Guidance for Accredited Registers

Supplementary guidance - Standard One

July 2021

professional™ standards authority accredited register

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1. Introduction

1.1 The aim of this guidance is to set out further information about how we will assess organisations applying for accreditation, and Accredited Registers undergoing renewal assessments, against Standard One of our *Standards for Accredited Registers*.

1.2 Standard One is split into two parts, as set out in the box below.

Standard One: Eligibility and public interest

The organisation holds a register of people in health and/or social care roles that are not subject to statutory regulation. The activities carried out by the registrants are beneficial to the health and/or wellbeing of the public and any harm is justifiable and mitigated.

1a) Eligibility of the register under our legislation

We will decide whether the register falls under the scope of our powers of accreditation as set out in the Act 2002, making reference to the definition of a "voluntary register" set out at Section 25E. This includes that the role(s) registered must not be required to be registered by law in order to use a title, practise as a member of a profession, or engage in work that involves the provision of health care, or of social care (within England).

1b) Public interest considerations

We will decide whether it is likely to be in the best interests of patients, service users and the public to accredit a register, with consideration of the types of activities practised by its registrants. This will include, but not be limited to consideration of the following:

i. Evidence that the activities carried out by registrants are likely to be beneficial.

ii. Evidence that any harms or risks likely to arise from the activities are justifiable and appropriately mitigated by the register's requirements for registration.

iii. Commitment to ensuring that the treatments and services are offered in a way that does not make unproven claims or in any other way mislead the public.

To meet Standard One, we will need to be assured that any harms or risks likely to arise from the activities can be mitigated by the register's requirements for registrants, and that they do not outweigh the likely benefits to patients, service users and the public. If Standard One is met, then these mitigations will be further tested during assessment of Standards Two to Eight before accreditation is granted.

1.3 Standard 1a has been a requirement since the programme was first established in 2013. Standard 1b was introduced in July 2021, following a public consultation[1] to seek views on whether, and how we should determine the scope of the programme. The report of the results of the consultation can be found on our website.[2]

1.4 The consultation found there was generally high support for us to take greater account of evidence of efficacy (or effectiveness) in our accreditation decisions. This was particularly the case with patient groups and their members who responded to our consultation. After reviewing responses, we decided to update our standards to take greater account of the risks and benefits of the services provided by registrants. We think that this will help ensure our Quality Mark, which can be used by Registers we accredit and their practitioners, is clear and understood by the public.

1.5 It is not our remit to decide which services patients and the public should choose. However, our overarching purpose as set out in the 2002 Act is to protect the public. To carry out our responsibilities of accrediting registers of roles not required to be registered with a statutory body, we believe it is important for us to consider the risks of the activities undertaken by registrants, as well as the benefits.

1.6 Standard 1b provides a mechanism for this 'public interest' test. It enables us to make a judgement on whether the benefits of activities undertaken by registrants outweigh the risks, and whether the register and its registrants are providing clear and accurate information in relation to these benefits and risks.

2. How we will assess Standard 1a

2.1 We will decide whether the register falls under the scope of our powers of accreditation as set out in the Act, making reference to the definition of a 'voluntary register' set out at Section 25E. This includes that the role(s) registered must not be required to be registered by law in order to use a title or practise as a member of a profession or engage in work that involves the provision of health care, or of social care (within England).

3. How we will assess Standard 1b

3.1 Registers must meet Standard One to be eligible to be assessed against the remaining Standards. As set out in our *Application Process Guidance,* during initial assessment a Register can apply to be assessed against Standard One before proceeding to full application.

[1] https://www.professionalstandards.org.uk/docs/default-source/publications/consultation-response/our-consultation/2020-accredited-registers-consultation/authority-consultation-on-the-future-shape-of-the-accredited-registers-programme.pdf?sfvrsn=69067620_13

[2] https://www.professionalstandards.org.uk/docs/default-source/accredited-registers/consultation/authority-report-on-the-future-shape-of-the-accredited-registers-programme-consultation-results.pdf?sfvrsn=2d84920_6

3.2 Registers that are already accredited will undergo assessment against Standard One at least once every three years, as set out in our *Guidance for Accredited Registers*. This allows us to check whether any changes in the external environment, or to the running of the Register, have affected whether Standard One is met.

3.3 We will gather evidence against Standard 1b as part of the initial application, annual monitoring or renewal assessments. The approach we take to assessing evidence will be the same with either type of assessment, although for Registers that are already accredited, our assessment will focus on changes since the previous review against Standard 1b.

3.4 We will gather evidence against each of the three criteria for Standard 1b as below:

i. Evidence that the activities carried out by registrants are likely to be beneficial.

ii. Evidence that any harms or risks likely to arise from the activities are justifiable and appropriately mitigated by the register's requirements for registration.

iii. Commitment to ensuring that the treatments and services are offered in a way that does not make unproven claims or in any other way mislead the public.

Types of evidence

3.5 The types of evidence that may be considered for i) and ii) will include material gathered from sources including the Register, stakeholders through our 'Share Your Experience' process, and published research and data from other bodies. For iii), the main sources of evidence will be our own checks of the Registers' website, and of its registrants' websites and other communications.

3.6 The types of evidence we review will include both qualitative and quantitative sources. It is not our role to determine whether these sources are definitive. It is also not our role to undertake or commission research on the effectiveness of health or social care activities. To make an assessment against Standard 1b, we will therefore be drawing on external forms of research and data and will need to take account of the conclusions of the authoritative bodies whose role it is to review evidence relating to health and social care.

3.7 For many Registers, this assessment may be straightforward. For registers of those who provide services within mainstream, conventional care such as within the NHS workforce there are likely to be existing bodies of evidence, which have been independently reviewed. For other areas, the evidence may be less clear.

3.8 The features of organisations we would consider as authoritative bodies for our purposes in gathering and reviewing evidence about benefits and harms include:

- Independent, not-for-profit organisations that are free from commercial sponsorship and other conflicts of interest. An example of this would be Cochrane.
- Bodies that specialise in producing evidence-based guidance and advice for health and social care practitioners. Examples of these would be the

Scottish Intercollegiate Guidelines Network, or National Institute for Health and Care Excellence.

- Organisations set up to promote health and wellbeing that can demonstrate accountability. Examples of these would be the National Health Service (NHS), and the World Health Organisation (WHO).

3.9 These types of bodies share commitment to consultation with stakeholders, accountability and transparency in how they achieve their aims. Their work is relevant for us to consider, as it allows us to draw on a wider range of expertise and perspectives about health and social care as relevant to a Register than we would be able to gather through our own resources alone.

3.10 The Accredited Registers programme applies throughout the UK. We will consider evidence that relates to the whole of the UK unless a Register operates within a limited territory.

3.11 We will not restrict the types of evidence that we will consider, but we will categorise the evidence according to its features, to help our assessment. A description of these categories is set out in the table below. These can apply to both quantitative and qualitative sources:

	Stronger evidence	**Moderate evidence**	**Weaker evidence**
Feature(s)	High-quality scientific study. Has been published and reflected on by wider stakeholders. Uses recognised sources of data, where relevant. Undertaken independently by body without interest in outcome. Corroborated by multiple sources of evidence and/or data. Different views are fairly represented.	Shares some of the features of 'stronger' evidence but has not been validated by independent sources to the same extent.	Individual anecdotes or opinions. Research or reviews that have not been objectively validated.
Example(s)	Systematic reviews. Peer-reviewed research papers. Independently commissioned research and reviews (e.g. by academic institution).	Surveys of service users undertaken by an independent organisation.	Limited members surveys undertaken by a professional association (that have not been independently verified).

	Robust patient reported outcomes data.		

Assessing the evidence

3.12 We will use a Red/Amber/Green (RAG) rating system to assess evidence for Parts i-iii. The table below sets out a description for each of the RAG ratings.

	i. Evidence that the activities carried out by registrants are likely to be beneficial.	**ii. Evidence that any harms or risks likely to arise from the activities are justifiable and appropriately mitigated by the Register's requirements for registration.**	**iii. Commitment to ensuring that the treatments and services are offered in a way that does not make unproven claims or in any other way mislead the public.**
Green	Authoritative bodies have concluded on the basis of objective and independent research and reviews that the activities are beneficial and/or effective to health and wellbeing.	Any harms or risks arising from the activities are low and can be addressed through the Register's requirements for registration.	Communications by the register and the majority of its registrants are clear and accurate, do not make unproven claims, and are in line with relevant advertising and trading standards requirements.
Amber	Some evidence that activities may be beneficial, but likely to rely on patient-reported outcome measures or secondary evidence.	The harms and risks arising from the activities have potential to cause significant physical, mental, financial or other harm but can be mitigated through the Register's requirements for registration.	Further actions need to be put in place to ensure that the Register and its registrants are providing clear and accurate information about treatments within a limited time.
Red	Very little or no evidence that activities have demonstrable benefits to health and/or wellbeing, and/or activity is not recommended for use by authoritative body.	The activities are likely to be unlawful on the basis of physical or mental harm, discrimination or any other reason.	A Register has failed to take appropriate action to ensure that communications by it and its registrants are clear and accurate, and there is a material risk of the public being misled.

3.13 More detail about how we will determine the RAG rating for Parts i-iii is set out below.

Part i): Assessing the benefits

3.14 A Register will need to provide evidence of how the activities registered provide benefit to the health and/or wellbeing of the public. The benefits could include the following types:

a. Curative – capable of curing a particular illness or condition.

b. Diagnostic – capable of diagnosing a particular illness or condition.

c. Palliative – does not diagnose or cure but provides relief from symptoms of an illness or condition, including from conventional treatment.

d. Preventative – helping to prevent poor health or social outcomes.

e. Wellbeing – supports positive quality of life from the point of view of emotional, mental and/or physical health.

3.15 On applying for accreditation, including renewal, we will ask the Register to set out the benefits it associates with the activities of its registrants. Responsibility for providing the best available evidence of these benefits will lie with the Register. The burden of proof will lie with the Register – i.e. they will need to show that the claim of the benefit is more likely than is not to be true. We will review evidence provided by the Register or any other source to inform our own view, as set out below.

3.16 We will tell the Register how we have categorised the evidence it provides about benefits, with reference to the table at paragraph 3.11.

Part ii): Assessing the risks of harm

3.17 There are risks associated with any type of health or care activity. This is as much the case for activities that require registration by law, as those which do not. Conventional medicine can have significant side effects that may cause harm as well as benefit, and decisions about treatment must weigh up the potential harms and benefits, as well as other considerations such as cost.

3.18 Although the treatments offered by Accredited Register practitioners will generally be considered lower risk than those which are subject to statutory regulation, there will still be risks of harm associated with them. The types of harm that we consider relevant to users of Accredited Registers as relevant to Standard 1b include those arising from:

a. The activities of registrants, including treatments provided.

b. Using the services of registrants as alternatives to conventional medicine, resulting in inappropriate treatment for medical conditions.

c. Financial harm associated with making unproven claims about treatments.

3.19 When a Register applies for accreditation, we will ask it to complete our risk matrix to identify the specific harms that it considers could arise from the practice of its registrants. We will ask it to include details of mitigations in place to manage these risks, such as training and guidance for registrants.

3.20 Once a Register has completed the risk matrix, we will review information provided to us during the Share Your Experience process, and from other sources identified during our review as being relevant. We will ask the Register to provide further information about any further risks we identify.

3.21 As with our assessment of benefits, we will look for the evidence that underpins identification of risk and mitigations. If a Register meets Standard 1b at initial application, we will further test the mitigations in place for risks through our assessment of the remaining Standards. If we find evidence that mitigations are not robust enough to provide effective mitigation, then we may review our earlier decision that Standard 1b was met.

Part iii): Assessing commitment to providing accurate information about treatments and services

3.22 It is important that a Register and its registrants provide clear and accurate information about the treatments and services provided. Any claims about benefits should only be made if they can be backed up by evidence.

3.23 The Advertising Standards Agency (ASA) publishes the UK Code of Non-broadcast Advertising and Direct and Promotional Marketing (CAP Code). This is the rule book for non-broadcast advertisements, sales promotions and direct marketing communications. The CAP Code provides specific guidance about some services relevant to the Accredited Registers programme, such as various complementary and alternative medicines (CAMs). We will have regard to the CAP Code where relevant but not be restricted to it, if we identify areas where we think claims are being made without evidence.

3.24 Our primary evidence for assessing against Part iii) will be our own checks of the Register's website and social media, and those of its registrants since many independent practitioners promote services online. We will also consider other evidence we become aware of about misleading claims through our Share Your Experience or other channels.

Weighing up the benefits and the risks

3.25 Once we have considered the available evidence and made an assessment against Parts i-iii, we will share our findings with the Register to check for factual accuracy.

3.26 At this point, we will also share the Impact Assessment with the Register. The Impact Assessment is a living document and used to gather information about how different groups may be affected by the decision to accredit a Register. Information gathered for Standard One will provide a useful starting point for this. More information about the Impact Assessment can be found in our *Impact Assessment Guidance*.

3.27 The decision about whether Standard 1b is provisionally met will be undertaken in the first instance by the Accreditation Team.

3.28 For those decisions where it is less clear whether the benefits of services provided by registrants outweigh the risks, the Accreditation Team will make a recommendation for a Panel to consider. The recommendation will be provided to the Register before the Panel meets. A 'red' or 'amber' rating in accordance with the table at paragraph 3.12 for Part i, ii or iii will automatically require a Panel.

3.29 If it is a new application, then the options available to the Panel will be:

a. To determine that Standard 1b is provisionally met, subject to meeting the remaining Standards, because the benefits of the services of practitioners are considered to outweigh the risks.

b. To determine that Standard 1b is not met, as there is not sufficient evidence for the benefits of the services of practitioners outweighing the risks.

c. To request further information, to include independent expert opinion and/or legal advice.

Document Control

Version Control

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1.0		New procedure	29 July 2021