Skin care advice for patients undergoing radical external beam megavoltage radiotherapy

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Summary

This clinical practice guideline is a set of evidence-based recommendations to assist radiographers, radiotherapy nurses, and the wider radiotherapy workforce, in advising patients how to care for their skin while undergoing a course of radical external beam radiotherapy (excluding proton therapy). It has been developed systematically using the best available evidence from research and expert opinion and subjected to peer, professional, and lay assessment. The guideline has recommendations for evidence based practice for individual practitioners, service managers, academic institutions and the Society and College of Radiographers.

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1. Introduction

1.1 How was the topic identified?

This guideline progresses work initiated in 2010 and resulting in the publication in 2011 of the Society and College of Radiographers (SCoR) radiotherapy skin care guidelines. This work was undertaken in partnership with the SCoR Public and Patient Liaison Group (PPLG) and six of its members participated in developing and shaping the questions for the original survey of professional

practice into radiotherapy skin care.

Since that time, a variety of new skin care products has emerged on the market, while some previously used products have been removed from pharmacy suppliers. A recent, (2014) updated SCoR survey of current practice in the United Kingdom indicates diversity of skin care practice across radiotherapy centres, prompting the need for this review.

1.2 Why is it important?

Skin reactions from external beam radiotherapy are one of the most common side-effects from treatment (Brown and Rzucidlo, 2011; Ryan, 2012), which may cause distress to some patients, and in certain cases may be a factor which can limit radiation dose and treatment schedules. Megavoltage linear accelerators with skin sparing capabilities have significantly reduced the severity of reactions from radiotherapy (Harris, 2002b); however accelerated radiation dose schedules with concurrent chemotherapy, and the use of biological agents such as epidermal growth factor receptor EGFR) inhibitors, have led to an increase in certain skin reactions (Bernier et al., 2008). The most severe reactions tend to be seen in those patients receiving high doses to large fields and where there are folds of skin (for example inframammary fold, groin, axilla) (Porock et al., 1998; Richardson et al., 2005). More recently the use of intensity modulated radiotherapy (IMRT) and hypofractionation have shown to offer the potential to reduce skin toxicity in some cases, especially the rates of dry and moist desquamation when treating cancers in the head and neck region (Freedman et al., 2004; Price et al., 2006; Freedman et al., 2006; Harsolia et al., 2007; Pignol et al., 2008; Freedman et al., 2009; Ciammella et al., 2014). Despite changes in radiotherapy practice and numerous published skin care guidelines (NHS, 2004; CoR, 2000; NHS, 2010; CoR, 2011) patient skin care appears to have changed little over the years, with no consensus amongst centres using different skin care regimens, product use and approaches (Barkham, 1993; Harris, 2002a; Harris et al., 2012).

Although it is unlikely that radiation reactions can be completely prevented, the current driver is to delay the onset and minimise the severity of a skin reaction, to reduce symptom related discomfort, and prevent further complications. Most skin reactions tend to peak towards the end of the treatment course and are often at their worst in the first two weeks after treatment has completed. The majority of skin reactions are acute and have significantly improved, if not resolved, by four weeks post treatment (McQuestion, 2011; Ryan, 2012;), however the extent of a skin reaction is often dependent upon the clinical site being treated. For example, patients undergoing radiotherapy for head and neck cancer usually require immobilisation and often receive concurrent chemotherapy or biological agents. These factors can make patients more vulnerable to intensified skin reactions and possible interruptions in radiotherapy and for these patients this can have a detrimental effect on treatment outcome (RCR, 2008).

1.3 How does it fit with existing radiotherapy practice?

The Society and College of Radiographers (SCoR) and The United Kingdom Oncology Nurses Society (UKONS) offer advice and guidance for professional development to promote patient-centred care and the highest quality services. The SCoR document library contains all of its policies, advice and guidance.

1.4 The policy context

The NHS England Radiotherapy Clinical Reference Group (and equivalent groups where in existence in the countries), with input from the UK-wide Radiotherapy Board and UKONS, should aim to provide national guidance. This guidance should be based on expert consensus of the evidence base, and support the need for further research into new products before they are introduced on an ad-hoc basis into skin care regimens. Radiotherapy services in England are now within NHS England Specialised Services, and it is stated that all patients should receive care to the same standard, irrespective of where they receive their treatment.

Despite the publication of best practice guidelines for radiotherapy skin care in 2011 and the results

of two surveys conducted by the College of Radiographers, a wide variety of practices are undertaken in radiotherapy departments in the United Kingdom (UK) with respect to both the prevention and management of radiation induced skin reactions by external beam megavoltage radiotherapy. There also remains disparity within the published research, with no one topical application or medical intervention being clearly deemed superior over another.

The extent of radiotherapy reactions across departments also appears to be unclear and unquantified. In Barkham's (1993) assessment of radiotherapy skin reactions and associated treatments, 52% of UK radiotherapy departments reported dry desquamation as a common event and 85% of departments reported moist desquamation as an occasional event. However, as Glean et al. (2001) noted, the incidence of skin reactions has not been accurately collected in departments and practices have changed since Barkham's (1993) survey. All patients receiving external beam radiotherapy are at a potential risk of developing a reaction but the results of the 2011 SCoR survey indicate that limited data is still collected by clinical departments and therefore actually quantifying the extent of the problem is difficult.

1.5 Background information

Turesson et al. (1996) demonstrated that the number of basal cells in the epidermis declines during fractionated radiotherapy due to increased cell cycle arrest and reduced mitosis. The reduction in the basal cells causes a thinning of the epidermis and an inflammatory reaction and the variation in the reaction appears to be a genetic predisposition related to individual DNA repair capacity (Tucker et al., 1992; Lopez et al., 2002; Twardella et al., 2003; Popanda et al., 2003; Chang-Claude et al., 2005; Pinar et al., 2007; Andreassen and Alsner, 2009), genetic radiosensitivity (Barber et al., 2000; Burrill et al., 2000; Suga et al., 2007), and/or intravascular thrombin generation (Lincz et al., 2009). Specific genetic tests could therefore be used to predict those patients most likely to develop a severe radiotherapy reaction (Badie et al., 2008; Iwakawa et al., 2006; Andreassen and Alsner, 2009).

Certain clinical factors can aid in the prediction of which patients are more likely to experience a significant radiation reaction (Russell et al., 1994; Russell, 2010). Extrinsic factors, which are treatment related, include: dose; volume; fractionation; adjuvant treatment; treatment in a skin fold area (e.g. inframammary fold or anal cleft); use of bolus material; type of immobilisation; and treatment technique (Porock and Kristjanson, 1999). These factors need to be under constant review with changing work practices; such as introducing IMRT, hypofractionation, or dose escalation treatments.

Intrinsic factors, which are individually patient related, include: larger breast size (Porock et al. 1998; Harris, 2002b); higher body mass index (BMI) (Kouvaris et al., 2001; Twardella et al., 2003; Wells et al., 2004); and/or pre-existing conditions and co-morbidities, such as diabetes (Turesson et al., 1996; Porock et al., 1999b). Such intrinsic factors may enhance an individual's propensity to experience a skin reaction and therefore should be recorded by baseline observations and closely monitored throughout, and after, a course of radiotherapy (Porock et al., 1998; Fisher et al., 2000; Richardson et al., 2005; NHS Scotland, 2010). Smoking has also been shown to be an independent risk factor, and patients should be advised about this and supported to stop smoking wherever possible (Wells et al. 2004; Wan et al. 2012; Sharp et al. 2013).

Gosselin (2010) noted that some skin care products showed promising results but comparing data across studies is difficult because of the wide variety of assessment tools. By utilising a validated skin assessment tool on at least a weekly basis, it would be possible to monitor and record an individual patient's skin reaction. An example of a validated assessment scale is the one developed by the Radiation Therapy Oncology Group (RTOG) (Cox et al., 1995). The use of an effective evidence-based skin care protocol and monitoring system (Campbell and Lane, 1996; O'Shea et al., 2003) would assist in a robust approach to radiation skin care management, aiding product evaluation and justification of practice.

Another important aspect of skin care during radiotherapy is that of quality of life. Patients often have fears and misconceptions about radiotherapy therefore consistent, current and relevant

reinforced information can help to alleviate some of these concerns (Harris, 1997). It may not be possible to stop or reduce the rates of skin reactions, but skin care products may provide comfort and enhance self care (Gosselin, 2010). Recording of patient symptoms, acceptability/satisfaction and compliance, as incorporated into some existing scales (Noble-Adams, 1999), would also be helpful indicators of how appropriate a product will be for future use.

Of significant note is the identification of certain products contraindicated for use on radiotherapy skin reactions:

- Topical antibiotics, unless there is a proven infection (Sitton, 1992; Campbell and Lane, 1996; Korinko and Yurick, 1997);
- Topical steroids on broken skin due to the adverse effect on the wound healing process (Blackmar, 1997; Rice, 1997; Jones, 1998);
- Gentian Violet due to potential carcinogenic side effects (Campbell and Lane, 1996; Rice, 1997; Boot-Vickers and Eaton, 1999).

Petroleum (Sitton, 1992; Blackmar, 1997; Korinko and Yurick, 1997) and silver sulfadiazine (Fackrell, 2013) based products have been considered to create a build up effect due to their radiation attenuation properties. However, more recent evaluation (Morley et al. 2013) of dosimetric considerations has shown that the amount of product layering required to cause a problem would be far in excess of normal skin care use.

2. Scope and purpose

The practice guideline is for the whole multiprofessional radiotherapy workforce, including students and learners. This encompasses clinical and non-clinical, registered and other practitioners, service managers, educationalists, and researchers. The population covered in the guideline is patients receiving external beam radiotherapy. The setting for the guideline is radiotherapy departments in the United Kingdom.

3. Guideline question

What current evidence is there to assist radiographers, radiotherapy nurses and the wider radiotherapy workforce to give the optimal skin care advice to patients undergoing radical external beam megavoltage radiotherapy?

4. Guideline development process

4.1 Core group

The core group of six (see **Appendix 1**) was established in November 2013 by the lead professional officer, who is also the core group leader. The remaining five members were two more professional officers, both with a responsibility for radiotherapy and one who works part-time in a clinical setting, an experienced academic therapeutic radiographer, an academic researcher with a therapeutic radiography background, and a clinical academic therapeutic radiographer from Canada with previous publications in the field.

4.2 Stakeholder group

The stakeholder group comprised nine members (see **Appendix 1**); three academics (two from a nursing background and one with a therapeutic radiography background), two clinical therapeutic radiographers, three radiotherapy nurses and one clinical oncologist. The names of both core and stakeholder group members are listed in **Appendix 1**.

4.3 Peer review and consultation process

A first draft of the recommendations was circulated to the stakeholder group for comment on 22nd April 2014. All stakeholders responded and their comments were assimilated in an action log. A second round of consultation comprising a draft of the practice guideline was conducted at the end of May 2014. A third round of consultation comprising a draft of the practice guideline was conducted during June/July 2014. A final and fourth round of consultation to agree final consensus occurred at the end of July 2014. Full consensus was achieved via e-mail discussion and evaluation of the evidence.

Further guideline versions were updates on wording and minor amendments which did not affect the recommendations agreed by the core and stakeholder groups.

Service users (33) from Newcastle-upon-Tyne Radiotherapy Centre were asked to read and comment on the patient information sheet (see **Appendix 2** for questionnaire and **Appendix 3** for comments).

The SCoR Public and Patient Liaison Group (PPLG) were sent the draft guidelines and appendices and asked to review on 25th July 2014. Draft copies of the documentation were sent to the SCoR Radiotherapy Advisory Group (RAG) for comment on 25th July 2014 and to the Information, Support and Review Radiographer Forum on the 28th July 2014. The project lead was approached by the tutor on a Master's module in On Treatment Review held on 06/10/14 and asked if they could review the guidelines; this was agreed and comments were received back on 10/10/14 (see **Appendix 4** for comments and responses).

4.4 Funding arrangements

The academic researcher on the core group was paid £500 to conduct and assimilate the literature review. Stakeholder group members gave their time and expertise voluntarily.

4.5 Conflict of interest

The SCoR policy and procedures for managing conflicts of interest was adhered to. (Process Manual Appendix G.) All members of the core and stakeholder group have signed the Conflicts of Interest Declaration Form. No conflicts of interest were declared.

4.6 SCoR approval process

The finalised practice guideline was submitted to the UK Council of the SCoR in November 2014 prior to submission to NICE.

5. Guideline methodology

5.1 Literature Search

The aim of the 2014 systematic review was to determine if, since 2010, there was any additional evidence which could further inform or improve current clinical practice and if so, what the impact of this additional evidence would be.

Initially a search question was formulated using the Population, Intervention, Control, Outcome (PICO) method (Table 1).

Table 1: PICO method

Population	Adult patients undergoing external beam radiotherapy: radiation therapy, irradiation
Interventtion	Preventative measures eg washing practices, topical applications. deodorant guidance and/or management measures - dressings, topical and medical applications
Control	Standard intervention
Outcome	Skin reactions, radiation effect, adverse effect, radiation dermatitis, erythema, moist desquamation, skin care, skin reactions

The review was based on a systematic search of Medline, Pub Med, CINAHL, EBSCO, Science Direct, ISI Web of Science and Index to Thesis.

Hand searches of the Journal of Radiotherapy in Practice (JRP), The European Journal of Cancer (EJC), Radiography, Journal of Medical Imaging and Radiation Science (JMIRS), the International Journal of Radiation, Oncology, Biology, Physics (IJROBP) and Radiotherapy and Oncology were also undertaken.

In addition, a secondary evaluation of the clinical trials' databases was searched for any ongoing research as well as a search of the 'grey literature', including index to theses and conference papers. Finally a broad search of Google Scholar was used as a 'mop up' technique to ensure no additional relevant research had been missed.

Owing to the fact that a wealth of evidence had been reviewed in 2010 and this is a continuation of that work, it was deemed appropriate to map out and replicate the initial search strategy and then include any additional resources.

The traditional pearl growing method of literature searching begins with a single document relevant to the topic under review and utilises key words or seminal text; pearl growing until more recent years has often been overlooked as a strategy for literature searching (Schlosser et al., 2006). The Comprehensive Pearl Growing (CPG) method has developed from this and uses multiple key documents rather than just one. It is considered to be more systematic in its approach and deemed an appropriate method to be used for yielding results in a systematic review (Schlosser et al., 2006). For the purpose of this review, Comprehensive Pearl Growing is an appropriate and important method to use in the initial stages of the strategy as this is following on directly from a seminal piece of previous published work and one other key document.

Table 2 indicates the key terms used within the search strategy, drawn from the seminal articles.

Table 2: Key Terms

Aspect	**Key term**
Radiotherapy	Radiotherapy, radiation therapy, irradiation
Outcome	Skin reactions, radiation effect, adverse effect, radiation dermatitis, erythema, moist desquamation, skin care, skin reactions, evidence-based practice

Those studies included initially had to fulfil the following criteria:

- All literature from November 2010 (when the last review by the SCoR was conducted);

- All papers that have an English abstract;
- Papers that assess the use of a topical agent;
- Papers where the primary focus is skin reaction to radiotherapy.

Studies were excluded for failure to meet the above criteria or for the following reasons:

- Reactions caused by a pre-existing genetic or medical disposition;
- Case studies;
- Rare skin reactions caused by topical agents or chemotherapy drugs;
- Papers where the primary focus is the impact of the immobilisation device or radiotherapy planning technique on the skin reaction;
- Late effects to the skin following radiation.

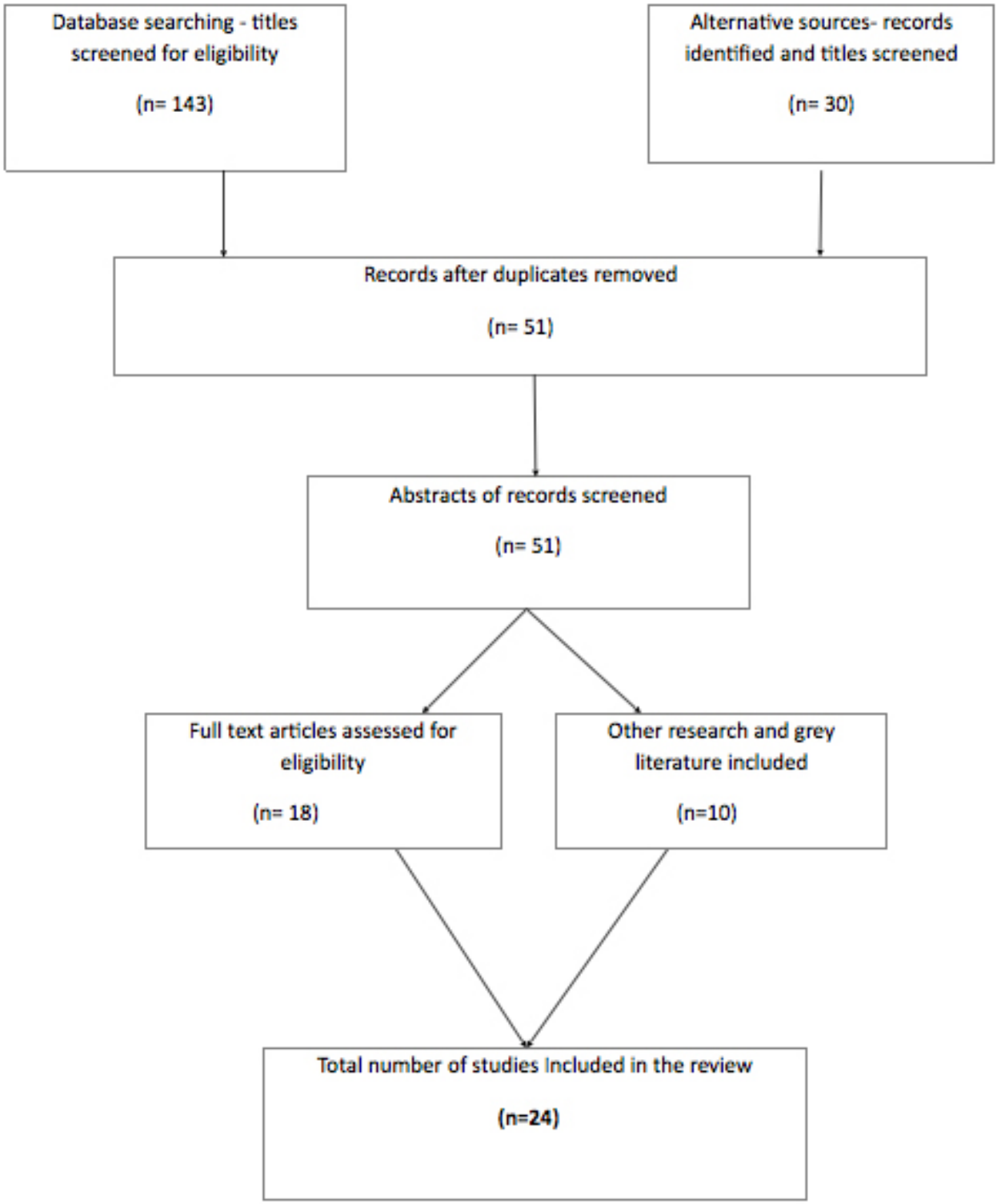
All appropriate full text articles underwent quality assessment using the Scottish Intercollegiate Guidelines Network (SIGN) quality assessment tool. Initially the Grading of Recommendation, Assessment, Development and Evaluation (GRADE) system was proposed, however upon further investigation the SIGN tool was deemed more appropriate and relevant for this particular study. To ensure the correct assessment questionnaire was used, all studies were mapped against the SIGN: “Algorithm for classifying study design for questions of effectiveness” (www.sign.ac.uk, 2013).

5.2 Literature review

A flowchart including the number of hits obtained in the database searches, those abstracts screened for relevance, down to the final number of articles included in the review, can be found under Diagram 1.

Research is continually emerging within this area, possibly due to the lack of conclusive evidence and the disparity between the published research as highlighted earlier, therefore it was deemed appropriate to include within the results any relevant ‘grey literature’, such as research protocols, conference presentations, symposiums and ongoing research related to Randomised Controlled Trials (RCTs).

Diagram 1: Flowchart of literature review



5.3 Description of how recommendations were developed

The core group considered the evidence and developed the recommendations for the practice guideline.

Randomised Control Trials (RCTs) and Systematic Reviews (SR)

- Quality assessment using the appropriate SIGN checklist was undertaken, a total of 17

articles were available for review: 2 Systematic reviews, 14 RCTs, I case control.
- Of the RCTs and systematic reviews (n=16): 5/15 (33%) were classed as high quality evidence; 8/15 (53%) classed as acceptable evidence; 3/15 (20%) rejected as unacceptable quality. (See **Appendix 5** for summary of articles table.)
- The final number of studies included in the review: 2 systematic reviews, 11 RCTs and I case control.

Of the RCTs (n=11)included in the final review, nine were studying a different topical emollient or product (Jensen et al., 2011; Kirova et al., 2011; Miller et al., 2011; Abbas and Bensadoun, 2012; Niazi et al., 2012; Graham et al., 2013; Sharp et al., 2013; Ulff et al., 2013; Herst et al., 2014,) and two studies were reporting the use of non-metallic antiperspirants (Watson et al., 2012; Lewis et al. 2014). (see **Appendix 6** for full systematic review report.)

Butcher and Williamson (2012) undertook a systematic review of the literature on the management of erythema and skin preservation for patients receiving external beam radiotherapy to the breast. All literature was assessed for quality and in total 10 studies were included in the final analysis. They concluded that no one product was considered superior to another. The review advocates the safe use of non-metallic deodorants. The review also highlights the wide variety of methods and assessment scales used to report study findings thus making meaningful comparisons very difficult.

Chan et al. (2014) undertook a systematic review and meta-analysis which included 47 RCTs from 1962-2012. This large date range is a slight limitation as studies conducted during the 1960s are likely to include orthovoltage energies and Cobalt treatments with subsequent associated skin reactions that are not relevant to the skin sparing effects achieved with modern linear accelerators. Studies examined a range of practices:

- 6 trials investigated oral systemic therapies
- 2 investigated washing practices
- 4 examined deodorant use
- 5 investigated topical steroidal therapies
- 23 examined non-steroidal topical therapies
- 6 investigated dressings
- 1 investigated light emitting diode photo-modulation

Thirty-six of the included studies were considered at high risk of bias, 10 rated at unclear risk and one as low risk; confirming our own experience of quality assessment of studies in this field. Allocation concealment was only reported in 22 of the 47 studies reviewed. Blinding of assessors was only adequately described in 21 of the 47 studies. Similarly, only 21 of the 47 studies adequately reported how attrition was handled in the analysis.

A small meta-analysis of two studies investigating oral systemic therapy (oral Wobe-Mugos E vs. no medication) indicated the odds of developing a radiation induced skin reaction was 87% lower for people receiving Wobe-Mugos E (although heterogeneity for the studies was high I^2=70%). A meta-analysis of 226 participants from two un-blinded studies found no difference in radiation induced skin reactions when comparing deodorant use to no deodorant use. Four trials investigated the role of topical steroidal agents on radiation induced skin reaction. Three of these studies identified no benefit while one small study (n=20) found a statistically significant benefit for using prednisolone with neomycin compared with no treatment. However, some of the topical steroid trials had small sample sizes and wide confidence intervals hence the results should be viewed with caution.

Overall the review concludes that the evidence for any intervention is ‘thin’ i.e. no strong evidence of effect for any of the included trial products to reduce radiation induced skin reactions. The study concludes that patients should be advised to wash gently and using non-metallic deodorant is not contraindicated. Recommendations for future studies include a focus on an area of promise such as oral Wobe-Mugos E and oral zinc. Future studies should also attempt to clarify which patients would benefit from corticosteroid cream, and appropriately powered RCTs comparing different dressings for

those who develop moist desquamation.

During the inclusion period of this current review there were other studies of some note, and a number of abstracts and short publications published, as well as conference presentations, which were assessed (see **Appendix 6**). In order to ascertain current research being undertaken in this field, a search of the clinical trials database was also undertaken (see **Appendix 7**).

This review has demonstrated that additional research has been published in the field. Nevertheless the scope of this research and the results are quite wide ranging, both in their methods and in the aspect of radiotherapy-induced skin reaction being researched. Many of the studies seem to concentrate on a particular topical application, which adds to the evidence-base, but still there is a lack of emergence of any one product as superior over another.

A number of studies have been undertaken investigating the use of topical steroids and Wong, et al. (2013) make strong recommendations in their guidelines for the use of prophylactic topical steroids. In spite of this some of the published research recommends exercising a degree of caution and that there is a need for more work to be undertaken, particularly to determine any long term implications of using steroids.

There are two areas where a more general consensus on guidance is closer to being achieved. Firstly with respect to the use of aqueous cream:

- this has now been reclassified in the British National Formulary (BNF) as a soap substitute and may be applicable in this usage for patients undergoing radiotherapy;
- it should not, however, be used as a leave-on moisturiser.

Secondly with respect to the use of deodorant, where a much stronger evidence base refutes the adverse impact that deodorants were once thought to have (Wong et al., 2013; Lewis et al., 2014). However, further research is still needed on the use of aluminium based deodorants.

5.4 Limitations of the guideline including consideration of possible bias

In terms of the strength of the recommendations contained within this guideline, considerable contradictory evidence was identified with often a weak level of agreement between all sources. The sources from which each recommendation was drawn are highlighted throughout the document. However, the guideline development core and stakeholder group have reached a consensus of agreement to allow for the application of this evidence within radiotherapy departments.

6. Radiotherapy skin care

Faithfull et al. (2002) noted ‘a growing awareness of the need for evidence based practice in radiotherapy’ but that there are ‘well documented disparities between clinical practice and research findings’; reflecting that supportive care is often based on no, little, or poor evidence. Comparing data across radiotherapy skin care studies is difficult as the methods used are often unclear, patient randomisations differ, different skin assessment scales are used, and follow-up data is inconsistent (Kedge, 2009). The findings from recent SCoR surveys would support such a view.

The surveys highlighted that few departments are following updated national guidelines and undertaking baseline assessment of a patient’s current skin condition. Despite papers emphasising the potential risk factors (Russell et al., 1994; Porock and Kristjanson, 1999; McQuestion, 2011) which may exacerbate a skin reaction, 52% of departments (2014 SCoR data) stated they did not record this information. Without the collection of such data it is difficult to attain a complete picture of the extent of radiotherapy induced reactions, which will be essential for improved research and skin care studies. Furthermore, 49% of departments (2014 SCoR data) failed to assess and record

skin care products currently being used by patients.

Linking with other sectors of care, Tissue Viability Nurses (TVN), or equivalent, and district nursing staff, with an understanding of radiation induced skin reactions, would strengthen improved communication. Understanding and consistency of radiotherapy skincare across the care pathway is needed to reduce patient and staff confusion (Harris, 1997; Cumming and Routsis, 2009).

A main area of variation across departments relates to washing instructions and the use of soap and deodorant (also confirmed by other studies by Barkham, 1993; Lavery, 1995; D'haese et al., 2009). The traditional patient advice of ‘not to wash’ the affected area with soap and water, or even to use water alone, is still given, despite updated evidence that this is unnecessary and there should be no restriction to using a specific type of soap (Campbell and Illingworth, 1992; Burch et al., 1997; Westbury et al., 2000; Roy et al., 2001; Rudd and Dempsey, 2002; Aistars, 2006; Bolderston et al. 2006; Aistars and Vehlow, 2007; Butcher and Williamson 2012). Seventy four percent of departments (2014 SCoR data) reported washing restrictions (i.e. either no soap, or limited to specific brands such as ‘Simple®’ and ‘Dove®’); this has the potential to control unnecessarily the choices and preferences that an individual may have.

Expecting patients to follow traditional practice advice of ‘not to wash’ and ‘not to use deodorant’, may affect their social well being. For example, breast cancer patients who are advised not to use a deodorant often cite this as one less area of control they have in their life and they note concern regarding body odour (Komarnicki, 2010). In the past it was felt that the metallic compounds, particularly aluminium, within deodorants might cause a secondary radiation effect (Korinko and Yurick, 1997); however more recent studies contradict this advice as unfounded and outdated (Bennett, 2009; Watson et al., 2012; Wong et al., 2013; Lewis et al.,2014). Currently 55% of departments advise patients not to use a deodorant under the axilla of the affected side being treated for breast cancer (2014 SCoR data). Patient compliance with these requests has not been assessed (Gosselin, 2010).

The 2014 survey illustrates that there are numerous products being recommended and supplied for radiotherapy skin care with no consensus as to the best practice, causing an inconsistency of care (Harris, 1997). As noted by Russell (2010), if the underlying cause of a radiation reaction is physiological, topical agents are unlikely to have any significant effect on the level of skin reaction. However, skin care products may not be effective at eliminating or limiting radiation induced skin reactions, but they may have certain therapeutic effects relating to patient comfort and the alleviation of symptom induced irritation. Currently the quality and quantity of studies evaluating topical agents appears to be insufficient to support or refute any specific product and there are few evaluations of skin care products; therefore progress into understanding what works is likely to be slow.

Aqueous cream is currently recommended and issued by 81% of departments (2014 SCoR data) as a prophylactic skin care product and by 65% of departments (2014 SCoR data) to alleviate erythema. The rationale behind the recommendation for this product was to aid patient comfort by ensuring the treatment area is moisturised and hence reducing the feeling of taut dry skin. Aqueous cream is a relatively cheap, readily available product and was advised in the now withdrawn College of Radiographer’s 2000 guidelines (CoR, 2000). However, the evidence base indicates that aqueous cream applied preventatively and to erythema appears to have no influence in a skin reaction occurring (Schreck et al., 2002; McQuestion, 2006; Gosselin et al., 2010); although there may be patient comfort benefits. Some departments are also stating that aqueous cream is being withdrawn by their pharmacy suppliers; possibly because of recent studies which have indicated that aqueous cream containing sodium lauryl sulphate may actually compromise skin integrity and have shown it to be an irritant (Tsang and Guy, 2010; Patel et al., 2013); although it should be noted that these were not studies of radiotherapy patients. Therefore, there needs to be further debate about this aspect of care and the evidence-base supporting actions. If sodium lauryl sulphate is a known irritant, departments need to investigate alternatives that do not contain it.

Furthermore, 11% of departments (2014 SCoR data) advise patients to use topical aloe vera for erythema which may incur a substantial cost either to the institution or to the individual, yet there is limited evidence (Haddad et al., 2013) as to any benefit obtained using this agent over another and

therefore no justification without further detailed studies for this recommendation to patients (Kaufman et al., 1988; Richardson et al., 2005; McQuestion, 2011).

Hydrocortisone 1% is used by 10% of departments (2014 SCoR data) for dry desquamation reactions, in line with the withdrawn College of Radiographer's 2000 guidelines (CoR, 2000) and supported by recent Multinational Association of Supportive Care in Cancer (MASCC) guidelines (Wong et al., 2013). However, some studies have produced evidence to support the use of steroid creams prophylactically and some have cited contradictory evidence (Sitton, 1992; Dunne-Daly, 1995; Sperduti et al., 2006; Bostrom et al., 2001; Miller et al., 2011; El Madani et al., 2012; Hindley and Dunn, 2013) and again this is an area of clinical practice that requires further investigation.

There appears to be a propensity to continue with familiar traditional practice rather than an openness to test the effectiveness of products. In the recent SCoR survey there was no evidence of any assessments into the cost effectiveness of using creams and topical agents for erythema or dry desquamation, and only four departments (2014 SCoR data) stated they were assessing products for moist desquamation. With the introduction of more expensive skin care treatments to a vulnerable clientele, health care professionals need to consider if such products are more effective than their cheaper comparators and why they choose one product over another (Fisher et al., 1999; Fisher et al., 2000; Pommier et al., 2004; Swamy et al., 2009). This is an important facet of modern healthcare with the necessity for justification for actions, particularly as 65% of departments stated they supplied the recommended prophylactic product and 78% of departments supplied the recommended product for erythema (2014 SCoR data). If a patient suffers an adverse reaction to a product that has been 'issued', the 'issuer' is likely to have to produce evidence to support the use of that product.

An evaluation into the treatment after care also requires review to ensure local continuity of care across the pathway; a general need highlighted by a recent Department of Health cancer patient experience survey (DH, 2012).

Radiation induced skin reactions can be uncomfortable and distressing, thereby affecting a patient's quality of life (Lawton and Twoomey, 1991). Skin care advice to patients undergoing external beam megavoltage radiotherapy in the UK is varied. Currently, some of the skin care provided may not alleviate the problem and indeed may even cause skin irritation. This area of patient care is time consuming and expensive, therefore it is important to understand what is being done and why (Harris, 2002b).

7. Guideline recommendations

Overall, the evidence base is not strong enough to either support or refute the use of any particular product for topical application. However, as Gosselin et al. (2010) noted, "patients prefer to take action rather than do nothing" so the focus for skin care should be on alleviating symptoms and providing comfort. Therefore the following guidelines are recommended.

1. The various factors that influence how people react to radiotherapy need to be considered in advice designed to be given to patients, particularly:

Intrinsic factors which include demographic or disease related characteristics such as age, hormonal status, infection, ethnic origin, smoking, obesity, and co-existing disease (eg diabetes).

Extrinsic factors that are treatment related and influence the delivery of therapy. They include treatment dose, volume, fractionation, site of treatment, beam energy, adjuvant chemotherapy, and targeted therapies. Combined modality treatment, in particular, may lead to an increased risk of skin reactions (Turesson, 1996; Porock et al., 1998; Porock and Kristjanson, 1999; Richardson et al., 2005; Barnett et al., 2011; McQuestion, 2011).

2. Before radiotherapy begins, it is essential that a baseline assessment of the patient's current skin

condition and care is documented, including what skin products are being used currently. Assessments and review of the skin should continue for all patients on a regular basis throughout treatment, and at least on a weekly basis (Richardson et al., 2005; Fisher et al., 2000; NHS Scotland, 2010).

3. Education and health promotion strategies and interventions given to patients pre-treatment such as nutritional advice and smoking cessation would be beneficial and are advised (Wells et al., 2004; Wan et al. 2012; Sharp et al. 2013(a)).

4. Within a radiotherapy department, a single validated assessment tool and scoring criteria such as the RTOG should be agreed upon and adopted. Using the agreed validated tool and scoring criteria, radiotherapy departments should standardise the initial assessment and continued regular monitoring of skin reactions, and ensure that these are recorded (Cox et al., 1995; Campbell and Lane, 1996; Harris, 2002b; O'Shea et al., 2003).

5. Recording of patient acceptability/satisfaction and compliance with skin care advice is recommended as such information can be used to evaluate the appropriateness of skin care products for future patients (Harris, 1997; Noble-Adams, 1999; Gosselin, 2010).

6. To reduce **friction** to the treatment area advise patients to:

- wear loose fitting natural fibre clothing next to the skin, for example a cotton T-shirt (Harris, 2002b; Gosselin, 2010).
- wash the skin gently with soap and water and gently pat dry (Aistars, 2006; Bolderston et al., 2006; Aistars and Vehlow, 2007; Butcher and Williamson, 2012).
- use aqueous cream instead of soap if wished but it is NOT recommended as a leave-on moisturiser (British National Formulary).
- wash hair gently with usual shampoo if the scalp is in the treatment field, but do not dry with a hairdryer (Westbury et al., 2000; Bolderston et al., 2006).
- avoid rubbing, heat and cooling pads/ice, shaving if possible, wax for hair removal and all hair removing creams/products, adhesive tape (Harris, 2002b; Gosselin, 2010).

7. To reduce **irritation** to the treatment area, advise the patient to:

- use a moisturiser that is sodium lauryl sulphate free (Tsang and Guy, 2013; Patel et al., 2013).
- avoid topical antibiotics unless there is a proven infection (Campbell and Lane, 1996; Korinko and Yurick, 1997).
- continue to use normal deodorant (unless this irritates the skin), but discontinue if the skin is broken (Bennett, 2009; Butcher and Williamson, 2012; Watson et al., 2012; Wong et al., 2013; Lewis et al., 2014).
- avoid sun exposure and shield the area from direct sunlight and use a high SPF sunscreen or sun-block. (Harris, 2002b).

8. On broken skin staff should:

- use appropriate dressings/products on broken skin to reduce further trauma and infection. Suitable products would be non-adhesive, silicone low adhesion, non- or low-paraffin/petroleum jelly based. (see **Appendix 9**).
- NOT use Gentian Violet (Campbell and Lane, 1996; Rice, 1997; Boot-Vickers and Eaton, 1999).

9. Establish effective, on-going liaison with community care/G.P services on post treatment skin (and other) care (Harris, 1997; Cumming and Routsis, 2009; CoR, 2011).

The core and stakeholder groups also suggest the following are necessary to ensure consistent

patient care:

- Standardised skin care education of all staff caring for patients receiving radiotherapy. All radiotherapy departments should implement pre-treatment skin assessment with baseline observations and pre-radiotherapy review and health promotion strategies. This should be followed with regular reviews (at least weekly, and more often depending on individual needs).
- This can be undertaken by members of the radiotherapy team who have been trained to use the tools, and inter-observer variability between clinicians, radiographers, and radiotherapy nurses should be assessed periodically.
- Agreement on standardisation of assessment tools across departments in the United Kingdom would aid in gathering information nationally.
- The NHS England Radiotherapy Clinical Reference Group (and equivalent groups where in existence in the countries) with input from the UK-wide Radiotherapy Board and UKONS, should aim to provide national guidance, based on expert consensus of the evidence base.
- Further investigations into the skin care reactions caused by superficial, orthovotlage, and proton beam radiotherapy are required.

8. Implementation strategies

8.1 Implementation and dissemination of learning resources

The core group has developed the following resources:

- A summary document outlining the rationale and key recommendations.
- A practice guideline for health professionals (see **Appendix 8**).
- A dressings recommendation list for treatment of moist desquamation based on the current evidence available (see **Appendix 9**).
- A presentation for use at conference and events and also for the SoR website (see **Appendix 10**).
- A poster and associated hand-outs for use at conference and events (see **Appendix 11**).
- A patient information summary leaflet (see **Appendix 12**).

8.2 Impact measures and audit tools

- Departments will be encouraged and expected to use the RTOG scale to monitor rates of skin reaction and to share these in a national data collection.
- Departments will also be expected to undertake patient satisfaction audits.
- The SCoR will re-audit skin care practice across the UK in 2016 (see **Appendix 13**) to assess use of and compliance with the guidelines, to assess the outcomes from the first two bullet points, and to monitor consistency of care.

8.3 Organisational or financial barriers to implementation

The majority of the recommendations have no financial implications. There is a requirement for additional training and some additional resources. The main blocks to implementation are likely to be organisational and cultural since they require changes to established working practices. However, many departments are working through the changes needed to embed person-centred care more fully into daily practice and this guideline’s recommendations should be integral to this process.

9. Recommendations for future research

- New high quality trials to investigate interventions for dry or moist desquamation are urgently required; enabling a more consistent approach for patients receiving radiotherapy and to inform guidelines. Funding bodies supporting radiotherapy research studies should prioritise these trials as the results would have a wide impact across all cancer patients referred for radiotherapy as part of their treatment pathway.
- There is a need for further research of new products before they are introduced on an ad-hoc basis, without evidence, into radiotherapy skin care regimens.
- Future research should include designs that allow assessor blinding and comparators should include ‘current best evidence practice' or 'no intervention'.
- Assessment and quantification of the extent of radiation-induced skin reactions is needed as currently it is unknown how many patients are affected and to what level. Departments need to audit radiation-induced skin reactions locally to monitor proportions of patients that develop different RTOG graded reactions across different treatment sites:
  a) increase the quality of information that can be given to patients;
- b) to allow departments to monitor their own practice and compare across centres.
- Evaluation into wet versus dry shaving and perfume and make-up use is needed.
- Evaluation of treatment aftercare requires review to ensure local continuity and consistency of care across the patient pathway.
- Research into patient preferences and compliance would inform future national guidelines. Decision tools would help patients make informed choices about radiotherapy skin care information.

10. Date of publication, review and updating

The evidence available for the College of Radiographers skin care guidelines must be reviewed at three yearly timelines and revised if required to ensure the evidence on which they are based is still valid.

An unplanned review may be required due to policy changes, published evidence or the emergence of new technologies and interventions. Identifying the need for unscheduled review is within the roles and responsibilities of the SCoR professional and educational (professional officer) team, under the direction of the Director for Professional Policy.

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Appendices

Appendix 7 - On-going trials table

Appendix 8 - Staff information sheet

Appendix 9 - Dressings table

Appendix 10 - Skin care presentation

Appendix 11 - Poster

Appendix 12 - Patient information sheet

Appendix 13 - Audit tool