WORKING PARTY REPORT ON MINIMUM STANDARDS FOR PHOTOTHERAPY SERVICES

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The remit of this Working Party was to provide a consensus statement for the British Association of Dermatologists (BAD) on minimum standards for Phototherapy service provision in the UK. The members were chosen for their specialist experience of phototherapy practice in a variety of delivery settings.

The need for a consensus statement is borne out of a move by some Commissioners in England to provide their Phototherapy services in a community setting. It is important that the care pathway and standards for delivering a Phototherapy service in the community are defined to assist providers and their patients. Additionally, it is recognized by this working party that standards for Phototherapy service provision in the UK show variation across secondary care departments. Further service provision information and resource tools to support BAD members in delivering their Phototherapy service accompanies this report are available on the BAD website http://www.bad.org.uk//site/492/default.aspx

Briefing materials considered:

1. *Phototherapy Guidelines, St Thomas' Hospital, July 2009*
2. *The South East of England Managed Clinical Network, February 2011*
3. *National Managed Clinical Network for Phototherapy Scotland, September 2010*
4. *Artificial Optical Radiation Directive (AORD), Moseley 2010*
5. *Gwent Healthcare NHS Trust, Phototherapy and Photodynamic Therapy Service Standards and protocols 2009*
6. *West Kent Light therapy community service specification 2011*

Introduction

In the UK for more than 50 years, phototherapy has been an established low cost[1,2] outpatient treatment for psoriasis and other inflammatory skin diseases.

Predominantly hospital based, it is commonly used prior to considering systemic therapy in those patients for whom topical treatment has proved unsatisfactory in moderate to severe disease.

In the past two decades, narrowband UVB (NB UVB) has emerged as the phototherapy treatment of choice for most indications, with photochemotherapy (PUVA) being for most diseases reserved for treatment failures. With both treatments, potential problems exist with lack of efficacy, acute skin

burns and an increased risk in skin cancer in the longer term.

Phototherapy has to be prescribed by clinicians knowledgeable of the many indications, as well as the available topical and systemic treatments, to enable a decision when phototherapy is appropriate and which form should be prescribed.

Audits of phototherapy provision[3,4] have revealed great variation in the quality of service provided between centres. This, along with legal[5,6] concerns with burning and in those patients who have had a lot of phototherapy exposures i.e. the cancer risk, has brought clinical governance issues to the fore.

In 2002, clinical standards and a managed clinical network were established, coordinating all centres in Scotland.[7] More recently, similar structures have been developed in South East England and Wales.

Referral and treatment management

It is essential that ALL referrals for phototherapy must be from a dermatologist or an accredited General Practitioner with Special Interest (GPwSI) in Dermatology (under the supervision of a Consultant Dermatologist) and must include the following patient and treatment information in the referral form:

- Details of current systemic medications and previous phototherapy treatments should be recorded.
- Details about absence or presence of any contraindications or risk factors to phototherapy.
- Details of which type of phototherapy is being requested and which disease is being treated.

For any Dermatology service it is expected that 90% of patients will start treatment within 6 weeks of referral for phototherapy. 90% of patients referred urgently to phototherapy should ideally be treated within 3 weeks.

Every Dermatology unit should have a named phototherapy Lead Consultant to oversee the delivery of the Phototherapy service. They should also be responsible for the department's use of written evidence-based treatment protocols, for all forms of phototherapy that are given by the Unit, including discharge protocols.

In providing a course of treatment it is essential the following areas are provided and recorded:

- A formal nursing assessment pre-phototherapy, must be recorded in the nursing or medical notes which should include the following information; cumulative doses of phototherapy, blood results, allergies and current medication.
- All clinical details of every appointment and every course of treatment to be recorded in a standardized agreed manner in a patient record which is easily accessible.
- Minimal Erythema Dose (MED) testing is desirable before proceeding to whole-body therapy as this allows the detection of unsuspected photosensitivity and minimizes the risk of burning.
- An essential procedure before starting bath psoralen (PUVA) photochemotherapy is the evaluation of the Minimal Phototoxic Dose (MPD). Erythematous reaction to the bath-PUVA can occur up to 3 days after irradiation so testing is essential to avoid phototoxic side-effects. Additionally, for oral PUVA, MPD assessment ensures that the psoralen dose given

does cause a phototoxic reaction. If it does not then MPD testing should be repeated after an increased psoralen dose or a switch to topical PUVA made.

- All patients with a cumulative total of 200 whole body PUVA or 500 whole body UVB treatments, as well as those otherwise considered at increased risk of skin cancer as a result of therapy, should have annual dermatological review to assess for signs of actinic damage as a marker of skin cancer risk, and for lesions of concern.
- There must be a record of informed patient consent when the dermatologist has seen the patient, either formal written consent or a record of the process in the patient's notes that the patient has verbally given informed consent. Consent can also be taken by a senior nurse and by a suitably trained specialist registrar.
- Every patient should be given a patient information leaflet with regard to the treatment they are receiving at their initial consultation and offered on an ongoing basis for every phototherapy treatment provided in the Unit.

There are many aspects to phototherapy regimens that influence effectiveness and safety. These include:

- Choice of type of therapy.
- How the radiation (ultraviolet B or ultraviolet A) starting dose is determined.
- In the case of photochemotherapy (PUVA) choice of psoralen and route of its administration.
- Treatment frequency.
- Treatment increments and;
- how it is decided when to stop a course of treatment.

For some phototherapy indications there is available study evidence on some of these aspects of methodology. Protocols based on available evidence should be available to guide treatment in all Phototherapy units. However, it should be recognised that individual patients may require treatment that does not follow the standard protocol so those prescribing, as well as those administering phototherapy need to have sufficient knowledge and experience to know when treatment should diverge from a standard protocol.

In summary, all patients treated with phototherapy should be treated according to optimally effective, and safe, regimens based on the best available study evidence, adapted as necessary to be appropriate to each individual patient, and to local Phototherapy unit circumstances.[8]

Equipment and safety

Ultraviolet light is a form of non-ionising radiation that is known to be carcinogenic. UV phototherapy equipment is designed to deliver high intensities of UV radiation without the protection of sealed enclosures found in other scientific or industrial environments.

Patients are exposed to therapeutic doses of UV radiation far in excess of maximum exposure levels for workers or members of the public. In order to minimise the risks of excessive or inadvertent exposure, it is essential that accurate values of UV doses delivered to individual patients are recorded.

The protection of phototherapy staff is necessary to comply with UV radiation safety standards. While visitors, relatives and staff not involved in phototherapy should also be protected from any inadvertent exposure to UV radiation from phototherapy equipment.

Minimum standards for UV phototherapy equipment

All equipment **must be** 'fit for purpose', 'CE' marked as a medical device, commissioned, installed and maintained according to manufacturer recommendation.

There must be a formal arrangement for annual maintenance and UV calibration by either a competent medical physicist or technician, or an engineer approved by the manufacturer. A record must be kept of maintenance visits and UV calibration results. These must be available should any technical problem arise between routine maintenance visits.

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Any radiometer or other dosimeters used must be calibrated with traceability to the National Physics Laboratory, and must be within the recommended calibration intervals. The following areas for UV lamp maintenance are essential:

- UV lamps must be shielded by acrylic or glass panels as appropriate.[9]
- Units must be checked for electrical safety at least annually.
- Small units with 13amp plugs must pass the Portable Appliance Test (PAT) for medical devices, and results of these tests must be recorded.
- Cabins or other large appliances with permanent connection to electrical power must be inspected for electrical safety by a competent person.
- A policy for the replacement of failed or low output UV lamps must be in place and must ensure that patients are not exposed to excessive directional exposure to UV ('hot spots').

Premises

Formal written risk assessments of the Phototherapy unit must be carried out at least annually.[10] This should include the assessment of risks from exposure to ultraviolet radiation and other wavelengths according to The Control of Artificial Optical Radiation at Work Regulations 2010[11] as follows:

- Waiting areas must be separate from treatment areas.
- All entrances to UV treatment areas must have UV warning signs.
- All drugs and other chemicals used in the Phototherapy unit must have a CoSHH assessment and be stored in a secure place.
- An infection control and hygiene policy must be in place to ensure adequate cleaning of equipment and other surfaces in the Phototherapy unit.

Clinical governance

Phototherapy services should operate in an environment that is determined by adherence to the principles of clinical governance. Ideally, to ensure equity of care across the UK, Phototherapy services should strive towards the introduction of UK-wide national clinical standards for phototherapy (as have existed in Scotland since 2002).

In the interim, until national clinical standards are agreed upon, a typical clinical governance framework for a local Phototherapy service should include, at least, the following elements:

- The service should have a **named phototherapy lead clinician** (usually a Consultant Dermatologist). The role of the lead clinician is to take clinical responsibility for ensuring that the service is safe and effective and complies with:

  - national service delivery standards
  - treatment-specific guidelines
  - disease specific guidelines
- The Phototherapy service is delivered by a **multi-professional team**. Members of the team and their roles in contributing to the service should be recorded. Team members would typically include the following: phototherapy lead clinician (usually a Dermatologist); Lead Phototherapist (usually an experienced nurse; less often a physiotherapist or medical physicist); junior Phototherapists (usually nurses); medical physicist; +/- trainee grade for any of the above.
- The Phototherapy team should have **regular team meetings**. The broad aim of these meetings is to ensure that the service is focused on the need to provide timely, safe and effective Phototherapy services to local patients. These should occur at least 4 times per year, ideally more often (every month).

The **agenda for these regular phototherapy clinical governance meetings** should include the following elements:

- **Review of phototherapy activity** since the previous meeting (in other words, summary of treatment numbers for each phototherapy modality).
- **Review of phototherapy waiting list data** (if a waiting list exists) to assess demands on the service and issues for service delivery.
- **Review of adverse events**. All adverse events should be discussed by the team. Where patient safety is an issue, the team needs to consider the cause of the adverse event, and measures to be taken if necessary to avoid a repeat in the future.
- **Discussion of difficult or instructive cases.** As with any high volume clinical therapy service, there are some cases that respond in an atypical or unusual way. Discussion of these few cases is often instructive for team members. Furthermore, such discussion is usually helpful in order to optimize treatment for individual cases and to improve patient outcomes generally.
- **Equipment issues**. The team should include discussion of equipment issues. Issues that might arise include planned replacement of phototherapy irradiation fluorescent tubes, planned routine phototherapy cabin maintenance, cleaning, electrical safety checks and cabin dosimetry, and planned replacement of old or obsolete equipment.
- **Audit**. The phototherapy team should audit the service to ensure compliance with national standards and guidelines. The team must plan to carry out and present such audit data to the local dermatologists at least once a year.
- **Training**. There is a need for on-going training of team members. Such training and Clinical Professional Development (CPD) should be discussed and planned to ensure that all team members fulfill professional requirements to be fully up-to-date with appropriate CPD compliance.

Staff training

Phototherapy services require staff to have specialist training, knowledge and clinical skills in order to ensure effective outcomes and quality care for patients. Staff must be assessed as being competent and safe in order to provide phototherapy treatments that maximise benefit and minimise the potentially serious acute and chronic adverse effects of therapies. The minimum standards required include:

- Staff should either be qualified as first level nurses registered with the Nursing and Midwifery Council or chartered physiotherapists registered with the Royal Society of Physiotherapists.
- Training and experience in Dermatology is important to provide holistic patient care. This knowledge includes:
    - anatomy and physiology of the skin
    - recognition and understanding of skin diseases
    - skin assessment
    - understanding photo-responsive diseases
    - patient education regarding skin care and use of topical therapies
    - understanding the psychological impact of chronic skin disease
- Attendance at a core phototherapy course to gain the necessary theoretical education and knowledge.
- A period of supervised practice for approximately 3 months with a competent practitioner to develop the necessary clinical skills to be safe and effective.
- Formal assessment of clinical competence using a specialist phototherapy competency framework.[12] A record of this document is necessary for audit, clinical governance and CNST requirements.
- Attendance, at least once yearly, at an update meeting.
- Provide phototherapy treatments which whenever possible are evidence-based.
- Managers should ensure that staff has access to the appropriate training and education to equip the staff member with the required knowledge.
- Managers should provide staff with phototherapy equipment which is fit for purpose and meets the health and safety requirements for patients and staff.

Summary of recommendations

In summary, these minimum standards for Phototherapy services have been written with the intention of ensuring that patient care in this important area of skin treatment is optimal. In particular, the working party expects that these standards will help inform Commissioners of the requirements and service standards for providing Phototherapy services in the UK. Additionally, the working party anticipates a benefit from these minimum standards for existing phototherapy clinics as a guide to improving standards. These recommendations are based on the knowledge and expertise of this multidisciplinary group, whose members were chosen on the basis of their experience of this therapeutic area. The need for a formal, evidence-based clinical governance guideline document to cover this subject area is acknowledged by the working party, and should now be a priority for the BAD and British Photodermatology Group.

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On behalf of the Working Party for Phototherapy Services

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