PAS 1616:2016

Healthcare – Provision of clinical services – Specification

CSAA
Clinical Services Accreditation Alliance

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Contents

Foreword

This Publicly Available Specification (PAS) was sponsored by the Royal College of Surgeons of England, on behalf of the Clinical Services Accreditation Alliance (CSAA). Its development was facilitated by BSI Standards Limited and it was published under licence from The British Standards Institution. It came into effect on 31 August 2016.

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- Chartered Society of Physiotherapy
- Clinical Services Accreditation Alliance (CSAA)
- Consumer & Public Interest Network (CPIN)
- Faculty of Medical Leadership and Management
- Health and Social Care Accreditation Forum (HaSCAF)
- MB3 Healthcare Ltd.
- Monitor
- National Institute for Health and Care Excellence (NICE)
- NHS England
- Patient and Public Involvement, Leeds Clinical Commissioning Group
- Professional Standards Authority for Health and Social Care
- Royal College of General Practitioners (RCGP)
- Royal College of Nursing (RCN)
- Royal College of Physicians (RCP)
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- Royal College of Surgeons (RCS)
- Scottish Intercollegiate Guidelines Network (SIGN)
- West Midlands Quality Review Service.

Acknowledgement is also given to the members of a wider review panel who were consulted in the development of this PAS.

This PAS is not to be regarded as a British Standard. It will be withdrawn upon publication of its content in, or as, a British Standard.

The PAS process enables a specification to be rapidly developed in order to fulfill an immediate need in industry. A PAS can be considered for further development as a British Standard, or constitute part of the UK input into the development of a European or International Standard.

Use of this document

It has been assumed in the preparation of this PAS that the execution of its provisions will be entrusted to appropriately qualified and experienced people, for whose use it has been produced.

Presentational conventions

The provisions of this standard are presented in roman (i.e. upright) type. Its requirements are expressed in sentences in which the principal auxiliary verb is "shall".

Commentary, explanation and general informative material is presented in italic type, and does not constitute a normative element.

Where words have alternative spellings, the preferred spelling of the Shorter Oxford English Dictionary is used (e.g. "organization" rather than "organisation").

Where URLs for websites and webpages have been cited, they aim to provide ease of reference for the PAS user and are correct at the time of publication. The location of a webpage or website, or its contents cannot be guaranteed.

Contractual and legal considerations

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a PAS cannot confer immunity from legal obligations.

Particular attention is drawn to the following specific regulations:

- Safeguarding Vulnerable Groups Act 2006 [1]
- The Children Act 2004 [2]
- Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20 [3]
- Health Care and Associated Professions (Indemnity Arrangements) Order 2014 [4]
- Personal Protective Equipment at Work Regulations 1992 [5]
- Health and Safety at Work etc. Act 1974 [6]
- Data Protection Act 1998 [7]
- Patient Rights (Scotland) Act 2011 [8]
- Management of Health and Safety at Work Regulations 1999 [9]
- Mental Capacity Act 2005 [10]
- Mental Health Act 1983 [11]
- Access to Health Records Act 1990 [12]
- European Working Time Directive 2003 [13].

0 Introduction

0.1 What was the motivation behind PAS 1616?

Healthcare is becoming increasingly challenging, with clinical service users presenting more complex needs while resources are constrained. There is also an increasing need to show stakeholders (e.g. regulators, commissioners, funders and system planners) that requirements are being met and improvements are being made, and, crucially, to show taxpayers that their taxes are well spent. Within this increasingly challenging context the prime motivation behind this PAS is to provide a specification to support clinical services in delivering better value for money, largely through reduced disease burden, but also through efficiencies.

Healthcare is provided in a wide range of facilities and settings, from public health, which includes screening and vaccinations in schools, to end of life care in specialist clinical services and in the home. To provide person-centred care and to deliver the best value for money, providers of care need to work together to adopt an integrated approach.

The scope of this PAS therefore includes the full range of services from preventative care through all aspects of care that clinical service users and their carer(s) encounter on their journey, from first contact with their primary care health professional through to their exit from the clinical service, including home care. It includes requirements for clinical users with complex needs and for clinical services to seek and adopt innovation when that is considered appropriate.

The future of healthcare depends on the quality of the future workforce. A typical clinical service supports the clinical training of students and trainees. Maintaining safe, quality clinical care whilst educating and training the future workforce in clinical settings is a challenge that clinical service leaders need to manage effectively. This PAS includes requirements for the clinical service to optimize training, while minimizing any negative impacts.

0.2 PAS format and terminology

This PAS is made up of a number of clauses, each of which is made up of requirements (instruction in the form of sentences using the auxiliary verb "shall"). Compliance with the PAS requires compliance with each of the requirements. However, it does not require compliance with informative text in italics in notes, which include recommendations (sentences using the auxiliary verb "should"). Further informative text, that provides background information and context, is included in commentary text in Annex A to Annex I. The informative text also includes further explanations, references and recommendations and PAS users are advised to read these annexes alongside the requirements. Whilst there are references to specific requirements in the home countries, these are not exhaustive and it is the responsibility of clinical services in each home country to review and look for equivalents.

Clause **2** contains the definitions of key terms used within the PAS. This is to clarify the meaning of the text for PAS users and avoid confusion, especially where the terminology across different specialties or clinical services might differ. For the purpose of the PAS, "clinical service" refers to a service which can be made up of a broad range of providers (these might include schools, health at work providers, public health, charities and voluntary groups as well as traditional primary, secondary and tertiary care) that delivers care to a group of clinical service users (see **2.2.16** for full definition), usually within a clinical specialty, or a clinical service that provides care or a service that works across many different specialties. To provide high-value, person-centred treatment and/or care, a clinical service would, ideally, form a local clinical network or similar structure in order to deliver seamless care across organizational boundaries. To comply with the PAS, different providers can work together and create transactional processes that enable effective collaboration.

The PAS intentionally does not use the terms: "primary care", "secondary care", "hospital" or "social care". This is to emphasize the point that the artificial boundaries between these entities stand in the way of providing truly person-centred and high-value care.

0.3 What does this PAS aim to achieve?

PAS 1616 provides CEOs, managers, and clinical leaders with a framework to follow for their clinical service; a first step in the long-term aim of raising standards and improving quality. It aims to fill a strategic and

organizational gap by providing a structure and guidance for clinical services, thereby saving time and reducing wasted resources. It is not intended to duplicate existing requirements or create extra unnecessary work for time-strapped and resource-poor clinical services. It is envisaged that the implementation of this PAS could maximize quality and minimize risk within available resources, with the intention of preventing disease and reducing the burden of disease, thus achieving good value care.

This PAS can be used in conjunction with other standards already in place for specific clinical specialties. It also allows for the possibility of the creation of suites of standardization documents that could work together and deal with different, or more specific, aspects of healthcare.

0.4 Application and implementation

PAS 1616 is intended to be implemented across a clinical service delivering treatment and/or care to clinical service users (regardless of age) across existing managed, or newly formed clinical networks. Application of this PAS can facilitate collaboration and communication across the different clinical services and healthcare providers that make up a clinical pathway, and provide them with consistency of structure, terminology and communications. This can allow clinical services, staff members and leadership teams ownership over the clinical service and empowerment to act within a clearly given remit. A clinical service might include primary, secondary and tertiary care as well as social care and the voluntary sector.

Any clinical service can use this PAS both to review its current level of provision and as a roadmap for improvement. As with formal standards, it is possible to make first, second or third party claims of compliance against PAS 1616. A clinical service might, for example, conduct internal reviews of its conformity to PAS 1616 requirements, ask another department or clinical service within the organization, for example, to check its conformity, or approach an external auditing/assessment body to formally check its conformity and provide certification (if desired). This means that compliance with the PAS does not necessarily require an external assessment; though a clinical service could choose to be externally assessed or audited against its requirements if it wished.

The implementation of a comprehensive standards framework can provide a lever to adopt and sustain good practice, enabling clinical services to achieve their potential more quickly, more completely, and in a more sustained way.

At a first glance, PAS 1616 might appear bureaucratic; however, it does not require anything that a high-performing clinical service would not be expected to undertake. Not every requirement is applicable to all clinical services, depending on the work of the clinical service. For example, the clause regarding the training of the future workforce is not applicable if students and trainees are not included in the clinical service. Any new elements this PAS introduces could be approached by a clinical service as an implementation or quality improvement project. Barriers to implementation and arguments likely to arise might be that it is largely process-driven and that there is a lack of control over what other clinical services (e.g. GP surgeries) do. In this instance, this PAS can be used as a common driver: clinical leaders can use it to enhance and increase collaboration and to influence clinical services and healthcare providers outside of their control. In the long-term it can save both time and resources and help clinical services achieve the best value for money.

This PAS is reviewed two years after publication, and feedback on usage, implementation of the requirements and how they can be improved can be used to inform part of the review process.

0.5 Benefits of the application and implementation

PAS 1616 could provide benefits to a number of stakeholder groups:

- **Clinical service users, e.g. patients:** Compliance with this PAS can provide clarity to clinical service users about what they can expect from the clinical service.
- **Clinical services and providers:** This PAS can enable a clinical service to continually self-assess and improve, regardless of whether there is any existing external evaluation scheme within that clinical service. Reducing the complexity of compliance with a generic set of requirements can reduce the administrative burden on clinical services and providers. It can also provide clarity for other clinical services working in partnership with the clinical service about the framework within which it works to facilitate collaboration and communication, and encourage the creation of other partnerships.
- **Service and systems planners and funders:** This PAS can enable service and systems planners and funders to commission on the basis of adherence to its requirements.
- **Regulators:** This PAS has the potential to reduce the burden and increase the effectiveness of regulation. PAS 1616 can help clinical services to maintain robust records and documentation which could be used to show compliance with regulations, if appropriate.

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1 Scope

This PAS specifies requirements for the provision of clinical services.

It covers aspects of the provision of clinical services, including:

- clinical service planning and clinical service definition;
- leadership, strategy and management;
- person-centred treatment and/or care;
- risk and safety;
- clinical effectiveness;
- clinical service users with complex needs;
- staffing a clinical service;
- improvement, innovation, and transformation; and
- educating the future workforce.

It does not cover service-specific requirements for an individual clinical service.

NOTE *These might be covered in existing standards.*

This PAS is for use by clinical services providing treatment and/or care to clinical service users.

2 Abbreviations, terms and definitions

2.1 Abbreviations

For the purposes of this PAS, the following abbreviations apply.

CPD	Continuing professional development
DNA	Did not attend
KPI	Key performance indicator
PROMs	Patient Reported Outcome Measures
RCA	Root cause analysis

2.2 Terms and definitions

For the purposes of this PAS, the following terms and definitions apply.

2.2.1 adverse consequence

negative impact on individuals

2.2.2 adverse event

untoward occurrence that affects an individual(s) and might result in death, be life-threatening, require further (or extended) treatment and/or care, or result in disability or incapacity

2.2.3 carer

individual who cares, unpaid, for a friend or family member who, due to illness, disability, a mental health problem or an addiction, cannot cope without the individual's support

NOTE *Further information regarding carers can be obtained from organizations such as the Carers Trust.*[1)]

2.2.4 clinical effectiveness

application of knowledge derived from research, clinical experience and patient preferences to achieve optimum processes and outcomes of care for clinical service users

NOTE *This involves a framework of informing, changing and monitoring practice.*

[1)] See the Carers Trust website, at: https://www.carers.org/what-carer