PAS 277:2015

Health and wellness apps – Quality criteria across the life cycle – Code of practice

Innovate UK
Technology Strategy Board

bsi.

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Foreword

This PAS was sponsored by Innovate UK. Its development was facilitated by BSI Standards Limited and it was published under licence from The British Standards Institution. It came into effect on 30 April 2015.

Acknowledgement is given to the following organizations that were involved in the development of this PAS as members of the steering group:

- Association of British Healthcare Industries (ABHI)
- BT
- BUPA
- Caton Bell Limited
- Digital Health & Care Alliance
- Health & Social Care Information Centre (HSCIC)
- Innovate UK
- INPUT Patient Advocacy
- INPS
- NHS England
- NIHR Mindtech Healthcare Technology Cooperative
- Omron Healthcare
- Royal College of Physicians
- South West Academic Health Science Network (SWAHSN)

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 It will be withdrawn upon publication of its content in, or as, a British Standard.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 code of practice to be rapidly developed in order to fulfil 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

As a code of practice, this PAS takes the form of recommendations and guidance. It should not be quoted as if it were a specification and particular care should be taken to ensure that claims of compliance are not misleading.

Any user claiming compliance with this PAS is expected to be able to justify any course of action that deviates from its recommendations.

Presentational conventions

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

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

The word "should" is used to express recommendations of this standard. The word "may" is used in the text to express permissibility, e.g. as an alternative to the primary recommendation of the clause. The word "can" is used to express possibility, e.g. a consequence of an action or an event.

Notes are provided throughout the text of this standard. Notes give references and additional information that are important but do not form part of the recommendations.

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:

- Medical Devices Directive (93/42/EEC) [1]
- Data Protection Act 1998 [2]
- Consumer Protection Act 1987 [3]

Innovate UK statement

Innovate UK – the new name for the Technology Strategy Board – is the UK's innovation agency. We fund, support and connect innovative businesses to accelerate sustainable economic growth.

Timely, consensus-based use of standards plays a vital role in ensuring that the knowledge created in the UK's research base is commercialized and brought to market as well as playing an important role in driving innovation.

Innovate UK is working with BSI, the Research Councils and Catapults to establish new standards earlier in the development of technologies. We are collaborating in four areas of innovation to define standards that aim to accelerate the development of those technologies and services to provide UK businesses with a competitive "first mover advantage", including the subject of this document: independent living.

The demand for support of those with long term health conditions is set to grow rapidly over the next 15 years and beyond. If the NHS and other UK organizations are to continue to offer high standards of health and care services, they will need to embrace more technology-enabled products, services and systems to provide more home-based care and self-care.

Innovate UK's Long Term Care Revolution work is aimed at changing conventional thinking about the institutional approach to long term care and stimulating disruptive innovation. If there is to be a significant move away from institutionalized care, this disruptive innovation needs to be supported by a range of standards that set out the principles for provision in the new environment, help to manage the risks involved, and provide clarity and consistency for consumers.

Through the Independent Living Innovation Platform, Innovate UK is delivering a wide-ranging programme to enable the ageing population and those with long term health conditions to live with greater independence.

In 2012 the Independent Living Innovation Platform launched dallas (delivering assisted living lifestyles at scale), a large scale demonstrator of independent living products and services, joint funded by the National Institute for Health Research and the Scottish Government. Read more here: **https://connect.innovateuk.org/web/dallas**

More widely, health and care is a key priority area in our work – with major innovation programmes to stimulate the development of new technologies, products and services, building on the UK's world-class science and technology base and its global presence in the biopharmaceutical and health technology sectors.

Read more about Innovate UK and our plans in health, care and other areas here: **www.innovateuk.gov.uk** or contact **support@innovateuk.gov.uk**

Introduction

The purpose of this PAS is to develop a set of principles for health and wellness app developers to follow throughout an app project life cycle, so that health care professionals, patients and the public trust their products and services. It has been developed for use in the United Kingdom. This PAS aims to encourage innovation in health care and the development of safe and effective apps that are of a high quality, and that are fit for purpose. These apps have the potential to change the way that health care is delivered in the future.

This PAS does not cover the requirements for apps that are classified as medical devices, nor is it a rigorous document to aid in classifying a health and wellness app as a medical device. The Medicines and Healthcare Products Regulatory Agency (MHRA) provides regulatory guidance [4] to establish whether an app meets the criteria defined in the Medical Devices Directive [1], and what steps need to be taken in that instance.

This PAS is primarily for app developers to define the quality criteria for app registries and app repositories, but may also be used by:

- health care professionals selecting apps to recommend; and
- providers, charities, and community organizations commissioning bespoke apps.

This PAS draws on existing standards for software life cycle processes in medical devices (see BS EN 62304), addressing risk, and for developing quality software (see BS EN ISO 14971). The structure of the PAS is based on BS EN 62304, and the correlations are outlined in Annex A.

The emergence of app platforms, and the app registries and repositories that are associated with them, has created a new environment that enables apps to be developed with limited amounts of new code, and reuse of functionality delivered by the platform.

Health and wellness apps may link with other apps on the platform and with network services to provide a rich user experience, that may include accessing electronic health record systems.

Apps and app registries and repositories are not limited to mobile app platforms – the same paradigm applies to apps that run on other computing platforms, such as desktop computers and terminals.

The combination of the rapidly evolving platforms and integration with other products introduces a new set of product opportunities and risks. This PAS aims to bring together current good practices of app development and health care information management to address these opportunities and risks, but is not appropriate for the development of more complex software applications (e.g. Health IT systems or medical software). Annex B outlines the relationship between this PAS and ISB 0129 – Clinical risk management [5], while Annex C and Annex D show the relationship between this PAS and other industry standards and guidance available at the time this PAS was published.

This PAS is equally applicable to a range of software development methodologies, including agile and waterfall.

1 Scope

This PAS gives recommendations for developers of health and wellness apps, intending to meet the needs of health care professionals, patients, carers and the wider public. It includes a set of quality criteria and covers the app project life cycle, through the development, testing, releasing and updating of an app, including native, hybrid and web based apps, those apps associated with wearable, ambient and other health equipment and apps that are linked to other apps. It also addresses fitness for purpose and the monitoring of usage.

This PAS does not cover the processes or criteria that an app developer or publisher follow to establish whether a health and wellness app is subject to regulatory control (e.g. as a medical device, or related to information governance).

This PAS informs the development of health and wellness apps irrespective of whether they are placed in the market, and including free of charge.

NOTE 1 *The development and placing on the market, including free of charge, of a health and wellness app may be covered by certain legislation, for example the Medical Devices Directive [1].*

NOTE 2 *The focus of this PAS is on commodity apps available through app repositories, but may also be relevant to specialized applications running on other platforms.*

NOTE 3 *This PAS is not intended to replace documentation provided by platform curators on requirements for apps made available on the platform, unless referenced by platform curators.*

NOTE 4 *It is not intended to cover apps for enforcement or legal advice purposes. For example, apps used to monitor alcohol levels for drivers are out of scope.*

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

BS ISO/IEC 90003, *Software engineering – Guidelines for the application of ISO 9001:2000 to computer software*