PrescQIPP Community Interest Company

Emollients, paraffin content and risk of fire

In 2007 and 2008 the National Patient Safety Agency (NPSA) and Medicines and Healthcare products Regulatory Agency (MHRA) highlighted the danger of fire and serious injury for patients using paraffin-based emollients on their skin, which is then covered with dressings or clothing when they smoke or go near naked flames. A reminder was issued in 2016 due to a fatal incident. Further deaths have been reported since then. In 2018, the MHRA strengthened their advice and extended the warning about risk of severe and fatal burns to all paraffin-based emollients regardless of paraffin concentration and indicated that data suggest there is also a risk for paraffin-free emollients. This bulletin aims to support healthcare professionals who are optimising emollient treatment in line with the NPSA and MHRA alerts. Clinicians should weigh up the risks and benefits of using paraffin-based or paraffin-free emollients before prescribing.

Recommendations

- Many CCGs have formularies with a range of preferred emollient products for effective treatment of dry skin conditions. Over the last decade, information about the risk of fire and serious injury for patients using emollients, particularly those containing paraffin has increased. Taking into account the very rare risk of fire, the modifiable risk factors, and their important therapeutic role, the benefits of emollients outweigh their risk and they should continue to be prescribed/used.
- Patients who use nasal cannulae (prongs) for oxygen administration can apply a water based moisturiser (such as KY jelly) to the lips and nose to prevent drying and cracking. Paraffin-based products are not recommended as they can plug air holes and are a fire hazard.
- Patients prescribed large quantities of any emollient to treat skin conditions (e.g. application of 100g or more at once, or over a short period of time e.g. a week) must be counselled about the risk of fire due to build-up of emollients on clothing.
- If patients regularly apply small amounts of emollients to the same part of the body (e.g. elbow, behind knee etc.), emollients will still contaminate the clothing over time, especially if they are washed at low temperatures (e.g. 20-30°C), making these areas more susceptible to ignition.
- Paraffin and non-paraffin containing preparations can contaminate clothing or dressings, so they ignite rapidly. To reduce the risk, advise patients that while emollients are in contact with their clothing or dressings they should:
  - keep away from open or gas fires, halogen heaters and naked flames, including candles
  - avoid gas hobs for cooking
  - not smoke and never smoke in bed.
- The build-up of residue on fabrics can be reduced by regular washing at a high temperature, e.g. 60°C. Bedding and clothing should be changed daily and washed at the highest temperature recommended by the fabric care instructions to minimise the build-up of impregnated paraffin/emollient, although it won't totally remove it.
- Be aware that emollients may seep into bandages which are not changed as regularly and therefore pose a fire risk if exposed to a naked flame.

Recommendations

- The fire risk of using small amounts of paraffin-based emollients occasionally is minimal.
- Prescribers should consider doing a risk assessment with the patient when prescribing emollients and give advice to reduce modifiable risk factors.
- If risk factors cannot be reduced, particularly with high risk patients such as those who have a history of smoking or have memory problems/are confused, prescribers may wish to seek advice from the local fire service. County fire services offer a free home fire safety check, and some have useful information on their websites.

Background

In November 2007 the NPSA issued an alert to all healthcare staff involved in the prescribing, dispensing or administration of paraffin-based skin products. The NPSA highlighted that the topical administration of paraffin-based skin products, for example, emulsifying ointment or 50% liquid paraffin +50% white soft paraffin (WSP) ointment have a potential fire risk as bandages, dressings and clothing that come in to contact with them are easily ignited with a naked flame or cigarette. The risk is greater when these preparations are applied to large areas of the body and clothing or dressings become soaked with the ointment. Patients should be told to keep away from fire or flames, and not to smoke when using these preparations.[1]

Following a patient death, the NPSA commissioned the Health and Safety Executive to undertake fire hazard testing with WSP on a variety of bandages, dressings and clothing. The three products used in the fire hazard testing all contained WSP at concentrations of ≥50%. The results showed the ability of WSP to reproduce the fire hazard in a controlled environment. Paraffin products are also constituents in some commonly prescribed 'specials' creams and ointments; for example, emulsifying ointment is often used as a diluent to lower the strength of a ready prepared ointment.

The evidence only related to WSP and there was no data at the time to show that there was a fire hazard risk with preparations containing concentrations of WSP lower than 50%, however, the NPSA took the view that this risk could apply to any paraffin-based product.[1]

Emollients are effective products for dry skin conditions and are available as creams, ointments, lotions, gels and sprays. Creams and gels are emulsions of oil and water and are less greasy than ointments which are made up of oils or fats. Hydrating gels also have a reasonably high oil content although they are relatively light and non-greasy to apply. Lotions have a higher water content than creams, which makes them easier to spread but less effective as emollients. There are only two emollient sprays available currently; both are paraffin based. The paraffin content is dissolved either in butane or volatile silicone.[2]

The cream and lotion emollients listed in the BNF and Drug Tariff contain varying amounts of paraffin.[3] Adults may be prescribed ≥100g emollient per week if they are applying it at least twice daily to their scalp, both arms, both legs. or their trunk.[3]

The information from the NPSA was also highlighted in a Drug Safety Update bulletin from the MHRA in January 2008.[4] As a result of a fatal incident where a naked flame ignited an emollient in contact with a patients' dressings and clothing, the risk was reiterated to health care professionals in another Drug Safety Update bulletin in April 2016.[5]

Since the Drug Safety Update bulletin in 2016, the fire risk of paraffin containing emollients has been highlighted in the media.[6,7] Freedom of information requests to fire services across England asking about the incidence of fire deaths where an emollient/paraffin-based cream was listed as a factor, indicated that between 2010 and 2017 there were 37 deaths. Between 2017 and 2018, a further eight deaths were recorded.

An investigation was carried out by the West Yorkshire Fire and Rescue Service on six pieces of material following a fatality they attended due to smoking in bed and use of an emollient containing 11% paraffin. Two pieces of material were used as controls – a washed clean fabric and an unwashed fabric with signs of previous paraffin-based contamination; two pieces were contaminated with 70g of a 21% paraffin containing cream over seven days, one unwashed and the other washed at 40 degrees in non-biological liquid and the last two pieces were contaminated with 70g of an ointment containing 74.5% paraffin over seven days, one unwashed and the other washed at 40 degrees in non-biological liquid.

The test showed that the material contaminated by the 21% paraffin cream burned slightly quicker than the 74.5% ointment (five times quicker than the clean washed fabric for the 21% vs four times quicker for the 74.5%) and reached its maximum temperature twice as fast as the fabric control, which means the patient has a reduced time to shed the clothing or douse the flame. The ointment contaminated material reached a higher temperature, 122°C hotter than the washed clean fabric control which means the patient would have far deeper and more severe burns. The washed contaminated material burned twice as fast as the control indicating that there was still some paraffin residue in the material even after washing. Despite having the least amount of paraffin, the tests found that the cream had the fastest fire development. The ointment, which contains more paraffin, had a slower flame development rate than the cream and it was suggested that this may be due to the other ingredients in the ointment slowing the fire development down. The Fire Service highlighted that the partial removal of the paraffin by washing at 40 degrees, doesn't remove the fire risk to the patient. The most vulnerable group are patients who have to use large amounts of paraffin based emollients to treat skin conditions and continue to smoke or are exposed to naked flames. Even if clothing is changed daily, there is an issue that the emollients seep into bandages which are not changed as regularly and therefore pose a fire risk if exposed to a naked flame.[7,8] The Fire Service report can be read here - https://www.westyorksfire.gov.uk/news/research-shows-hidden-fire-risk-of-emollients/

In December 2018 the MHRA extended the warning about risk of severe and fatal burns to all paraffin-based emollients regardless of paraffin concentration. The likelihood of fabric that has been in contact with emollient products catching fire through an individual smoking or being near a naked flame is low, but if this does occur it could cause severe burns which may result in death. The risk is greater when emollients are applied in large quantities or to large areas of the body. The emollient products are not flammable in, or of themselves. It was previously thought the risk occurred with emollients which contain more than 50% paraffins. However, evidence now points to a risk with emollients which contain lower levels of paraffin and with paraffin-free emollients as they have a fire accelerant effect. When emollient residue builds up and dries on fabric, the speed of and intensity of the fire is increased when the fabric is ignited. The benefits and important therapeutic role of emollients, and modifiable risk factors outweigh the very rare fire risk.[9,10]

The fire risk of using small amounts of emollient is minimal. The build-up of emollient residue on fabrics can be reduced by regular washing at a high temperature, e.g. 60°C. However, if patients regularly apply small amounts of emollients to the same part of the body (e.g. elbow, behind knee etc.), emollients will contaminate the clothing over time, especially if they are washed at low temperatures (e.g. 20-30°C), making these areas more susceptible to ignition.[11]

All patients and their families should be warned regarding the following risks:

- The risk of fire should be considered when using large quantities of any emollient (e.g. application of 100g or more at once or over a short period of time) or small quantities on a regular basis, as there is a chance that paraffin and non-paraffin containing preparations could contaminate clothing or dressings so they ignite rapidly. To minimise the risk, patients should be advised, where appropriate to:
  - Keep away from open or gas fires, halogen heaters and naked flames, including candles.
  - Avoid gas hobs for cooking.
  - Not smoke and never smoke in bed.

- Bedding and clothing should be changed daily and washed at the highest temperature recommended by the fabric care instructions to minimise the build-up of impregnated paraffin/emollient although it won't totally remove it.

This information should be given on the first occasion that such treatment is prescribed, dispensed or administered by a healthcare professional and a record kept confirming that such advice has been given. When dispensing, pharmacists and technicians should take care to avoid covering the fire safety warnings printed on emollient packaging with dispensing labels. A check should be made on subsequent occasions that the advice has been received previously and understood.[1]

Prescribers may wish to consider doing a risk assessment with the patient when prescribing emollients and give advice to reduce modifiable risk factors (see above). Patients may be considered higher risk if they are elderly, live alone, smoke, misuse alcohol or drugs, have a mental health issue, dementia or cognitive / memory impairment, or a learning disability. If risk factors cannot be reduced, particularly with higher risk patients, prescribers may wish to seek advice from the local fire service. County fire services offer a free home fire safety check, and some have useful information on their websites for the public, carers and healthcare professionals. For example:

https://www.westyorksfire.gov.uk/your-safety/home/emollient-skin-products/

https://www.cheshirefire.gov.uk/public-safety/book-a-home-safety-check

http://www.essex-fire.gov.uk/_img/pics/pdf_1533558848.pdf

Medical oxygen therapy and use of emollients

Medical oxygen is non-flammable but strongly supports combustion (including some materials that do not normally burn in air). It is highly dangerous in the presence of oils, greases, tarry substances and many plastics due to the risk of spontaneous combustion with high pressure gases. Where moisturising creams are required for use with a facemask or in nasal passages, oil-based creams should not be used. Hands must be clean and free from any oils or grease before handling liquid medical oxygen vessels or equipment. Naked flames and smoking are prohibited when medical oxygen is in use.[12] Patients who use nasal cannulae (prongs) for medical oxygen administration who require an emollient to prevent drying and cracking of the skin around the nose and lips should consider using water-based skin products instead of paraffin-based emollients e.g. KY Jelly, Aqua Gel.[13,14]

Product labelling

The MHRA contacted all marketing authorisation holders for emollients in 2008 following the NPSA alert and requested that emollients classed as medicinal products which contained 50% or more of a paraffin base should carry a warning about fire risk. As there was no legal requirement for companies to action this request, the MHRA have updated their advice to state that where an emollient is authorised as a medicine, there is an expectation that the product labelling will include appropriate warning advising of the risk from fire.[15] It should be noted that some emollient preparations are classed as medical devices and some as cosmetics. The December 2018 Drug Safety Update highlights that the Commission on Human Medicines advised that to protect public health, emollient outer packaging and product containers should include a warning about the fire hazard with advice not to smoke or go near naked flames. Where available, the Patient Information Leaflet or Instructions for Use and the Summary of Product Characteristics should be updated to include warnings about the risk and how best to minimise it.[9]

Emollient formularies

A review and comparison of emollient formularies across all clinical commissioning groups (CCGs) and local health boards (LHBs) in England and Wales has shown that there is huge variation between them in terms of choice of products and rationale for recommendations. The report discusses which products are commonly included in the formularies, although there is no mention of the 2008 NPSA alert or the paraffin content of emollients.[16]

The PrescQIPP bulletin for cost effective emollients may also be useful in to assist in developing formulary choices locally - https://www.prescqipp.info/our-resources/bulletins/bulletin-239-emollients/

Summary

Paraffin and non-paraffin based products are effective emollients. There is a rare risk of fire and serious injury for patients who use emollient products as a result of fabric that has been in contact with emollient catching fire through someone smoking or being near a naked flame. The risk is greater when emollients are applied in large quantities to large areas of the body (legs, arms, scalp and trunk) or regular use of small quantities to specific areas. It was previously thought the risk occurred with emollients which contain more than 50% paraffins. However, evidence now points to a risk with emollients which contain lower levels of paraffin and with paraffin-free emollients. Healthcare professionals must ensure patients and their carers understand the fire risk associated with the build-up of emollient residue on clothing and bedding and can take action to minimise the risk.

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