journal editorial: Transparency in clinical trial reporting
BMJ 2018;363:k4224
www.bmj.com

Research integrity: clinical trials transparency Report by the House of Commons Science and Technology Select Committee
https://publications.parliament.uk

Health Research Authority
www.hra.nhs.uk

A study comparing the efficacy (does it work) of etanercept monotherapy (single therapy) and etanercept plus methotrexate (combined therapy) to methotrexate monotherapy in patients with psoriatic arthritis was presented in a late-breaking poster session at the 2018 American College of Rheumatology (ACR) / Association of Rheumatology Health Professionals (ARHP) annual meeting in Chicago in October.

This study was undertaken to address key knowledge gaps, regarding the optimal use of methotrexate and TNF inhibitors (tumour necrosis factor alpha - part of the immune system that causes inflammation), such as etanercept, in people with early disease, who have not previously received treatment with biologics and methotrexate for psoriatic arthritis.

Results showed that a significantly higher proportion of patients on etanercept monotherapy and on combination therapy achieved the primary endpoint of ACR 20 response compared with patients on methotrexate monotherapy.

Patients on etanercept monotherapy and on combination therapy also had greater responses on additional secondary endpoints of ACR 50 and ACR 70 compared with patients on methotrexate monotherapy.

"The SEAM-PsA trial results suggest that methotrexate is generally efficacious in treating psoriatic arthritis symptoms in patients with early disease. Etanercept monotherapy has greater efficacy compared with methotrexate as monotherapy across key measures of psoriatic arthritis activity…" said Dr Philip Mease, lead SEAM-PsA investigator and study author,of the Swedish Medical Center and University of Washington

"These results provide information of practical value for psoriatic arthritis patients and their doctors to optimally manage the disease while addressing potential challenges associated with combination therapy."

The study, which was funded by Amgen, makers of Enbrel, which is the branded name for etanercept, which was approved to treat psoriatic arthritis, in 2003 to treat moderate-to-severe plaque psoriasis in adults in 2004. In 2017, the UK patent expired (licenced for a set period) and there are now biosimiliar versions (copycat drug) of etanercept available.

About etanercept:

Etanercept is a soluble form of a tumor necrosis factor (TNF) receptor available on prescription and given by injection.

In SEAM-PsA, patients were randomly assigned to one of the three treatment groups. At 24 weeks, patients were assessed for ACR 20 response, a standard measure of 20% or greater improvement from baseline in ACR response criteria, a composite measure based on tender and swollen joint counts, patient assessment of pain, patient and physician global assessment of disease activity, patient assessment of physical function and a measure of inflammation called the acute-phase reactant value.

About SEAM-PsA

Study of Etanercept And Methotrexate in subjects with Psoriatic Arthritis (SEAM-PsA) is a phase 3, multi-center, double-blind, randomised controlled study conducted in biologic-naïve patients, with no prior use of methotrexate for PsA. Patients were assigned 1:1:1 to one of the three treatment groups and followed for a total of 48 weeks. At 24 weeks, patients were assessed for ACR 20 response and MDA criteria, along with additional secondary and exploratory endpoints. Patients with inadequate response were provided rescue treatment of Enbrel plus methotrexate combination therapy for the remainder of the study, though remained blind.

What is the ACR score?

ACR score is a scale to measure change in rheumatoid arthritis symptoms. It is named after the American College of Rheumatology. The ACR score is more often used in clinical trials than in doctor patient relationships, as it allows a 'common standard' between researchers.

Different degrees of improvement are referred to as ACR20, ACR50, ACR70.

ACR20 was initially proposed with ACR scoring, measuring a 20% improvement on a scale of 28 intervals. ACR50 and ACR70 were later proposed, corresponding to 50% and 70% improvements.

Source:
Media release

The Future of Healthcare

Outdated and obstructive NHS IT systems will become a thing of the past, says health and social care secretary, Matt Hancock, as he launches his technology vision in 'The Future of Healthcare'.

This vision transforms NHS technology to allow appropriate access to real-time data, underpinning the digital services and data innovations needed.

The vision outlines plans to introduce minimum technical standards that digital services and IT systems in the NHS will have to meet. Having these open standards in place means systems will be able to talk to each other securely and ensure they are upgradeable.

Any system that fails to meet these standards will be phased out. The government will look to end contracts with providers who do not understand these principles for the health and care sector.

Outside those standards, all trusts and clinical commissioning groups (CCGs) will have freedom to buy what they need. This should encourage competition on user experience and better tools for everyone.

Matt Hancock

The changes will secure a brighter future for the health and social care system and are central to unlocking the potential of innovative technologies to support care.

The government wants to hear from staff, technology experts and suppliers to make sure the standards are the best choices for our users and can help improve outcomes in every area of the health and care system.

Introducing his iniatiative, Matt Hancock said:

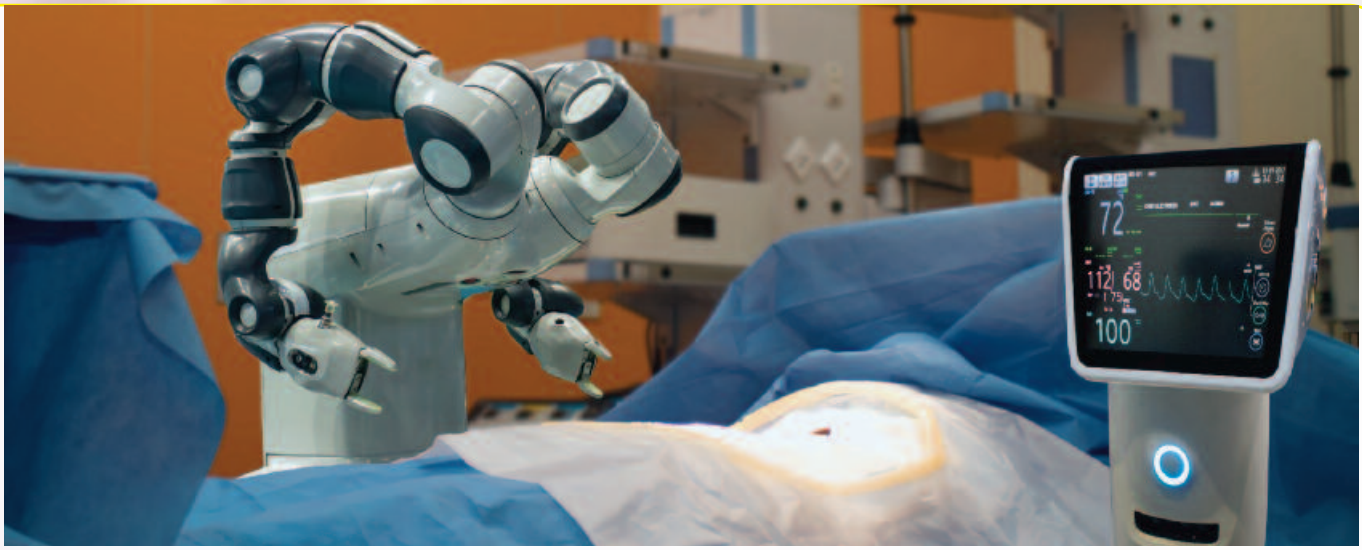
"The tech revolution is coming to the NHS. These robust standards will ensure that every part of the NHS can use the best technology to improve patient safety, reduce delays and speed up appointments.

A modern technical architecture for the health and care service has huge potential to deliver better services and to unlock our innovations. We want this approach to empower the country's best innovators – inside and outside the NHS – and we want to hear from staff, experts and suppliers to ensure our standards will deliver the most advanced health and care service in the world."

Dr Simon Eccles, chief clinical information officer for health and care, NHS England, said:

"Investing in excellent digital systems means patients can access the best and safest treatment pathways available, as swiftly as possible at the best value for taxpayers.

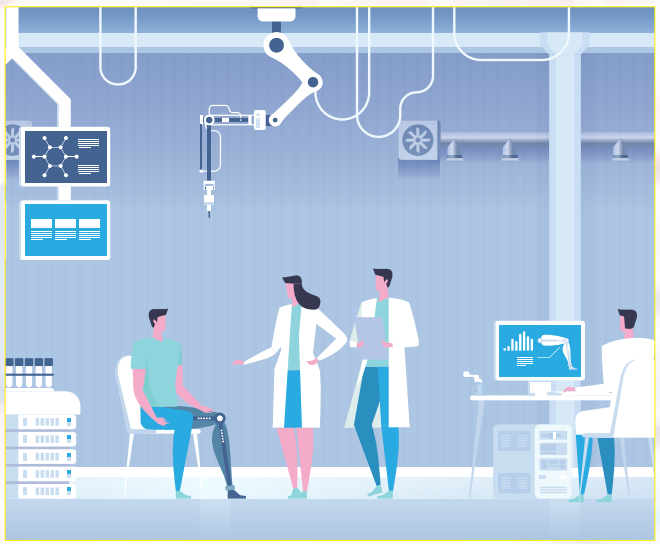
This, combined with our plan to use technology to improve existing treatments and join up information across the NHS, will set the health service in England on track to be the world leader in innovative health care."



Sarah Wilkinson, chief executive at NHS Digital, said:

"Greater standardisation of data, infrastructure, platforms and APIs (application programming interface) will create a health and care system that is more joined-up, and as a result safer and more efficient. Connected systems ensure that clinicians have immediate access to all relevant and appropriate patient data from all care providers and settings, and ensure that data is communicated between systems with absolute fidelity, eliminating misinformation and misunderstandings. In addition, we will increasingly be able to provide citizens and patients with direct and immediate access to their medical records.

Everyone understands the value of this work but progress in recent years has been limited.



Responding to a direct challenge from the secretary of state to transform the fortunes of this work, we are injecting a new level of energy and commitment. NHS Digital is providing a new, clear framework to simplify the guidance on those standards that matter most. We are going to build the detailed guidance on these standards in partnership with technologists across the system and with industry partners.

We recognise that the implementation journey is complex. Through consultation we will seek to understand in detail what the challenges are for different parties and throughout implementation we will focus on providing clear specifications, detailed guidance and extensive support. Our goal is to ensure successful implementation through engagement and facilitation, ensuring that changes that are mandated are reasonable and achievable.

This work matters too much for any of us to shy away from the challenge."

Source:

Department of Health and Social Care

www.gov.uk/government/news

Published 17 October 2018

Fake medicines crackdown

A crackdown on fake medicines and medical devices by the Medicines and Healthcare products Regulatory Agency (MHRA) has netted a haul of more than 1 million doses worth in excess of £2 million.

The seizures were part of Interpol's globally coordinated Operation Pangea, an international initiative involving 116 countries. Operation Pangea is an international initiative to target the illegal internet trade in medicines. It was instigated by the MHRA in April 2006 and started as the UK Internet Day of Action (IDA). There were 116 countries participating in Op Pangea XI.

The annual operation is the largest internet-based enforcement action of its kind to date and was coordinated by INTERPOL, together with the World Customs Organization (WCO), the Permanent Forum of International Pharmaceutical Crime (PFIPC), the Heads of Medicines Agencies Working Group of Enforcement Officers (WGEO), Europol and the Pharmaceutical Security Institute (PSI), and supported by the Center for Safe Internet Pharmacies (CSIP) and private sector companies including LegitScript, Google, Mastercard, Visa, American Express and PayPal.

Between 9-17 October the MHRA and UK partners found falsified and unlicensed medicines and medical devices in the UK including diazepam, modafinil and dermal fillers.

Using intelligence, MHRA enforcement officers raided a semi-detached property and a small lock-up unit in connection with the illegal supply online of potentially harmful medicines. This led to one arrest.

Raids on the properties in the north of England involved local police and forms part of an international response coordinated through Interpol to the growing illegal trade in online medicines and medical devices. Worldwide, Operation Pangea led to 859 arrests and yielded items worth in the region of £10.9 million.

As well as the property raids, the team also targeted airports and mail delivery centres. During the searches, officers found numerous packages containing illegal consignments of medicines and medical devices, including many hidden within other innocent items such as video games and clothing.

Fake medicines crackdown

The team also targeted websites on the open and dark web that offer falsified and unlicensed medical products. Their action has led to 123 websites being shut down and the removal of 535 online adverts.

MHRA head of enforcement, Alastair Jeffrey said:

"Criminals who sell medicines over the internet have absolutely no regard for your health and taking medicine which is ether falsified or unlicensed puts you at risk of serious harm.

"Our intelligence-led enforcement operations have seized millions of counterfeit and unlicensed medicines and devices in the UK. This is just the tip of the iceberg, and we will continue to take action against known criminals – working with our international partners to stop illegal medicines from entering the UK.

"To protect your health, visit your GP, get a correct diagnosis and buy medicines from a legitimate high street or registered pharmacy which can trade online with a distance selling logo".

The MHRA has also issued the following safety advice when buying medicines:

Be careful buying medicines online – criminals are known to exploit vulnerable people by supplying medicines through unregulated websites and stealing their credit card details.

Do not self-prescribe

Self-diagnosis and self-medication can be very dangerous. If you have a concern about your health, visit your GP, get a correct diagnosis and, if medicines are prescribed, buy them from a legitimate source.

Report it!

If you have any knowledge of criminal activity relating to the medicines offences then you should report this to: CaseReferrals@mhra.gov.uk

You may also provide information anonymously through 0800 555111 or Crimestoppers.

Prescription-only medicine should only be taken in consultation with a GP or other healthcare professional. These people have access to patient health records and can take into account the risks and benefits associated with every medicine as well as providing ongoing monitoring of the treatment.

Source:

Department of Health and Social Care

www.gov.uk/government/news

Published 17 October 2018

Regular readers of this publication and those who have signed-up to our free eNewsletter will often receive invitations to complete surveys. This is part of our continual process of data gathering which also includes a questionnaire, which new subscribers and those joining the PAPAA Register can complete.

Getting involved in this process is completely voluntary and in most cases is anonymous; we believe that this allows people to be honest and provide a real view of how both psoriasis and psoriatic arthritis impacts on daily life.

We use this data to give us a view of our demographic (selected groups), their needs, and issues where we can raise support and awareness. During 2018 we have made submissions to both the National Institute for Health and Care Excellence (NICE) and the Scottish Medicines Consortium (SMC) for appraisals of new medicines. Included in those submissions are anonymous quotes and views which have been taken directly from the surveys which people have generously taken the time to complete. The submissions from patients and those that represent them is an integral part of the decision-making process and is regarded as qualitative research, which is more text and opinion-based, whereas the other evidence considered is quantitative with statistical analysis of data obtained from clinical trials.

It is often suggested that quantitative (measured) data is superior to the anecdotal data gathered as qualitative (personal experience) but, as outlined in the article on pages 10-12, perhaps that may not be such a relevant viewpoint. In our view, this rich, real-life data is just as important as any measured clinical trial data. It is also our view that this real-life data is presented in the context in which it is gathered. For our surveys, those who take part are generally a self-selected group and may only provide a snapshot or particular view point in time, which does not make the information less important but does reflect the subtle differences that happen.

Our surveys

The online surveys that are available to complete and which we analyse are as follows:

- **Psoriasis and psoriatic arthritis health website survey**
- **Psoriasis: Quality of life survey**
- **Psoriatic arthritis: Quality of life survey**
- **Psoriasis and psoriatic arthritis: UK research priorities**
- **Your experience of being diagnosed with psoriasis or psoriatic arthritis.**

These surveys, along with the 'share your story' section of the website with the ability to provide free text comments via our 'your views', provide a valuable insight which often can only be obtained from real-life experiences.

The following is an analysis of views submitted via a short survey called *Your experience of being diagnosed with psoriasis or psoriatic arthritis.*

The survey asked a series of questions; below is an interpretation of those submitted with some representative selected answers:

In the first question PAPAA asked *"What was the one question you wanted answering when you were first diagnosed with psoriasis or psoriatic arthritis?"* The most common reply was "Can it be cured?" This was followed by "Why me?" with long-term prognosis and of course treatments being very commonly the questions people asked or wanted an answer.

In a second question "What would you have liked to have known about psoriasis or psoriatic arthritis before your diagnosis?" The answers to this question nearly all related to psoriatic arthritis with frustration and some annoyance that there was little pre-warning or awareness of the possibility of developing an arthritis associated with psoriasis. Much of this annoyance was

targeted at GPs. There were also issues about symptoms such as fatigue not being mentioned and the unpredictable nature of flaring..

In answer to another question, "How has psoriasis or psoriatic arthritis changed your life?" People were very honest and shared details of how psoriasis often made their life impossible. The constant shedding of skin was difficult to cope with, along with the problems that creams also caused. Self-confidence and issues around relationships were also highlighted, with one respondent citing the failure of her marriage due to psoriasis.

For those with psoriatic arthritis the general feeling was that of desperation and hopelessness, with depression and anxiety about living with immobility being a strong concern. As with the skin, going out and socialising was also the main change seen in lifestyle. One respondent said "It has completely changed every aspect of my life, I have no future."

For the question "How old were you at the time of your diagnosis?" the results were wide-ranging; the youngest age of diagnosis was two years old, with the oldest being 70 years of age. If we apply a statistical average, we end up with 36 years of age being the mean average, which perhaps might not fully reflect the differing issues that might affect such a wide age range.

PAPAA often asks for respondents to provide some basic demographic data. In responses we learnt that people lived in all four nations of the UK, along with a number of responses from people in the United States of America.

Although we know that both psoriasis and psoriatic arthritis affect both men and women equally, for question 6, what is your gender? Only one fifth of those who responded were male, so in our survey, responses might bias towards a female viewpoint. PAPAA found that this female-dominated response applies to all our surveys; whatever the reasons, it is important to recognise that survey responses need to be analysed and attributed appropriately, otherwise it can easily distort the outcomes, and we may miss a group with an unmet need.

The final question, *"Any other comments you would like to share?"* allowed respondents the opportunity to share other issues that were of concern to them. There was an emphasis on the need for greater awareness amongst the medical profession and general public, while lack of access to appointments and latest therapies also caused concern.

These useful real-life views help PAPAA to reflect and consider the true feelings that may not be obvious, so we thank all those who have taken the time to share their thoughts. It is not in vain and does make a difference.

The survey is still available and to date we have had 60 fully completed responses, which is a small number; our aim is to continue to gather this data and build on it over time. If the number of people who complete the survey increases we will then be able to get a real-life picture of what is important to people and where changes need to be made.

If you would like to be sent the latest news, opportunities and access to our online surveys, why not sign up to our free eNewsletter – go to:
www.papaa.org/newsletter

Marketplace

Promotional material

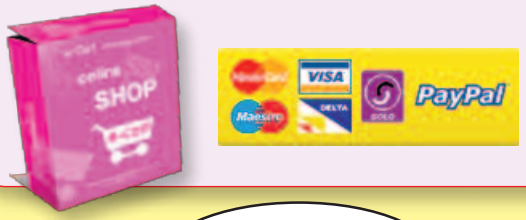
If you are thinking about supporting PAPAA or raising awareness on behalf of PAPAA about psoriasis and or psoriatic arthritis.

Why not check out some of the merchandise we have available?

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.

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/**