British Association of Dermatologists

healthy skin for all

Service Guidance and Standards

For

Photodynamic Therapy (PDT)

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NICE accredited

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NICE has accredited the process used by the British Association of Dermatologists to produce Service Guidance and Standards. Accreditation is valid for 5 years from 7 March 2017.

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Preface

The British Association of Dermatologists (BAD) is responsible for developing guidance that is solely or mostly focused on the organisation and delivery of dermatology healthcare services. These differ from clinical guidelines which mainly deal with the process of care and consider how interventions should be delivered and by whom. Service guidance attempts to link these issues with the broader remit of the health service - in particular the interaction between structures and processes. For example, to deliver effective care it is necessary to ensure there are appropriate facilities, sufficient equipment and staff to deliver the required service or clinical intervention safely to service users etc.

Our approach to the development of current and pending service guidance is based on the core principles and methods guide set out by the National Institute for Health and Care Excellence (NICE) for developing service guidance to meet its accreditation requirements.

Photodynamic Therapy Service (PDT) Guidance

Beginning in August 2013, the BAD invited a range of professionals and service-user representatives of Photodynamic Therapy (PDT) to form a multi-disciplinary Working Party Group (WPG). The remit of this WPG was to undertake an evidence-based review following our NICE Service Guidance accreditation process (see Appendix 1: BAD Developing Dermatology Service Guidance) to develop service standards and guidance for conventional PDT. WPG members were chosen for their specialist skin cancer experience in the use of PDT (normally provided within cancer units and cancer centres) across the United Kingdom (UK). A broad range of stakeholder representatives are included in the WPG: Dermatologists, PDT Nurses, Medical Physicists, and patients.

Statement of Our Service Intentions:

1. To develop service guidance and core standards covering patient referral and assessment, patient information, informed consent, treatment and discharge; with outcome criteria that will be routinely audited.

2. To ensure all healthcare professionals have the requisite training and maintain an up-to-date portfolio of continuing professional development and revalidation.

3. To regularly monitor and update treatment protocols to ensure PDT services conform to best clinical practice and skin cancer guidelines.

4. To ensure light sources for conventional PDT services are well maintained and correctly calibrated, with routine checks for reliability and safety.

5. To ensure the PDT unit provides a safe patient-centred environment and meets required regulatory standards.

In order to achieve these aims, each PDT Service Standard defined within the guidance provides a rationale and criteria which should be demonstrated by departments. Each standard contains a list of evidence and audit criteria which departments should assess themselves against. This self-assessment process is supported by a self-audit questionnaire to help departments improve their services and flag up areas of clinical concern within existing Trust governance and risk management protocols.

The self-assessment and audit processes have been subject to pilot tests within a number of National Health Service (NHS) Trust sites and Health Boards. An extensive public consultation with all professional groups involved in the provision of NHS PDT services has been undertaken in order to ensure appropriate feedback has been disseminated and actioned by the WPG, prior to the publication of this guidance.

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Aims, Purpose and Scope

Aims

The core aims of our national PDT service guidance and standards are:

- To define core aspects for the delivery of PDT services for skin cancer patients in the United Kingdom;
- To improve access to PDT treatments for skin cancer patients;
- To quality assure PDT training standards within services;
- To quality assure patient outcomes and improve clinical recording in PDT services.

Purpose

BAD Service guidelines for PDT are designed to provide a set of required Service Standards which underpin NICE clinical guidelines and inform NICE quality standards (outcome indicators). This document forms the basis of a quality assurance programme for PDT services and has identified the standards and minimum requirements for the care of patients receiving PDT. All areas are supported by acute clinical governance frameworks for outpatient services provided by hospital trusts and within the terms of the NHS service Contract.

Scope

It is important for PDT service guidance and accompanying standards to reflect the issues which make a difference to the experience of the patient using the service. For this reason, this guidance follows the patient care pathway for PDT. As far as possible, standards are written from the service user perspective and reflect the service infrastructure required to reduce risk and harm.

We recognise that services are under increased pressure to demonstrate that they comply with national policies and guidelines. For this reason, our guidance incorporates existing requirements and standards (recommendations) set out nationally for NHS services and are aligned with:

- Department of Health Policy Implementation Guides;
- NICE guidance;
- Recommendations by NHS Estates and the BAD Staffing and Facilities guidance;
- Patient Safety Domain of NHS England;

- Existing UK services which have accreditation frameworks and or managed clinical networks in place;
- Care Quality Commission (CQC) Regulations;
- Health Safety Executive and COSSH Risk Assessments;
- Department of Health Building Notes for facilities;
- NHS Standards Contract terms and conditions;
- NICE IOG Skin Measures and Peer Review (England, Wales and Northern Ireland);
- Scottish Intercollegiate Guidelines Network (SIGN) Guidelines for Skin Cancer (Scotland);
- General Medical Council (GMC) Good Medical Practice and Ethical Guidelines;
- NHS England and Health Boards Quality Governance.

Introduction

The following standards contained within this service guidance include the rationale and demonstrable essential criteria which are drawn from existing national policies and guidelines for NHS service delivery.

They clearly define the expectations for achieving safe, effective and high-quality PDT Services, which providers operating outside of the NHS will also find useful.

Clinicians who deliver PDT services are also bound by the standards set by their respective professional bodies in relation to their clinical practice.

Definitions

Standard

A standard is something considered by an authority or by general consensus as a basis of comparison in measuring or judging adequacy or quality. These standards have been developed by a multidisciplinary group set up by the BAD to carry out this work.

In this document standards are expressed as something which PDT services should meet as an overriding duty of principle in order to provide a quality service. They provide the basis for evaluating the quality of services and identify areas for improvement to provide safe and equitable care for patients wherever they are treated.

Evidence/Minimum requirements

The evidence requirements are intended to be well-defined and easy to understand. They must be met to satisfy the standards contained within the guidance. Some of the evidence requirements relate to existing national policy and guidelines.

Examples of suitable evidence

Examples of suitable evidence are the records that applicants can use to demonstrate that they meet the standards, such as anonymised patient case examples. The defined evidence in the next section illustrates the types of information required to demonstrate compliance against a standard. This is not intended to be either prescriptive or exhaustive (recommendation only). Service providers may provide what they consider to be the most convincing evidence available for their achievement of each standard, whether or not it appears among the listed evidence (see Appendix 2 – Core List of Evidence).

Self-Assessment and Audit

Self-Assessment against the PDT Service Standards will be a voluntary and cyclical process. This process provides independent validation that a service has demonstrated competence measured against the standards and is considered to be fit for purpose. It drives continuous improvement by allowing services to identify areas for improvement and take the necessary remedial action(s) within recognised NHS clinical governance and risk reporting frameworks.

Who is this guidance for?

The service guidance and standards are integral to quality assuring safe and effective care for PDT patients. They help to:

- Ensure that new services are set up in a way that will ensure patient safety and optimised treatment;
- Ensure that existing service infrastructure (facilities, equipment and staffing etc.) contributes to the safe and effective delivery of care to patients;
- Clarify service expectations for patients, clinicians, management, commissioners and NHS employees;
- Drive service improvement and development of PDT services to meet local need;
- Contribute to improved clinical monitoring and recording of quality, results-based outcomes.

Service guidance and standards are developed primarily for commissioners of NHS services, service providers (NHS and private practice) and those regulatory bodies involved in the scrutiny of care. They aim to reinforce governance and accountability by making service provision transparent and increase patient confidence by demonstrating commitment to service excellence. This will also ensure commissioners of NHS services procure services from appropriately qualified and accredited providers.

What approach have we taken to develop this guidance?

This guidance was developed in accordance with the core principles and methods set out by NICE for the developing service guidance. The methodology for developing Service Standards is underpinned and informed by an evidence review and existing national policies.

Each service standard is supported by the available national evidence and expert clinical judgment of the WPG. PDT Service Standards have been piloted on a number of hospital sites using our

self-assessment and audit process with evidence submitted for review by the WPG. This allows accurate feedback to be obtained on the operational process and updates to be made to the Service Standards by the WPG. The finalised PDT service guidance and standards have been scrutinised and approved by the BAD Officers prior to consultation with our stakeholders.

A formal consultation period (normally one month) also took place to allow for stakeholder registration and feedback on the PDT service guidance and standards. Comments received have been collected using a standard proforma recognised by NICE. Stakeholder feedback has been responded to by the WPG and any necessary changes to guidance actioned prior to its publication.

The Standards Framework

PDT is used predominantly by dermatologists with standardised protocols and purpose-built light sources to treat a variety of superficial cancerous and pre-cancerous lesions including actinic keratoses (AKs), certain basal cell carcinomas (BCCs) and Bowen's disease (squamous cell carcinomas (SCC) in-situ). Ideally treated lesions should be non-pigmented, non-hyperkeratotic, thin, or superficial in nature. NICE have approved the use of PDT specifically for these indications.

The efficacy of PDT depends on the structure of the photosensitiser, the administration modality, the light source, and the treatment procedure. The three main types of PDT for patients with non-melanoma skin cancers include:

Conventional PDT: A range of light sources can be used for topical PDT including, filtered xenon arc and metal halide lamps, fluorescent lamps and light-emitting diodes (LEDs). Non-laser light sources are popular in topical PDT, possessing the advantages over lasers of being inexpensive, stable, easy to operate, requiring little maintenance, and providing wide area illumination fields. Retrospective comparison of laser and filtered broadband sources suggests equivalent efficacy in topical PDT.

Daylight PDT: This is suitable for people with large sun damaged areas of skin or those who have been diagnosed with precancerous skin lesion such as AKs (grade I and II on the face and scalp). The treatment involves applying a cream containing a prodrug of a photosensitiser to the affected area. Natural daylight (PDT) will then activate the photosensitiser, which destroys the abnormal cells. Discomfort associated with daylight PDT is much less than that from conventional PDT.

Ambulight PDT: This is one treatment option for people with non-melanoma skin cancer in the community. It is a novel development in the area of PDT that shows some promise, but further work is needed to support its case for adoption in the NHS. (NICE Ambulatory guidance).

The standard framework outlined herein applies to the delivery of all approved protocols for topical PDT (excluding ambulight). In England, Wales and Northern Ireland, PDT services are provided in line with NICE IOG 2006. In Scotland, SIGN Guidelines apply the same methodology to practices.

Conventional PDT treatment for skin cancer patients is largely provided by skin cancer clinicians working within skin cancer units or centres across the UK. The diagnosis of the skin lesion and assessment of the patient is essential to inform on the suitability of PDT as a non- surgical treatment.

PDT shares a number of similarities with other phototherapies: UVB and PUVA. As such, PDT treatments are normally carried out by either skin cancer nurses or phototherapy nurses. The most comprehensive and tested phototherapy standards for the UK are defined by the Managed Clinical Network for Phototherapy services in Scotland HDL (2007).

PDT standards underpin the core set of values which have been developed by our expert advisory group and will be further refined through our formal consultation with stakeholders. Our standards are covered by the following topic headings:

STANDARD 1:	Referral and Patient Assessment
STANDARD 2:	Patient Information and Consent
STANDARD 3:	Staff Training and Education
STANDARD 4:	Clinical Management & Monitoring
STANDARD 5:	Equipment and Facilities
STANDARD 6:	Clinical Governance and Audit
STANDARD 7:	Discharge Protocol

Each service standard sets out the rational, criteria and audit outcomes specific to the service frameworks for providing PDT services. These standards have been developed by our expert advisory group on PDT and have been refined in consultation with front-line staff, patients, carers and other interested groups.

The Self – Assessment Process

There are examples of good practice already in services in many areas of the country but delivering all 'essential criteria' defined under each service standard requires a long-term programme of change. Service providers will require additional support and tools for evaluating their performance and areas for improvement.

Therefore, each service standard's 'essential criteria' is supported by a range of documentary evidence and auditable outcomes. The main source of evidence for auditing essential criteria is obtained from patient case notes. As a minimum, 20 cases should be selected for this purpose along with the collation of core evidence for each standard. Some of the activities to be undertaken by departments will include:

- Activity data review on referral to treatment start times;
- Staff and patient/carer and unit/ manager questionnaires;
- A service user feedback;
- A review of case notes;
- An audit of treatment, with relevant documentation of equipment and facilities.

Self-Audit and Reporting

The data and evidence collected during self-assessment against the PDT Service Standards should be used to complete the PDT Service Self Audit Form. The audit outcomes are contained within each standard and outline the level required to meet essential criteria. The following flag status system is used to identify each essential criteria and areas of most risk and should be applied to the self- audit outcomes.

For Example:

	Essential Criteria	Comments	Status
1B.	90% of all referrals will start treatment within six weeks of referral from dermatology outpatients	69% of patients started treatment within 18 weeks of referral.	>90% Green Flag 70-90% Yellow Flag <70% Red Flag

Red Flag [Action Absolutely Required]: A Red Flag Service Standard is one which any Service has to meet. Failure to meet a Red Flag Service Standard places undue clinical risk on patients, breaches their rights or dignity and mandatorily requires action to correct this failure.

Yellow Flag [Action Recommended]: A Yellow Flag Service Standard is one which a good Service would be expected to meet. Failure to meet a Yellow Flag Service Standard does not imply the level of clinical risk of a Red Flag, but it is recommended that action is taken to meet the Standard.

Given the variation to current service provision providers implementing these new PDT Service Standards have a grace period (12 months) to identify shortfalls in their service provision. This enables the multi-disciplinary team to review their local procedures and practices against the accredited PDT Service Standards and, if necessary, implement the changes required. A summary of the results from the self-assessment and audit would form the basis of a business case for any identified areas of service improvement.

All BAD service guidance will be produced within recognised NICE accreditation standards (kite marked). As such all our guidance (clinical and services related) are required to inform all service specifications for dermatology within the NHS Standard Service contract. The self-audit reporting tool can be used by providers and commissioners to inform on key contractual performance and quality outcomes for dermatology services.

STANDARD 1: Referral and Patient Assessment

Standard Statement 1A - Referral	
Rationale All patients with a suspected non-melanoma skin cancer should be referred to an accredited cancer unit or cancer centre for review by an accredited Consultant (on Specialist Register) who is a core or affiliated member of the Skin Cancer MDT or by another accredited practitioner working under the supervision of a Consultant Dermatologist. An accurate diagnosis, assessment and clinical decision on appropriate treatment is essential before administering PDT. Where appropriate, diagnosis may be confirmed by previous histology and must accompany the referral letter.	
Essential Criteria	
1A.1	All referrals for PDT should go to an accredited Consultant on the specialist register who is a core or affiliated member of the skin cancer MDT (or a practitioner worker under the supervision of the Consultant), for confirmation of diagnosis and the prescribing of PDT.
1A.2	The Dermatologist must provide the following information with the patient prescription for PDT in the pre-assessment or request letter: • Where clinically indicated histology and depth of invasion <2mm (>2mm should not be referred for PDT); • Details about absence or presence of any contraindications or risk factors to PDT. Details of the treatment being requested indicated skin cancer for treatment.
1A.3	Each lesion area to be treated shall be identified in the referral along with a medical history of the patient. Details should include the absence or presence of any contraindications or risk factors to PDT; details of indication for which PDT is being requested.
Examples of Suitable Evidence	
• Referral letters for appropriate PDT treatment, dictated to the prescribing doctor, is in each patient's main and PDT notes.	
• A copy of, or reference to, histological confirmation, is in each patient's main and PDT notes.	

Audit Outcomes		Status	
100%	Evidence of prescription can be identified in patient notes.	>90% Green Flag 70-90% Yellow Flag <70% Red Flag	
100%	Clear identification of lesion(s) or area(s) to be treated is referral letters.	>90% Green Flag 70-90% Yellow Flag <70% Red Flag	
100%	Histological evidence of confirmation of lesions is present in referrals where pathological diagnosis has been obtained.	>90% Green Flag 70-90% Yellow Flag <70% Red Flag	
Self-Assessment and Audit Questionnaire – Review of 50 Patient Cases		**YES**	**NO**
Q1.	Is there clear documentation as to how the patient was referred and assessed appropriately for PDT treatment?		
Q2.	Did the pre-assessment/request letter clearly detail: identification of lesion; area to be treated; and histological evidence of confirmation (where indicated)?		
Q3.	Are patients requiring PDT referred to an accredited cancer unit or cancer centre?		
Q4.	Are patients requiring PDT referred to either an accredited Consultant (on Specialist Register) who is a core member of the Skin Cancer MDT, or another accredited practitioner working under the supervision of the Consultant?		

Standard Statement 1B – Assessment

Rationale

A comprehensive assessment and review of the patient's skin lesion must be carried out by an accredited Consultant (on Specialist Register) who is affiliated with a Skin Cancer MDT or by a doctor working under the supervision of a Consultant Dermatologist. PDT is prescribed by a trained dermatologist or another PDT practitioner working under the supervision of a Dermatologist. Both surgical and non-surgical options must be provided to the patient. Patients with special needs e.g. children, learning difficulties, language barriers, will have PDT suitably adapted to ensure safety of the patient at all times.

Essential Criteria

1B.1	A formal assessment pre-PDT must be recorded in the PDT and/or medical notes which should include the following information: indication, body map of site of lesion(s) to be treated, previous PDT history, allergies, current medication, whether clinically or histologically diagnosed and previous treatment of the lesion, if any.
1B.3	Conventional PDT treatment should be provided as a day case, due to the length of treatment – i.e. 30-minute consultation followed by three-hour treatment.
1B.4	Protocols for conventional PDT recommend some form of lesion-preparation, so as to enhance the photosensitising agent's absorption and penetration. Debulking of a lesion may be appropriate for days/weeks prior to treatment. Treatment sites should be covered with occlusive dressings during incubation periods for topical photosensitiser for the treatment of AKs, SCC in-situ and BCC.
1B.5	The dermatology life quality index (DLQI) is tool that is validated for use in various skin diseases that can be used to assess the physical, psychological and social wellbeing of patients being treated in the PDT unit.
1B.6	Photograph of lesion site where possible is recorded in the patient's clinical notes.

Examples of Suitable Evidence

- A proforma assessment sheet with body map should be included within the diagnosis in the patient case notes.
- Activity report for 12 -24 months of PDT Patients with dates of referral and waiting times.

Audit Outcomes		Status
100%	Patients start treatment within 18 weeks of referral to PDT.	>90% Green Flag 70-90% Yellow Flag <70% Red Flag
100%	Documentation of treatment response within 3 months of treatment.	>90% Green Flag 70-90% Yellow Flag <70% Red Flag

Self-Assessment and Audit Questionnaire – Review of 50 Patient Cases		YES	NO
Q1.	Is there evidence of the patient's starting treatment within 18 weeks of referral?		
Q2.	Is there evidence that all newly referred patients have undergone a pre-operative consultation with a core member of the Skin MDT?		

STANDARD 2: Patient Information and Consent

Standards Statement 2A- Provision of Written Patient Information		
Rationale All patients treated with PDT and their parent/carers have equitable access to information tailored to individual needs and their specific condition. Patient knowledge of the possibility of minor adverse effects (such as discomfort/pain during treatment) makes such events during treatment easier to manage and can lead to patients being more likely to continue to successful completion of a treatment course. It is recommended that the information and its delivery to patients and carers follow the principles of the NHS Information Prescription.		
Essential Criteria		
2A.1	All patients should be provided with written patient information leaflet (PIL) prior to treatment to inform on the potential risks and benefits of PDT.	
2A.2	PILs should be provided in plain English and in a variety of formats and languages as appropriate for those patients accessing the service.	
2A.3	Information on the PDT service and treatment should be available on the departments webpage and reviewed at least every two years.	
Examples of Suitable Evidence		
• Pre and post-operative information provided to patients in letters and or leaflets.		
• Comprehensive information on the MMS service is available on the Dermatology Department website and includes links to local skin cancer support group.		
• Macmillan or other information resources on skin cancer care.		
Audit Outcomes - what will be audited for each Standard		**Status**
100%	Written evidence of consent in case note reviews.	>90% green 70-90% yellow <70% red

100%	Record of patients have been offered written or electronic patient information material (as part of consent process).	>90% green 70-90% yellow <70% red	
100%	PDT Service information is available on the department webpage.	>90% green 70-90% yellow <70% red	
Self-Assessment and Audit Questionnaire - Review of 50 Patient Cases		**YES**	**NO**
Q1.	Is there comprehensive information available for patients about the PDT service on the department website?		
Q2.	Does the PDT service have a standardised pre and post-operative information sheet to provide to patients?		

Standard Statement 2B – Two stage Consent

Rationale

All patients being treated with PDT should be familiar with the contents of their consent form **before** they arrive for the actual procedure *and* should have received a copy of the page documenting the decision-making process. They may be invited to sign the form, confirming that they wish treatment to go ahead or continue, at any appropriate point before the procedure. A member of the healthcare team **must** check again with the patient at each treatment session whether they have any concerns and whether their condition has changed.

Essential Criteria

2B.1	The patient's medical records or a consent form must be used to record the key elements of any clinical discussion with the patient. This should include the information discussed, any specific requests by the patient, any written, visual or audio information given to the patient, and details of any decisions that were made.
2B.2	The GMC guidance states that the task of seeking consent may be delegated to another person, as long as they are suitably trained and qualified. In particular, they must have sufficient knowledge of the proposed investigation or treatment, and understand the risks involved, in order to be able to provide any information the patient may require.

Examples of Suitable Evidence

- Pre and post-operative patient information sheet specific to PDT
- Consent checklist covering the details explained to the patient including the procedure, pain management, risks and recovery.
- Signed and dated consent form.

Audit Outcomes		Status
100%	Patient initial assessment forms checkbox is ticked.	>90% green 70-90% yellow <70% red
100%	Patient notes contain a signed and dated consent form.	>90% green 70-90% yellow <70% red
100%	Patient information leaflets have version number and review date and are up to date.	>90% green 70-90% yellow <70% red

Self-Assessment and Audit Questionnaire – Review of 50 Patient Cases		YES	NO
Q1.	Is there a signed patient consent contained in all PDT patient records?		
Q2.	Does the department have an up to date standard operation policy (within the last 12 months) for PDT procedures?		

Standard Statement 2C – Patient Experience Exercise

Rationale

Each skin cancer MDT should have undertaken or be undertaking an exercise during the previous two years prior to review or completed self-assessment to obtain feedback on patients' experience of the PDT services offered. The exercise should have been presented and discussed at an MDT meeting and the team should have implemented relevant points from the previous exercise. The department also has a statutory duty to engage and involve the public/patients/carers in the planning of its service under the NHS Constitution[1] for England. These core principles are shared across all health care services provided in Wales[2], Scotland[3] and Northern Ireland[4].

Essential Criteria

2C.1	The exercise should at least ascertain whether patients were offered: • Opportunity to see a key worker, who may be the MDT CNS; • The MDTs information for patients and carers (written or otherwise); • The opportunity of a permanent record or summary of a consultation at which their treatment options were discussed.
2C.2	Staff are given the opportunity to review and respond to patients' queries and complaints.
2C.3	PDT Patient feedback should be used to inform on clinical audit and governance discussions for the service and ongoing training and education of PDT practitioners.

Examples of Suitable Evidence

- Minutes of PDT meeting or clinical audit and governance department meetings, and any MDT cases where PDT has been discussed.
- Examples of responses to complaints and queries by patients with lessons learned outcomes.
- Patient surveys and feedback of the PDT service or dermatology department as a whole.

Audit Outcomes

	All PDT patients are offered a permanent record or summary of a consultation at which their treatment options were discussed.	>90% green 70-90% yellow <70% red
	All PDT patient complaints are dealt within the required timeframes.	>90% green 70-90% yellow <70% red

[1] The NHS Constitution for England. The Department of Health. 2015.

[2] National Principles of Public Engagement in Wales. The Welsh Government. 2011.

[3] Informing, Engaging and Consulting People in Developing Health and Community Care Services. The Scottish Government. 2010.

[4] Personal and Public Involvement Consultation Scheme. The Department of Health, Social Services and Public Safety (NI). 2011.

	PDT Patient feedback is used to inform on clinical audit and governance discussions and training and education programmes for PDT practitioners.	>90% green 70-90% yellow <70% red	
	Two yearly audit report with PDT outcomes actioned.	>90% green 70-90% yellow <70% red	
Self-Assessment and Audit Questionnaire – Review of 50 Patient Cases		YES	NO
Q1.	Do all the PDT patient records contain written evidence of being offered a permanent record or summary of their consultation?		
Q2.	Have all the PDT patients been offered access to key worker?		
Q3.	Has the PDT service produced an audit with actioned outcomes within the last two years?		

STANDARD 3: Staff Training and Education

Standard Statement 3A - Qualified Professional Staff

Rationale

PDT services require staff to have specialist training, knowledge and clinical skills appropriate to the role they are undertaking to support the Dermatology Consultant. Staff must be assessed as being competent and safe in order to provide treatments that maximise benefit and minimise the potentially serious adverse effects of therapies.

Clinical Nurse Specialists (CNS) should be qualified and registered with the Nursing and Midwifery Council (NMC), and Health Care Assistants (HCAs) should be trained, supported and recognised by appropriate bodies.

Essential Criteria

3A.1	All consultants charged with supervising PDT in their department have attended an update course within the previous 3 years.
3A.2	All PDT units must have at least one trained PDT practitioner in the department whenever patients are being treated.
3A.3	PDT practitioners should attend at least one PDT educational session every 3 years.
3A.4	All Clinical Leads must ensure that their PDT practitioners have the knowledge, skills, qualifications, experience and training for the treatments they provide.
3A.5	All PDT practitioners must ensure they have an annual appraisal and their personal development plans for CPD supports their ongoing practice in this area.
3A.6	The skin cancer MDT lead for the cancer unit, or another appropriate consultant lead will provide clinical expertise and into key matters of treatment delivery, staff support and supervision, and overall service co-ordination. The Consultant's job plan should include up to two Programmed Activities (Whole Time Equivalent)) to reflect this input.

Examples of Suitable Evidence

- Evidence of annual review for training/ continuing professional development of all PDT practitioners.
- Protocols to specify the scope of practice of PDT practitioners and check clinical adherence.
- Defined roles and responsibilities for PDT practitioners in their job plans.

Audit Outcomes Status

100%	Up to date record of all PDT clinical service practitioners and their training (within the last three years) and ongoing education.	>90% green 70-90% yellow <70% red
100%	Named consultant lead for the skin cancer PDT service with allocated PA time for the PDT service in their job plan.	>90% green 70-90% yellow <70% red
100%	PDT treatments are provided by PDT practitioners who have up-to-date, specialised training (within the last three years).	>90% green 70-90% yellow <70% red
100%	PDT practitioners and consultants responsible for delivery of PDT Service should have undertaken a Training Course for PDT certification.	>90% green 70-90% yellow <70% red
100%	Yearly schedule for reviewing staff job plans and caseload within the PDT Unit.	>90% green 70-90% yellow <70% red

Self-Assessment and Audit Questionnaire – Review of 50 Patient Cases		YES	NO
Q1.	Does the PDT unit undertake an annual detailed review of its staffing requirements?		
Q2.	Does the cancer unit have a named skin cancer MDT lead (or other appropriate consultant) to provide clinical expertise and input into key matters of the PDT service; staff support and supervision; and overall service co-ordination?		
Q3.	Do all PDT practitioners have this clinical time allocated in their job plans?		
Q4.	Are there records that all PDT practitioners have up-to-date specialised training?		

STANDARD 4: Clinical Management & Monitoring

Standard Statement 4A – Monitoring Treatments		
Rationale It is important that both patient and PDT practitioner have an agreed set of criteria to define the best time to start and stop treatment, to enable consent and treatment explanation. Suitable time is then required to prepare the lesion, to ensure absorption of the photosensitising agents. A three-hour period is required for conventional PDT. Due to the length of time that patients will require for treatment, each PDT should be undertaken as a day case.		
Essential Criteria		
4A.1	Written protocols for PDT for skin cancers and all relevant indicators for treating with PDT are available and used in the PDT service.	
4A.2	Patient records of drug used, incubation period, light source used and dosage, plus number of treatments in a single cycle.	
4A.3	All serious adverse events should be noted at the clinical governance and audit meetings and recorded on the DATX/serious incident form. Any adverse event and the outcome recorded on the adverse event form and if appropriate on a Hospital Incident Form.	
4A.4	Both new and follow-up treatments must be carried out in a timely manner and follow waiting time targets.	
4A.5	All departments to use written evidence-based treatment protocols for all forms of PDT that are given by the Unit.	
Examples of Suitable Evidence		
• Each treatment protocol has a last reviewed and a review-by date.		
• Clear documentation of treatments: to include indication of therapy, drug used, incubation time, light type, irradiation and dosage.		
• Documentation of review of cases where a low (<50%) clearance rate has been achieved.		
• Incident reports and PDT risk assessments.		
• Written evidence-based protocols for reporting incidents.		
Audit Outcomes -		**Status**
100%	Yearly audited outcomes of post treatment clearance rates (and record of treatment parameters) for topical PDT patients analysed by the individual clinician (Lead).	>90% green 70-90% yellow <70% red

100%	All PDT treatment are carried out within the required times for efficacy.	>90% green 70-90% yellow <70% red	
100%	PDT treatment protocols are up-to-date and are reviewed annually (or according to local Trust requirements) and updated as necessary.	>90% green 70-90% yellow <70% red	
100%	All serious adverse events are documented and follow protocol.	>90% green 70-90% yellow <70% red	
Self-Assessment and Audit Questionnaire – Review of 50 Patient Cases		**YES**	**NO**
Q1.	Is there evidence of the drug used, dosage, incubation period and light source used (plus number of treatments in a single cycle) in the records?		
Q2.	Does the unit have written protocols and clinical indicators for treatment with PDT for skin cancers (and all relevant indicators)?		

Standard Statement 4B - **Recording PDT Activity**

Rationale

All patients receiving PDT treatment should be admitted as a day case for the duration of their treatment. The recording of accurate clinical information of each PDT patient is essential for assessing patient compliance, clinical audit and service planning. A clinical patient administrative system should be by the PDT unit to record the patient's episodes of care and consent.

ICD 10 Codes for the diagnosis of the skin lesion being treated should be recorded for day case activity along with the patients existing co-morbidities in the patient notes.

Nationally recognised OPCS codes for PDT apply to all four areas of the UK for day case and outpatient services:

- S07.8 Other specified photodynamic therapy of skin – per lesion
- S07.9 Unspecified photodynamic therapy of skin – per lesion
- Plus, a body site code for each of the areas treated

For English commissioned services, these OPCS codes map to an HRG tariff for payments (HRG code JC46Z) for 2018-19. Activity should be recorded as a day case for the present time England to cover the cost of the drug for PDT.

PDT units should record all PDT treatments (as above) for subsequent patient follow up appointment.

Essential Criteria

4B.1	The following clinical activities must be recorded for all patient undergoing PDT treatment: New Consultation with PDT Consultant (pre-assessment with histology provided by referrer or without histology): • WF01B First Attendance - Single Professional plus where required; • Biopsy of lesion of skin of head or neck – S151 plus body specific site Z code; • Biopsy of lesion of skin NEC - S152 plus body specific site Z code. Where the diagnosis is clinically obvious, and PDT has been scheduled without a prior biopsy, debulking of lesion site will be undertaken by the Consultant. Follow-Up PDT Appointments – DAYCASE: • WF01A Follow Up Attendance(s) - Single Professional;

	• Primary Diagnosis (ICD10) code along with any existing co-morbidities which affect the patient's treatment; • Other specified photodynamic therapy of skin - S078 – per lesion plus body specific site Z code; • Unspecified photodynamic therapy of skin - S079 – per lesion plus body specific site Z code. A post treatment assessment should be undertaken 3 months after completion of treatment by the patients' General Practitioner (GP).
4B.2	Agreed protocols in place for recording PDT treatments with the Hospitals coding team.
4B.3	Regular review PDT activity data (at least monthly) by the PDT practitioners to ensure accuracy of clinical information before charges are made to NHS England.

Examples of Suitable Evidence
• Monthly/quarterly activity data reports for the PDT service.
• Audit of the PDT service and outcomes report.
• MDT discussion and recommendations for PDT for suitable patients.

Audit Outcomes		Status
100%	Patient treatments are recorded accurately in their record.	>90% green 70-90% yellow <70% red
100%	Protocols are place for recording PDT treatments and regular review of PDT activity is undertaken.	>90% green 70-90% yellow <70% red

Self-Assessment and Audit Questionnaire – Review of 50 Patient Cases		YES	NO
Q1.	Is there evidence that the patient's treatment was recorded accurately?		
Q2.	Is there evidence of a post-treatment assessment recorded?		
Q3.	Are there documented protocols for the PDT service?		
Q4.	Is PDT activity for the service reviewed on a regular basis?		

STANDARD 5: Equipment and Facilities

Standard Statement 5A – Safety and Compliance		
Rationale Routine calibration and service checks ensure early detection of equipment problems, minimising risks to patients, and maintain traceable records of safety and quality assurance systems. Regular risk assessments of the PDT unit will ensure the safety of patients, staff and visitors. Expertise and equipment to undertake such dosimetry is only available from Medical Physics. The privacy, dignity and respect of healthcare users should be maintained at all times, through the effective use of private rooms, curtains, screens, blankets and appropriate clothing. Staff should ensure that there is sufficient space within curtained areas for a patient to dress and undress in privacy, with assistance when required. The limits for room temperature set-point are generally between 16^{o}C and 25^{o}C depending on the particular application but are adjustable within a predetermined range by the user.		
Essential Criteria		
5A.1	Up-to-date risk assessments and local rules are required for the administration of PDT in the clinic space identified for delivering PDT.	
5A.2	Annual electrical safety checks (i.e. servicing of PDT lamps) must be carried out by a suitably qualified person, typically a medical physicist or company engineer.	
5A.3	All work carried out in the clinic should comply with the Artificial Optical Radiation Regulations (AORR).	
5A.4	The clinic should ensure that the light dose prescribed is delivered to an acceptable level of accuracy.	
Examples of Suitable Evidence		
• Maintenance record.		
• Risk assessment checklist, identifying risks, hazards and control measures.		
• Certification of AORR compliance.		
• Written treatment protocols to be available for inspection.		
Audit Outcomes		Status
100%	Local Safety and Equipment Policy reviewed annually and signed by 100% of users.	>90% green 70-90% yellow <70% red
100%	PDT lamps serviced once per year and never more than 4 weeks overdue.	>90% green 70-90% yellow

		<70% red	
100%	Evidence that PDT facilities are suitable with respect to design, layout and service users' rights to privacy and dignity, as specified in the Department of Health's Health Building Notes 00-02; 00-03 and 12, respectively.	>90% green 70-90% yellow <70% red	
100%	Evidence that ventilation requirements are met - implicit under the Health and Safety at Work Act 1974 and COSHH, have been made explicit by the Management of Health and Safety at Work Regulations 1999, the Workplace (Health, Safety and Welfare) Regulations 1992 and the Provision and Use of Work Equipment Regulations 1998, all issued as a result of European Directives.	>90% green 70-90% yellow <70% red	
Self-Assessment and Audit Questionnaire – Review of 50 Patient Cases		**YES**	**NO**
Q1.	Does your medical physicist/company engineer have written dosimetry protocols?		
Q2.	Are the PDT unit's facilities suitable with respect to design, layout and service users' rights to privacy and dignity?		
Q3.	Does your service comply with AORR?		
Q4.	Does the PDT unit have scheduled checks for an engineer to check PDT lamps?		

STANDARD 6: Clinical Governance and Audit

Standard Statement 6A - Clinical Governance and Reporting Incidents	
Rationale The management of patients receiving PDT requires the co-ordinated contribution of various healthcare and other professionals. Although most patients referred for PDT are not required to be discussed at an MDT, a case list should be made available to core members at each meeting. Reports of adverse incidents should be made available, so that others can benefit from the lessons learned, and any problems with equipment, staff or procedures can be identified before they cause further adverse events or interruption to the service. Review of protocols and procedures allows these to be checked against current best practice or national guidelines and updated if necessary.	
Essential Criteria	
6A.1	Written evidence-based protocols for pain control during PDT are available and are used in the department.
6A.2	All members of the PDT team are involved in some form of clinical governance activity at least twice per year, including a governance meeting which covers the topics of: • Clinical incidents; • Health and safety; • Audit and guidelines.
6A.3	All members of the PDT team should be encouraged to attend the department's clinical governance and audit meetings.
6A.4	All PDT adverse events should be discussed at the department's clinical governance meetings and the outcome recorded on the adverse event form and if appropriate, on the Trust incident form.
6A.5	The PDT service should present a review of adverse events annually to the Dermatology Directorate and Audit meeting.
Examples of Suitable Evidence	
• Minutes of the Dermatology Directorate Audit meeting(s).	
• Trust Incident Forms, DATIX (or similar) or Incident Reporting Log.	
• Minutes of clinical governance meetings discussing clinical incidents, health and safety review of PDT.	
• Pain protocol management.	
• Allergic reactions protocol for anaphylaxis and contact allergy.	
Audit Outcomes	**Status**

100%	Adverse events plus at least one other aspect of the PDT service to be audited and presented to the Directorate Audit meeting annually.	>90% green 70-90% yellow <70% red	
100%	At least 2 local clinical governance audit meetings to be held per year for PDT.	>90% green 70-90% yellow <70% red	
Self-Assessment and Audit Questionnaire – Review of 50 Patient Cases		**YES**	**NO**
Q1.	Does the unit convene for at least two local clinical governance audit meetings in any one year?		
Q2.	Is there evidence that PDT incidents are recorded and discussed at department clinical governance meetings?		
Q3.	Are all serious adverse events reported (including to the MDT)?		

STANDARD 7: Discharge Protocol

Standard Statement 7A – Discharge Protocols			
Rationale All units should have a clear protocol to guide those administering treatment on when a course should be stopped. Patients should be able to access treatment, if necessary, for any relapse in their presenting skin condition following PDT.			
Essential Criteria			
7A.1	There is a protocol guidance on when to stop treatment or repeat a cycle of treatment.		
7A.2	At discharge, patients have information, tailored to individual needs on access to assistance and follow-up services.		
7A.3	The patient's GP is notified within ten working days following completion of a course of PDT and informed of any follow-up arrangement.		
Examples of Suitable Evidence			
• Protocol guidelines for stopping PDT treatment.			
• GP discharge letter in patient notes.			
• Monitoring advice to patient and GP.			
Audit Outcomes		**Status**	
100%	Discharge protocol up-to-date and available in PDT unit.	>90% green 70-90% yellow <70% red	
90%	GP letter stating reasons for discharge present in 90% of patient notes.	>90% green 70-90% yellow <70% red	
Self-Assessment and Audit Questionnaire – Review of 50 Patient Cases		**YES**	**NO**
Is the GP notified within ten working days of the patient's discharge from outpatients?			
Is the patient given discharge information which includes how to obtain advice if the condition reoccurs?			

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Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 15: Premises and Equipment.					X		

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Cantisani C, Paolino G, Bottoni U, Calvieri S. Daylight-Photodynamic Therapy for the Treatment of Actinic Keratosis in Different Seasons. J Drugs Dermatol. 2015 Nov;14 (11): 1349-53.	X	X	X	X	X	X	X
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Evidence Review: Prevalence and Incidence

A snapshot of the current service provision situation helps to understand health service users, their health status and the PDT service they access. Understanding local demographic profiles and patient activity including unmet need are essential to supporting their longer-term health needs.

Photodynamic therapy is a non-surgical technique for treating non-melanoma skin tumours which can include Basal Cell Carcinoma (BCC), Bowen's disease and Actinic (or solar) keratosis.

Many cancer registries record only the first NMSC of each histological type (e.g. BCC or SCC) per person, and information on small NMSCs treated in primary care or the private sector may never reach the registries. An estimated 30-50% of BCC and around 30% of SCC goes unrecorded, though this may vary by registry.

Non-melanoma skin cancers (NMSC) are extremely common, but relatively few deaths are caused by them. In 2011, there were 585 deaths from NMSC in the UK; of which 62% were in males. In 2011, there were 102,628 cases of NMSC registered in the UK: 57,800 (56%) in men and 44,828 (44%) in women, giving a male: female ratio of around 13:10.

Actinic keratoses are ultraviolet (UV) light-induced lesions of the skin, which are by far the most common lesions with malignant potential to arise on the skin (they can progress to invasive squamous cell carcinoma (SCC)).

Relevant disease summaries with prevalence statistics and co-morbidity information is provided below:

Skin Disease Prevalence	Risk factors and Co-Morbidities
The majority of NMSCs are either basal cell carcinomas (BCCs), also known as rodent ulcers, or squamous cell carcinomas (SCCs). Bowen's disease is squamous cell carcinoma (SCC) in-situ of the skin. Together, BCC and SCC (also known as keratinocyte cancers) are highly treatable and survival rates for NMSCs are very high[5]. The incidence in the UK is estimated at around 15 per 100,000 per year but can be much higher in Caucasians living in areas of high sunlight exposure[6]. It is more common in women (70-	Lowered Immunity Patients who are immunosuppressed following organ transplantation have a markedly increased risk of developing AKs and of developing malignant change in the AKs. This also applies to people who have undergone chemotherapy for malignant disease, and those with HIV infection.

[5] European Age-Standardised rates calculated by the Statistical Information Team at Cancer Research UK, 2011 using data from GLOBOCAN 2008 v1.2, IARC, version 1.2.http://globocan.iarc.fr.
Madan V, Lear JT, Szeimies RM. Non-melanoma skin cancer Lancet 2010;375(9715):673-85.
[6] Guidelines for management of Bowen's disease; British Association of Dermatologists

85% of cases) and most commonly appears between the ages of 60 and 70 years. BCC is the commonest type of cancer in the UK, with an average of 48,000 new cases registered each year in England between 2004 and 2006[7]. The incidence of BCC in the South West region is 2.9 times higher than that of lung cancer and places a significant burden on NHS resources. BCCs rarely metastasise and are unlikely to be fatal, although if untreated the tumours can become destructive and cause disfigurement[8]. In contrast SCCs sometimes spread and can therefore lead to death.[9] SCC incidence increased by a similar amount (34% in males and 39% in females) over the same time period. Whilst improved registration may partly explain these increases, some of the increase is probably genuine, reflecting increased UV exposure from the sun or sunbeds[10].	Squamous cell cancers are the most frequent, but basal cell cancers and melanomas are also more common in these people than in the general population.

[7] Improving Outcomes for People with Skin Tumours including Melanoma. The management of low-risk basal cell carcinomas in the community. NICE.

[8] Madan V, Lear JT, Szeimies RM. Non-melanoma skin cancer. Lancet. 2010;375(9715):673-85.

[9] Miller SJ, Alam M, Andersen J et al. Basal cell and squamous cell skin cancers. J Natl Compr Canc Netw. 2010;8(8):836-6.4.

[10] National Cancer Intelligence Network (NCIN). Non-melanoma skin cancer in England, Scotland, Northern Ireland, and Ireland. London: NCIN; 2013.

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Actinic keratosis (AK) occurs most often in fair-skinned individuals at a rate according to cumulative UV exposure.
Frequency increases according to a number of risk factors:

Increasing age, as the dose of UV is cumulative.
Proximity to the equator, as this affects UV dosage and cumulative exposure.
Lifestyle and time spent outdoors. Outdoor lifestyles, whether with work or recreation and sport, will increase risk.
Other specific practices, such as use of tanning booths. Artificial sunlight is a risk factor and may produce lesions in unusual places.
How fair the individual's skin is: skin is graded from Fitzpatrick type I to VI according to sensitivity to sunlight, as displayed by a tendency to burn or to tan. These lesions are almost entirely confined to fair skin types I and II.

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Exposure to chemicals

Another rare possible cause for non-melanoma skin cancer is overexposure to certain chemicals at work. These include:

• coal tar
• soot
• pitch
• asphalt
• creosotes
• paraffin waxes
• petroleum derivatives
• cutting oils
• arsenic.

Very small amounts of these chemicals used in the home are unlikely to cause skin cancer.
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AKs are more common in men than in women. Traditionally men are more likely, with work and recreational activities, to spend time outdoors.

AK has also been associated with a high-fat diet.

They tend to present between the ages of 30 and 60 years but can present earlier or later. As the years progress, and especially with continued exposure to strong sunlight, about 10% will undergo malignant change.[11] This is more likely in those that are erythematous, elevated and indurated. It may be necessary to remove the layer of keratin to see this layer.
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Genetic conditions

Most skin cancers are not caused by an inherited faulty gene that can be passed on to other family members. However, families are likely to have the same skin type, which may increase their risk of developing a skin cancer.
People with certain rare hereditary conditions, such as xeroderma pigmentosum (XP), have a higher risk of developing skin cancer. Naevoid basal cell carcinoma syndrome, a rare

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[11] Glogau RG; The risk of progression to invasive disease. J Am Acad Dermatol. 2000 Jan;42(1 Pt 2):23-4.

	autosomal dominant condition characterised by multiple and early onset basal cell carcinomas as well as developmental abnormalities. It affects one in every 50 to 100,000 people. • These people may have dozens of BCCs, should be referred to and managed by the local skin cancer multidisciplinary team (LSMDT) or the specialist skin cancer multidisciplinary team (SSMDT) (as recommended in the NICE guidance on skin cancer services). The management of these BCCs can impose a significant workload on both primary- and secondary-care services. The management of high-risk BCCs requires expertise to ensure curative treatment is combined with a good cosmetic result and low risk of complications.
Widespread lesions and suspected malignant change require referral. Patients with multiple and confluent actinic keratoses (AKs) are likely to be at higher risk of non-melanoma skin cancer, particularly patients with organ transplants[12]	•

[12] Guidelines for the management of actinic keratoses, British Association of Dermatologists (2007)

Glossary of Abbreviations and Terms

AK	Actinic Keratoses
ALA-PDT	Aminoevulinic Acid Photodynamic Therapy
AORR	Artificial Optical Radiation Regulations
BAD	British Association of Dermatologists
BCC	Basal Cell Carcinoma
BSDS	British Society for Dermatological Surgery
CCG	Clinical Commissioning Group
CNS	Clinical Nurse Specialist
COSHH	Control of Substances Hazardous to Health
CPD	Continuing Professional Development
CQC	Care Quality Commission
CQUIN	Commissioning for Quality and Innovation
DLQI	Dermatology Life Quality Index
GMC	General Medical Council
GP	General Practitioner
HCA	Health Care Assistant
LED	Light Emitting Diode
LSMDT	Local Skin Multi-Disciplinary Team: all level 3 and 4 care cancer health professionals involved in patient care
MAL-PDT	Methyl Aminoevulinate Photodynamic Therapy
MDT	Multi-Disciplinary Team: all health professionals involved in patient care
NCIN	National Cancer Intelligence Network
NHS	National Health Service

NICE	National Institute for Health and Care Excellence
NMC	Nursing and Midwifery Council
NMSC	Non-Melanoma Skin Cancers
PDT	Photodynamic Therapy
Photonet	National Managed Clinical Network for Phototherapy in Scotland
PIL	Patient Information Leaflet
SCC	Squamous Cell Carcinoma
SIGN	Scottish Intercollegiate Guidelines Network
SSMDT	Specialised Skin Multi-Disciplinary Team: all level 5 care cancer health professionals involved in patient care
UK	United Kingdom
WPG	Working Party Group
XP	Xeroderma Pigmentosum

Accredited specialist

An accredited specialist in dermatology is a doctor whose specialty is recorded as 'Dermatology' in the GMC's list of specialist-registered medical practitioners (consultants). He/she is a doctor who has completed either specialist UK training in dermatology approved by the GMC; or has been assessed as having equivalent experience.

Audit

Systematic review of the procedures used for diagnosis, care, treatment and rehabilitation, examining how associated resources are used and investigating the effect care has on the outcome and quality of life for the patient.

Clinic Letters

NHS England has included a new requirement on providers to communicate clearly and promptly with GPs following outpatient clinic attendance, where there is information which the GP needs quickly in order to manage a patient's care. For 2017/18, they intend to strengthen this requirement, requiring electronic transmission of clinic letters to practices as with discharge summaries to a similar timescale.

Clinical audit

Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery (National Institute for Health and Clinical Excellence).

Clinical governance

Clinical governance provides a quality framework through which healthcare organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which clinical excellence will flourish.

Clinical Networks

Groups of commissioners and providers of health or social care, concerned with the planning and/or delivery of integrated health or social care across organisational boundaries, whether on a national, regional or local basis.

Clinical practice guidelines

Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances. They aim to provide evidence-based interventions to improve patient outcomes.

Clinical supervision
Clinical supervision is a formal process of professional support and learning which enables individual practitioners to develop knowledge and competence. Clinical Supervision is central to the process of learning and to the scope of the expansion of practice and should be seen as a means of encouraging self-assessment analytical and reflective skills.

Clinician
A clinician is a professionally qualified person providing clinical care to patients.

Commissioning for Quality and Innovation (CQUIN)
CQUIN is the national quality incentive scheme. Guidance on CQUIN will be available at: https://www.england.nhs.uk/nhs-standard-contract/16-17/.

Competent
Competent means that the individual can perform the task with ability.

Consent
The intention of this regulation is to make sure that all people using the service, and those lawfully acting on their behalf, have given consent before any care or treatment is provided. Providers must make sure that they obtain the consent lawfully and that the person who obtains the consent has the necessary knowledge and understanding of the care and/or treatment that they are asking consent for. Providers must make sure that they take into account people's capacity and ability to consent, and that either they, or a person lawfully acting on their behalf, must be involved in the planning, management and review of their care and treatment.

Consultant
A person employed or engaged by the provider of equivalent standing and skill as a person appointed by an NHS Body in accordance with the Law governing the appointment of consultants.

Consultant Led Service
A service for which a consultant retains overall clinical responsibility (without necessarily being present at each service-user appointment), and in respect of which referrals of service-users are made directly to a named consultant.

Data
Data refers to all records and correspondence.

The Data Protection Act

The Data Protection Act controls how your personal information is used by organisations, businesses or the government. Everyone responsible for using data has to follow strict rules called 'data protection principles'.

Department of Health
The Department of Health in England of HM Government or other relevant body, or such other body superseding or replacing it from time to time and/or the Secretary of State.

Dermatology Life Quality Index (DLQI)
A quality of life questionnaire for adult dermatology patients. When using DLQI, healthcare professionals should take into account any physical, sensory or learning disabilities, or other communication difficulties that could affect the responses to the DLQI. In such cases, healthcare professionals should ensure that the DLQI continues to be a sufficiently accurate measure.

Dignity and Respect
The intention of this regulation is to make sure that people using the service are treated with respect and dignity at all times while they are receiving care and treatment. To meet this regulation, providers must make sure that they provide care and treatment in a way that ensures people's dignity and treats them with respect at all times. This includes making sure that people have privacy when they need and want it, treating them as equals and providing any support they might need to be autonomous, independent and involved in their local community. Providers must have due regard to the protected characteristics as defined in the Equality Act 2010.

Directly Bookable
In relation to any Service, the Provider's patient administration system being compliant with and able to communicate with the NHS e-Referral Service enabling available appointment slots to show on the NHS e-Referral Service, thereby enabling a Referrer or Service User to book a Service User appointment directly onto the Provider's patient administration system.

Duty of Candour
The intention of this regulation is to ensure that providers are open and transparent with people who use services and other 'relevant persons' (people acting lawfully on their behalf) in general in relation to care and treatment. It also sets out some specific requirements that providers must follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology when things go wrong.

Equality
This means recognising that while people are different and need to be treated as individuals, everyone is the same in terms of having equal value, equal rights as human beings and a need to be treated with dignity and respect.

E-Referral Guidance
The guidance in relation to e-referrals is available at: www.chooseandbook.nhs.uk/staff/overview/guidance.

Expanded Uncertainty

Expanded uncertainty is a standardised, internationally recognised method of expressing the margin of doubt for irradiance measurements.

Fit and Proper Staff

The intention of this regulation is to make sure that providers only employ 'fit and proper' staff who are able to provide care and treatment appropriate to their role and to enable them to provide the regulated activity. To meet this regulation, providers must operate robust recruitment procedures, including undertaking any relevant checks. They must have a procedure for ongoing monitoring of staff to make sure they remain able to meet the requirements, and they must have appropriate arrangements in place to deal with staff who are no longer fit to carry out the duties required of them.

Fit to practise

The health professional possesses the appropriate knowledge, skills and experience to practise safely and effectively.

Formulary

A list of medications that are approved by the Provider on the basis of their proven efficacy, safety and cost-effectiveness to be prescribed for Service Users by the Provider's clinical Staff.

Good Clinical Practice

Using standards, practices, methods and procedures conforming to the Law and reflecting up-to-date published evidence and using that degree of skill and care, diligence, prudence and foresight which would reasonably and ordinarily be expected from a skilled, efficient and experienced clinical services provider and a person providing services the same as or similar to the Services at the time the Services are provided, including (where appropriate) assigning a Consultant to each Service User who will be clinically responsible for that Service User at all times during the Service User's care by the Provider.

Good Governance

The intention of this regulation is to make sure that providers have systems and processes that ensure that they are able to meet other requirements in this part of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Regulations 4 to 20A). To meet this regulation; providers must have effective governance, including assurance and auditing systems or processes. These must assess, monitor and drive improvement in the quality and safety of the services provided, including the quality of the experience for people using the service. The systems and processes must also assess, monitor and mitigate any risks relating the health, safety and welfare of people using services and others. Providers must continually evaluate and seek to improve their governance and auditing practice. In addition, providers must securely maintain accurate, complete and detailed records in respect of each person using the service and records relating the employment of staff and the overall management of the regulated activity.

Health Building Notes
Health Building Notes give "best practice" guidance on the design and planning of new healthcare buildings and on the adaptation/extension of existing facilities. They provide information to support the briefing and design processes for individual projects in the NHS building programme

Health Care
Health care refers to services provided for or in connection with the prevention, diagnosis or treatment of illness, and the promotion and protection of public health.

Health Technical Memoranda
Health Technical Memoranda give comprehensive advice and guidance on the design, installation and operation of specialised building and engineering technology used in the delivery of healthcare (for example medical gas pipeline systems, and ventilation systems).

Multidisciplinary
A multidisciplinary team is a group of people from different disciplines (both healthcare and non-healthcare) who work together to provide care for patients with a particular condition. The composition of multidisciplinary teams will vary according to many factors. These include: the specific condition, the scale of the service being provided, and geographical/socio-economic factors in the local area.

National Price
The national price for a health care service specified by the National Tariff, as may be adjusted by applicable national variation specified in the National Tariff under section 116(4)(a) of the 2012 Act.

National Quality Requirements
The requirements set out in Schedule 4B (*National Quality Requirements*).

National Tariff
The national tariff, as published by Monitor under section 116 of the 2012 Act (including any rules included under section 116(4)(b) of the 2012 Act), as applicable at the time at which the relevant Service is provided.

Never Events, Serious Incidents and Patient Safety Incidents
Never Events are a particular type of serious incident that are wholly preventable, where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level, and should have been implemented by all healthcare providers. Each Never Event type has the potential to cause serious patient harm or death.

The current framework, including the detailed list of Never Events, is available at http://www.england.nhs.uk/ourwork/patientsafety/.

NHS Constitution for England

The Constitution sets out rights for patients, public and staff. It outlines NHS commitments to patients and staff, and the responsibilities that the public, patients and staff owe to one another to ensure that the NHS operates fairly and effectively. All NHS bodies and private and third sector providers supplying NHS services are required by law to take account of the Constitution in their decisions and actions.

NHS Service Contract

The NHS Standard Contract must be used by CCGs and by NHS England where they wish to contract for NHS-funded healthcare services (including acute and community-based services).

The National Institute for Health and Care Excellence

Special health authority responsible for the provision of national guidance on: the promotion of good health; and the prevention/treatment of ill health.

NICE Safe Staffing Guidelines

The National Quality Board has set out the immediate expectation of NHS providers in providing safe staffing levels. This guidance is a comprehensive review of the evidence in this area and produce definitive guidelines on safe staffing to support local decisions at ward and organisational level.

Peer review

Peer review is a structured, consistent and objective evaluation of an organisation or its services or processes reflecting accepted standards. It should be performed by true peers i.e. similar professionals.

Premises and Equipment

Are defined in regulations with the intention to make sure that the premises where care and treatment are delivered are clean, suitable for the intended purpose, maintained and where required, appropriately located, and that the equipment that is used to deliver care and treatment is clean, suitable for the intended purpose, maintained, stored securely and used properly.

Quality

Quality is used in this document to denote a degree of excellence.

Quality of Care

The Health and Social Care Act 2012 defines quality as encompassing three dimensions: clinical effectiveness, patient safety and patient experience.

Quality assurance
Quality assurance refers to the planned and systematic activities in a quality system that gives confidence or make certain that quality requirements for a product or service will be fulfilled.

Research
Research is the gathering of data, information and facts and aims to derive generalisable new knowledge.

Scope of practice
Scope of practice refers to the areas of a health professional's occupation where they have the knowledge, skills and experience to practise safely and effectively.

Secondary Care
Services provided as part of the health service in a hospital setting, or by those working in or based in a hospital setting, other than emergency services, primary care services etc.

Service level agreement
A service level agreement or customer service agreement is a document which specifies the services that will be delivered and the way in which they will be delivered to ensure uniform understanding.

Service Specification
The service specifications are one of the most important parts of the NHS contract, as they describe the services being commissioned and can, therefore, be used to hold the provider to account for the delivery of the services, as specified.

Staff
The entire group of people who work at an organisation including those who are:
- Employed / agency / bank / voluntary;
- Clinical e.g. nurses, doctors and occupational health technicians;
- Non-clinical e.g. administrative staff.

Staffing
The intention of this regulation is to make sure that providers deploy enough suitably qualified, competent and experienced staff to enable them to meet all other regulatory requirements described in this part of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. To meet the regulation, providers must provide sufficient numbers of suitably qualified, competent, skilled and experienced staff to meet the needs of the people using the service at all times and the other regulatory requirements set out in this part of the above regulations. Staff must receive the support, training, professional development, supervision and appraisals that are necessary for them to carry out their role and responsibilities. They should be supported to obtain

further qualifications and provide evidence, where required, to the appropriate regulator to show that they meet the professional standards needed to continue to practise.

Treatment

In Regulation 2(2) of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, treatment includes: a diagnostic or screening procedure carried out for medical purposes, the ongoing assessment of a person's mental or physical state, Nursing, personal and palliative care, and giving vaccinations and immunisations.

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We would also like to thank those NHS Hospital Trust departments who agreed to pilot these Standards ahead of publication, and the individuals and stakeholders who responded to the formal public consultation. Your valuable feedback was very much appreciated.

PDT Standards Feedback Form

We hope that you have found the PDT Service Guidance useful and would very much appreciate your feedback.

Your comments will be acknowledged by the CSU and any necessary changes to guidance incorporated into our next review of this publication.

1. Have you found these standards useful? Yes/No
Comments: *Type here*

2. Do you have suggestions for new sections or topic areas you would like to see included in future versions?
Type here

3. Do you have suggestions for new standards you would like to see included in future versions?
Type here

4. Do you have any general suggestions about this document that would improve its usefulness?
Type here

5. What is your profession?
Type here

Thank you for taking the time to complete this form. Please return to the attention of Paul Callaghan at servicestandards@bad.org.uk or posted to The British Association of Dermatologists, Clinical Services Unit, Willan House, 4 Fitzroy Square, London, W1T 5HQ.

Appendix 1: Developing Dermatology Service Guidance 2016

http://www.bad.org.uk/shared/get-file.ashx?itemtype=document&id=4147

Appendix 2: Specialised Service Specification for Dermatology

https://www.england.nhs.uk/wp-content/uploads/2013/06/a12-spec-dermatology.pdf