Health care accreditation and quality of care

Exploring the role of accreditation and external evaluation of health care facilities and organizations

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Abbreviations and acronyms

FCV	fragile, conflict-affected and vulnerable
ISQua	International Society for Quality in Health Care
LMIC	low- and middle-income country
NHIS	National Health Insurance Scheme
OECD	Organisation for Economic Co-operation and Development
SWOT	strengths, weaknesses, opportunities and threats
UHC	universal health coverage
WHO	World Health Organization

Executive summary

Accreditation of health care facilities and organizations is often used to assess, assure and improve quality of care. However, the evidence base related to the effectiveness of accreditation is unclear, as are the potential wider implications of this intervention on the health system.

This document gives a wide view of accreditation as a health care quality intervention by using a broad evidence base of accreditation and of other similar external evaluations, quality interventions and health systems research, combined with global interdisciplinary experience and expertise. It considers the linkages between accreditation and other key attributes of the health system and, using a health systems lens, discusses strategic questions that a health system decision-maker should consider. It does *not* represent normative guidance on whether or how to introduce or review accreditation or external evaluation, nor does it outline the process of setting up an accreditation body or programme. Also, this document focuses on accreditation and related external evaluations for improving quality of care in health care facilities or organizations; it does not discuss other forms of external evaluation, or accreditation of individuals or educational institutions.

Technical background

Characteristics of accreditation

- Accreditation is a form of external evaluation of health care facilities or organizations. In the health care context, external evaluation involves an external body gathering objective data in line with predefined requirements or standards, to produce an assessment stating whether the facility or organization in question has achieved those levels. Accreditation is an umbrella term that encompasses a range of related activities that vary in their scope and scale (e.g. licensing, certification and accreditation).

- In practice, licensing, certification and accreditation overlap to form an "external evaluation spectrum", with licensing being the most straightforward of these activities and accreditation the most complex. Accreditation involves the systematic assessment of performance (including clinical and organizational aspects) related to predefined standards to advise a process of continuous improvement, with cycles of re-accreditation after a set period.
- Globally, programmes for accreditation (and overlapping forms of external evaluation) may have attributes from several different evaluation processes and are not always defined as accreditation.
- Accreditation is explicitly linked to health facility initiatives on quality of care, because it seeks to measure and support quality improvements over successive cycles. In practice, accreditation is often seen as a binary endpoint (i.e. "accredited" versus "not accredited") and is used to provide assurance to the government or to the public. This document focuses on the potential to use accreditation as a continuous process to improve quality outcomes and processes.
- Often, accreditation focuses on hospitals; however, accreditation of primary care providers as organizations is becoming more common. Such accreditation is sometimes mandatory (or "quasi-mandatory" due to attached funding) for all public facilities and in other cases is sought voluntarily by the facility or organization itself.
- Accreditation may be provided through a national or government agency, or through commercial or non-commercial private organizations.
- Accreditation differs from other health service assessments in that it is an independent external recurrent assessment against quality standards, with a reported outcome related to quality improvement recommendations and action at the level of the facility.

Pointers from theory and practice

Evidence of the impact of accreditation on quality of care and other dimensions

A review of peer-reviewed evidence on accreditation, focusing on impact on quality outcomes and organizational processes, revealed mixed results. Notably, evidence was lacking on accreditation in low- and middle-income countries (LMICs); the impact on health workers, patients, the public and communities; and cost-benefit or cost-effectiveness.

In reviewing accreditation research, a particular challenge is comparing different types of interventions and interpretations of accreditation globally.

Considering these issues, it is difficult to make any general conclusions on the effectiveness of accreditation on quality of care. Given the highly context-dependent nature of this intervention, rather than asking "Does accreditation work?", it may be more useful to ask "What aspects of accreditation might work in my context?" and "How can accreditation and external evaluation processes within my setting be improved to support enhanced quality of care?"

Legal matters

Two core aspects of law need to be considered in relation to accreditation: the accreditation body as a legal entity, and the links between accreditation and other laws around health care provision. An assessment of laws, potentially at both national and subnational levels, is important in designing or amending an accreditation programme.

Financial matters

- Accreditation programmes can be costly, leading to financial implications for the target facility or organization.
- Often, the cost-effectiveness and opportunity costs of accreditation programmes are unclear.
- It is vital to involve the financial system and carry out extensive costing of accreditation programmes to ensure sustainability, efficiency and effectiveness; to allow an options appraisal with other quality interventions; and to minimize negative impacts on the wider health system.
- There are examples of explicit strategic linkages between health financing mechanisms and accreditation programmes (e.g. performance-based contracting and purchasing bodies specifying accreditation requirements for participating providers).

Illustrative country experiences

- Country examples are useful to understand how accreditation has been implemented in different contexts.
- This document presents examples of approaches on the external evaluation spectrum that incorporate different important elements of accreditation (even if not explicitly named as such).
- The examples are not intended to represent best practice, but rather to outline important aspects of external evaluation. 'They range from the use of a rating system and the management of low scoring facilities in the United Republic of Tanzania to the challenges of mandatory accreditation in the Islamic Republic of Iran and links to regulatory systems in England.

Strategic considerations: using a health systems lens

Critical to the decision to implement accreditation or to optimize the effectiveness of new or existing accreditation programmes is consideration of the impact and opportunity costs on the wider health system, the link between other assessments and interventions, and the inclusion of the views and experiences of health workers, patients and communities. Important considerations when designing, modifying or implementing a health systems accreditation programme include the following:

- In the absence of a mandatory system, voluntary or non-universal accreditation may cause an increased **demand** in accredited facilities, which may draw people away from or erode trust in other important health services (e.g. primary care or the public system). This is exacerbated because voluntary accreditation is usually sought by larger private facilities, given the associated cost.

- Voluntary or non-universal accreditation can encourage financing to favour facilities that are already more financially stable or provide higher quality of care (and hence are seeking accreditation status), exacerbating a "quality divide" between regions or areas that affects both health care **supply** and **health equity.**

- Making accreditation mandatory raises issues; for example, it risks **mandatory** accreditation being seen as a regulatory requirement to achieve an outcome (i.e. to become "accredited") instead of a process of continuous quality improvement that requires engagement and commitment from the accredited facility or organization and its staff, and ongoing support from the accreditation body or other health system governance structures. Hence, the decision about whether accreditation should be mandatory or voluntary must be carefully weighed.

- National accreditation programmes often need to consider **fragmented** and **poorly integrated** health system components. Accreditation is often sought independently by different levels of the health system or areas within that system, each operating in a different context. In addition, traditionally accreditation has predominantly focused on hospital settings, or on clinical specialities or disciplines within that setting. However, well-functioning health systems require integration and coordination between component parts. Iterations of accreditation should take this situation into account (e.g. considering a patient's journey through primary to secondary or tertiary care for a clinical condition, or assessing integrated care between several chronic conditions).

- Many countries have developed specific measurement tools and performance assessment instruments to support the accreditation process, often drawing on a **range of data sources** (e.g. patient records, facility registers and national statistical systems) to ascertain adherence to standards of care and performance. There is a need for a rapid review of existing efforts, tools and methods to identify best practices, and to inform the development of global standard survey instruments and evaluation methodology to support the accreditation process.

- There is a critical need for **comprehensive and integrated quality interventions** spanning the health system at facility, district, national and community levels. Accreditation should not be a standalone intervention, but instead should be one piece of a wider process to monitor performance, improve quality of care and assure public accountability. The **sequencing** of facility-level quality interventions is also important; foundational interventions (e.g. water, sanitation and hygiene, electricity and a trained workforce) and potentially simpler forms of external evaluation (e.g. licensing) should be considered before moving to accreditation, which is more complex and costly.

- Accreditation programmes should not be seen as fully external to the health system; they should involve key **stakeholders** from across the system, especially in the development of standards, oversight mechanisms and links to wider quality governance mechanisms.

- The role and the appropriate protection of **health workers** should be paramount in accreditation programmes, with attention to potential unintended consequences to the workforce. Any negative impact on the workforce (e.g. through punitive measures or increased job strain during accreditation cycles) is counterproductive because the health workforce is a central driver of quality of care and supporting health workers is an important quality intervention. Health workers' views should be sought as routine throughout the process, for their important insights and to avoid any harm.

- The involvement of **patients** or **consumers, the public** and **communities** is also important when planning external evaluation processes and gathering data on quality. The evidence base is lacking in this area.
- It is vital to calculate and monitor the **wider financial impacts on the health system, cost-effectiveness and opportunity costs**, because accreditation programmes demand significant financial and human resources. It is also vital to understand whether a programme represents value for these investments and how it compares with other quality interventions. The evidence base is also lacking in this area.
- **Evaluation of the quality and outcomes of individual accreditation programmes** is necessary, to understand their impacts, outcomes and cost-effectiveness compared with other interventions.

A spotlight on fragile, conflict-affected and vulnerable (FCV) settings

Sustained efforts to improve quality of care in FCV settings is challenging and there is a lack of evidence around accreditation in such settings. However, there are examples of implementation of accreditation linked to national basic packages of health services. Accreditation programmes for services provided by humanitarian actors are another important part of this picture, and efforts have been made to standardize these programmes.

WHO perspective

Globally, accreditation includes a range of complex, highly context-dependent programmes and interventions that require thorough deliberation, taking into account the broad impacts on the health system and opportunity costs related to other quality interventions. They are resource-intensive interventions and the evidence base is not straightforward. Integration into a suite of quality interventions spanning different levels of the health system is critical for accreditation to potentially play a role in improving quality.

WHO proposes the following 10 key points to help national decision-makers or policy-makers to understand how or whether to implement an accreditation programme in their setting:

1 Due care should be taken when considering, planning or implementing accreditation programmes to ensure that they are aligned with commitments to universal health coverage (UHC) and quality essential health services with a people-centred approach. Accreditation can risk skewing demand and supply, and exacerbating inequalities in standards of care; this should be considered before making any decision to implement. All accreditation processes should place improvement in the quality of care for patients and the overall population at the heart of efforts.

2 Accreditation is a lengthy, expensive and recurrent process that requires funds to be allocated, especially in low-resource settings, to support quality improvements and the achievement of standards at target facilities. Attention should be given to careful assessment of costs and opportunity costs in relation to potential benefits from accreditation versus other quality improvement processes. Thus, those responsible for health financing need to be involved in decision-making related to accreditation.

3 Decision-makers will need to understand how the accreditation programme fits into the wider health system, ensuring integration into other national or subnational initiatives focused on quality of care. This involves a careful appraisal of alternative or complementary interventions. This may involve sequencing interventions, starting at basic assessments and improvements to essential functions and infrastructure (e.g. water, sanitation and hygiene, and trained workforce) and moving up the external evaluation spectrum, potentially starting from the simpler option of licensing before moving towards accreditation. Any external evaluation or accreditation programme should either incorporate the more foundational processes further down this spectrum or ensure that these are otherwise fulfilled before developing more complex interventions. Accreditation may need to be considered in longer-term plans once short-term foundational goals have been achieved.

4 Accreditation should be viewed as one intervention to support the continuous process required to improve quality of care and processes in the target facility or organization, as opposed to a "one-off" achievement of accreditation status. Standards should be set that outline improvement goals and steps, and re-accreditation cycles should measure successive improvements over multiple cycles.

5 Accreditation programmes should involve health workers and the public from their inception, valuing and carefully considering their views and concerns as the potential beneficiaries of programme implementation. Health workers of all cadres are central gatekeepers and drivers of quality of care, and should be supported before and throughout accreditation cycles. Likewise, patients, the public and communities hold critical information on quality of care and should be involved before and during decision-making.

6 Accreditation programmes themselves must comprise high-quality, independent structures and processes. Given the significant variation worldwide, accreditation programmes are only as useful and effective as the processes and standards used in each case. These should be context-specific, with tools and standards tailored to each setting's need and capacity, and developed within and for unique health systems. However, a careful balance must be made between local adaptation and standardization, ensuring optimal accreditation standards that both allow assessment and recommend improvements, and that align with national or global standards.

7 Accreditation should be a supportive process, not a punitive one. The health workforce should be supported throughout any external evaluation process, and their engagement and satisfaction should be monitored and maintained. Facilities or services found to be below required standards should be provided with optimal support to sustainably achieve the necessary improvements.

8 People-centred primary health care, community engagement, health emergency preparedness and effective wider public health functions are critical to UHC, and they warrant a rethink of traditional accreditation processes. New accreditation models may wish to focus on primary care, user experience of health services, care packages for clinical pathways of certain conditions, community or public health services, or health facility preparedness and resilience.

9 The global body of research on external evaluation or accreditation is incomplete. Notably, evidence is lacking on accreditation in LMICs; the impact on health workers, patients, the public and communities; and cost-benefit or cost-effectiveness. Evaluation and research on accreditation programmes, with a focus on these and other gaps, are required for an evolving global knowledge base on the subject.

10 Further systematic learning from country experiences on design, redesign and implementation of accreditation programmes and its linkages to quality of care is vital. This paper calls for learning to be generated and shared throughout the global community working to improve quality of care.

1. Introduction

1.1 What is accreditation and external evaluation?

Accreditation is one form of external evaluation of health care facilities or organizations, used to improve quality of care. In this context, accreditation and external evaluation are broad terms that are used to describe an external assessment against predefined, evidence-based requirements or standards, and the use of standardized quantitative and qualitative metrics to evaluate, recommend improvements to and report on levels of quality, from clinical and organizational perspectives, in health facilities or organizations. These processes take many forms worldwide, using different frameworks, approaches, standards and outcomes.

> **The use of the terms "accreditation" and "external evaluation" in this document applies only to health care facilities or organizations; it does *not* apply to educational programmes or facilities or individuals (workforce),** which is covered elsewhere *(1, 2)*. Accreditation of health care facilities or organizations can include standards for the health workforce (e.g. quantity, skill mix, competence and quality assurance) but this is separate from accreditation of health professional education programmes and regulation of individual health workers.

The International Society for Quality in Health Care (ISQua) defines accreditation of health facilities or organizations as:

A self-assessment and external peer review process used by health and social care organisations to accurately assess their level of performance in relation to established standards and to implement ways to continuously improve the health or social care system *(3)*.

Accreditation – like the related concepts of licensing and certification described in the following section – falls under the umbrella term of "external evaluation". For the purposes of this paper, external evaluation can be understood as defined by ISQua, as a:

> Process in which an objective independent assessor gathers reliable and valid information in a systematic way by making comparisons to standards, guidelines or pathways for the purpose of enabling more informed decisions and for assessing if pre-determined and published requirements such as goals, objectives or standards have been met. An organization, object, process or individual may be assessed and evaluation may be undertaken by peers, including organisations and professionals, private professional auditors or consultants, purchasers/ funders/insurers, consumers/patients or governments *(3)*.

This document uses a broad understanding of accreditation based on the ISQua definition, recognizing it as a *variable* form of external evaluation. Given the highly contextual nature of this intervention, these variations in the way accreditation is designed and delivered can be advantageous. This paper supports external evaluation as a *continuous process* to improve quality, as opposed to a means to an end. These important distinctions and the blurred lines between them are discussed below in Section 2.1. Examples of different forms of external evaluation that we would include under our definition of accreditation are given in Section 2.2.4.

1.2 Why is this discussion paper needed?

Accreditation and similar forms of external evaluation of health care facilities or organizations are widely used formats across the world. They receive consistent and increasing attention from those responsible for designing and reforming health services, yet their utility as a standardized mechanism for improving the performance of an organization (and hence improving the quality of care) has been the subject of intense debate. These are resource-intensive interventions that may, in practice, be relied on to improve quality of care outcomes and processes; therefore, it is vital that the evidence base and the impact on the wider health system is sufficiently characterized. The effectiveness and efficiency of accreditation programmes in improving quality of care (and ultimately population health) and how this can be optimized are important questions given the extent to which these methods are already used, the costs and opportunity costs associated, and the alternatives available to improve quality. Health system decision-makers often need to decide whether and how to implement accreditation to optimize beneficial impacts on quality outcomes and on the wider health system but lack sufficient information to do so.

This paper explores the evidence base underlying the use of accreditation and its effectiveness at improving quality processes or outcomes. More broadly, it outlines how accreditation or the external evaluation of health care facilities or organizations interact with the health system, including health service supply and demand, and how they link to wider quality initiatives. It considers links to financial and legal systems and the involvement of stakeholders, health workers, patients, the public and communities in the design and implementation of these programmes. The paper also builds a systems view of accreditation as a quality improvement intervention,

highlighting complexity and some of the widespread considerations and assessments required to understand the attributes, value and potential impacts of accreditation in any given setting. This paper will be useful to any health system actor who wishes to understand the wider implications of accreditation in their context or who is involved in making decisions on assessment, accreditation or external evaluation of their health services.

Here, we use a broad evidence base of accreditation and external evaluation, quality interventions and health systems research, combined with interdisciplinary experience and expertise from across the world, to give a broader view of accreditation and its place as a health care quality intervention. The paper considers the linkages between accreditation and other key attributes of the health system and, using a health systems lens, discusses strategic questions that a decision-maker should consider. It does not, however, represent normative guidance on whether or how to introduce or review accreditation or external evaluation, nor does it outline the content or process of setting up an accreditation body or programme.

1.3 Approach to developing this discussion paper

This paper was developed through a collaborative, multi-disciplinary process, combining literature reviews with expert insight and experience. Its scope was informed by questions and technical support requests from WHO country and regional offices relating to the role of accreditation and external evaluation in addressing quality of care.

As a foundation for this paper, WHO performed a narrative scoping review to identify and examine the literature published on the subject of accreditation and external evaluation. This scoping study employed a systematic review methodology to scrutinize the available literature on accreditation programmes over the period 2009–2019. The final content analysis included 71 peer-reviewed and published papers, which were then analysed to inform on the impact of accreditation, as well as critical knowledge gaps that may have relevant implications for decision-makers in health care. A WHO internal working group, bringing together expertise on quality of care, health services performance assessment, and clinical services and systems, was convened to reflect on the identified literature and draft a discussion paper to help inform deliberations on the role of accreditation and external evaluation in addressing quality of care. The paper subsequently went through various rounds of revision and a targeted consultation with subject-matter experts within and beyond WHO, to refine the content and improve its usefulness among the intended user groups.

1.4 Accreditation and quality

The definition of quality of care used by the World Health Organization (WHO) is:

> … the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with evidence-based professional knowledge *(4)*.[1]

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[1]   This definition was originally derived from the Institute of Medicine *(5)*.

Quality health services should be effective, safe, people-centred, timely, equitable, efficient and integrated *(5)*. Each aspect (and, critically, the sum of the various aspects) has clear implications for the delivery of health services. These foundational quality considerations should influence how accreditation and external evaluation mechanisms are designed and used in their various distinct contexts.

Quality is inherent in universal health coverage (UHC) – a critical global commitment stating that "all individuals and communities should receive the health services they need without suffering financial hardship" *(6)*. UHC includes all essential, *quality* health services such as health promotion, prevention, treatment, rehabilitation and palliative care *(6)*. Improving health system quality (including the consideration of interventions such as external evaluation and accreditation, when appropriate) should be seen as an essential element of the path towards UHC *(7)*.

National policies and strategies aimed at improving quality of care can provide a strong foundation for improving quality across the health system. At the heart of national quality policy and strategy there must be a pragmatic package of interventions that reflects the action needed across the health system to shape the system environment, reduce harm, improve clinical care and engage patients, families and communities. The WHO *Handbook for national quality policy and strategy* provides an illustrative list of quality interventions for each of these areas, for countries to consider *(8)*. One of the many quality interventions listed within those interventions targeting the system environment is external evaluation and accreditation. This emphasizes the need to consider accreditation within the context of a set of interconnected and mutually supportive quality interventions.

This paper has been written at a time when the Coronavirus disease (COVID-19) pandemic is having a hugely disruptive impact on health services across the world. It is more critical than ever that health systems take a careful look at how the quality of health services will be built back, or indeed addressed for the first time, as we emerge from the pandemic. The role of accreditation and external evaluation is likely to again be questioned, given the significant investment required within the uniformly resource-constrained health services environment.

2. Technical background

2.1 Characteristics of accreditation

Accreditation is often viewed as a key intervention for assessing and assuring the implementation of relevant standards in health care settings, and hence being a driver of quality of care and safety in many countries globally *(8–12)*. However, there is some confusion (both in theory and practice) about the definition, concept and scope of accreditation and about how it differs from related methods of external evaluation. Section 2.1.1 outlines the defining attributes of accreditation, compares this with the main related forms of external evaluation (i.e. licensing and certification) and underlines the importance of recognizing these interventions as forming a "spectrum" of external evaluation processes. Section 2.1.2 discusses how these interventions relate to other health service and health system assessments.

As outlined in the introduction, accreditation is defined by ISQua as:

> A self-assessment and external peer review process used by health and social care organisations to accurately assess their level of performance in relation to established standards and to implement ways to continuously improve the health or social care system. *(3)*

Further, a pivotal paper from WHO, the Organisation for Economic Co-operation and Development (OECD) and the World Bank, *Delivering quality health services: a global imperative for universal health coverage*, describes external evaluation and accreditation as:

> the public recognition, by an external body (public sector, non-profit or for-profit), of an organization's level of performance across a core set of prespecified standards. *(13)*

Further features listed by accreditation organizations include *(14–18)*:

- demonstrating commitment to safe, high-quality care;
- enabling services to be independently measured and surveyed against national standards;
- creating an integrated framework for coordinating quality improvement initiatives;
- establishing an ongoing process of assessing against standards of excellence, to identify what is being done well and what needs to be improved; and
- spreading a culture of patient safety and containing the key elements of governance or stewardship; that is, a standards-setting process with external evaluation of compliance against those standards, a remediation or improvement process, and promotion of continuous quality improvement.

These varying definitions demonstrate the different interpretations by setting and by organization. They also highlight how accreditation can be seen from the perspective of the facility (demonstrating commitment), the health system (ways to continuously improve the health or social care system, or the use of national standards) and the public (public recognition and informing provider choice).

Although the output of accreditation is accreditation status (i.e. whether accreditation has been achieved and, if so, at what level), accreditation should be seen as a *continuous process to improve quality*, not simply to achieve an end-point (i.e. to become accredited) *(19, 20)*. At each accreditation cycle, a report is provided that summarizes the accreditation survey and provides recommendations for improvements. This continuous quality improvement differentiates accreditation from some other forms of external evaluation *(20)*.

2.1.1 Accreditation, certification and licensing

In general, an accreditation programme will involve an authorized body assessing a health care organization (e.g. through self-assessment, scrutiny of data and field visits by reviewers with specific experience and expertise) and publicly endorsing that the organization meets applicable pre-established criteria for clinical and organizational or management practices, usually set at an optimum level to stimulate performance improvement (i.e. assessing more than adherence to minimum standards). These authorized bodies may have an international presence, be a commercial entity or be a state-run independent organization (see country examples in Section 2.2), and more than one such body may be active in some settings.

Accreditation programmes are often designed to provide health care organizations with a framework to promote changes in organizational structures, processes and behaviour of health care providers, to contribute to improving operational effectiveness, patient health outcomes and care, and potentially to lower costs *(3, 8, 9, 11, 21, 22)*. Programmes are often run in cycles of 3–5 years between evaluations, with successive cycles seeking to assess more mature quality improvement frameworks *(19)*.

Accreditation has traditionally been a voluntary process in which organizations choose to participate rather than being mandated by laws and regulations. However, this voluntary nature has undergone significant changes over the past two decades, and several countries have implemented mandatory accreditation

programmes *(23, 24)* or programmes have become "quasi-mandatory" because of the degree of funding attached to participation and achievement of standards *(7)*. Although accreditation programmes have focused on hospitals, recently they have been increasingly introduced to primary care facilities *(23)*. Accreditation can also relate to individual disciplines or services within an organizational setting (e.g. to cardiology or radiology), through what are sometimes called "focused accreditation models" *(23)*. Accreditation programmes have mainly been designed and evaluated in higher income settings; hence, much of the evidence presented within this paper is drawn from such settings. However, the number of low- and middle-income countries (LMICs) pursuing such programmes is growing *(3)*.

The process of developing an accreditation body and programme, and programme content, is highly variable and context dependent, as highlighted throughout this paper and illustrated by the country examples in Section 2.2. This paper does not go into detail about the content of programmes or developing standards, but a recent paper from ISQua outlines the key components of a programme, including standards to evaluate structure, process, outcomes and culture, and a clear methodology for evaluation *(19)*. Further guidance is available for developing standards *(25)* and designing programmes *(3)*. A list of internationally recognized accreditation bodies can also be accessed via the ISQua website.[2]

Certification includes processes through which authorized bodies (both governmental and nongovernmental) evaluate and recognize "either an individual, organization, object or process as meeting pre-determined requirements" *(3: p. 6)* or performance criteria, often addressing legal provisions. Certification is often non-recurring and typically involves fewer standards than accreditation but a larger number than licensing.

Licensing comprises processes through which governmental authorities, such as recognized professional organizations, "grant permission to an individual or health … care organization to operate or engage" *(3: p. 7)* in a medical occupation or profession. Licensure procedures generally aim at ensuring that health care organizations, facilities or individuals meet minimum standards; they involve the granting of a licence that allows an organization or person(s) to provide services within a prespecified scope, pursuing the primary objective of protecting the public's health and safety. Licensure is always mandatory, and its maintenance is an ongoing requirement for health care facilities or organizations to have permission to operate and for caring for patients *(3, 23)*.

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[2] https://isqua.org/membership/institutional-members.html

2.1.2 Accreditation and health system assessment

In any given health system setting, there are numerous other activities that may have some overlap with accreditation programmes; for example, other types of external evaluation (as discussed above), other quality improvement initiatives and other assessments of health facilities, services or systems. It is important to understand how current or planned accreditation mechanisms – as processes of assessment and evaluation of facilities – relate to other assessments (e.g. routine monitoring and evaluation) or to periodic national assessment of health services. In general, these assessments differ quite substantially in scope and aims; however, it can be useful to understand how different tools and initiatives may complement or overlap accreditation processes, to reduce duplication and promote a holistic approach to quality.

Accreditation differs from routine or periodic health service or system assessments in some critical ways:

- As a form of external evaluation, accreditation, by definition, is undertaken by an independent agency, whether by an external or commercial agency, or an independent governmental body.

- The accreditation process results in some form of recognition or assurance that a facility or service is complying with quality improvement standards and meets (or is working to meet) pre-established criteria or standards (which differ by programme).
- Accreditation aims to provide a quality improvement cycle, with assessment followed by recommendation and re-accreditation, as opposed to a one-off (or infrequently recurrent) or continuous assessment process. Thus, accreditation is both an outcome (becoming "accredited") and a process – the latter framing yielding more benefits in terms of quality improvement.
- Accreditation may form a criterion for participation in health insurance programmes or receipt of government subsidies, and thus is often linked to the health financing system.
- Many assessment tools aim to provide a picture of the services availability, readiness and quality across a region or country but are often not focused on individual facility results and their improvement (although some data may nevertheless be useful to individual facilities or organizations).

Where a country chooses to implement accreditation, that accreditation may add to an already complex environment of health service and system assessments; thus, the added value and complementarity of this process must be carefully considered, as discussed throughout this paper.

2.2 Pointers from theory and practice

2.2.1 Evidence of the impact of accreditation on quality of care and other dimensions

Given the considerable investments by governments and the costs to the health system of health care accreditation programmes, it is vital that policy-makers can scrutinize evidence about the impact that accreditation programmes might have on structure, processes, outcomes and culture in health care. A review of pertinent literature reveals a complex picture with mixed research quality, mixed findings, a relatively narrow scope (mostly focused on hospital settings in high-income country settings[3]) and heterogeneous views on the effects and value of accreditation programmes.

Limitations of the research

Accreditation has varied significantly both globally and over time *(26)*. Any comparison or aggregation of outcomes must be cautiously interpreted because, as with any assessment, accreditation is only as useful and as high quality as the processes and standards used in each case. Accreditation is also highly context specific and, as with any complex intervention in complex systems, outcomes will depend both on the quality of the programme and the system response. One accreditation programme or process may yield better or different results in certain areas or facilities than in others.

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[3] A total of 71 papers were reviewed, of which 52 presented evidence from high-income countries, 27 from upper-middle-income countries, seven from lower-middle-income countries and three from low-income countries, according to the World Bank categorization of countries by income status. Some papers contained evidence from multiple countries.

This is compounded by the fact that most research stems from high-income settings, limiting its generalizability to other contexts.

There are significant difficulties in attributing the influence of specific interventions on multidimensional constructs such as quality of care, and challenges in misinterpreting correlation as causation. It is hard to identify the "active ingredient" of an intervention as complex as accreditation *(27)*, and this problem can be intensified by the complexity of health care organizations and their components *(9, 19)*. If an accreditation process identifies deficiencies in the care delivered in a health facility, then the anticipated response could include multiple adjustments at the organizational level, with potential changes in care processes and consequently patient outcomes. Accreditation may be the trigger and driver for such a series of events, but the further along the causal chain, the less obvious its immediate influence as a direct cause of any changes. In addition, the impact of an accreditation process might only be observable several years after it has been initiated, and published research does not have sufficiently long follow-up of results to capture this.

Finally, accreditation is often a voluntary process, where health facilities or organizations may wish to put themselves forward to gain, for example, reputation, funds or participation in an insurance scheme. Facilities may already have committed to quality improvement processes or already have access to funding or other resources. This pre-existing advantage may bias any assessment of the impact of accreditation on outcomes in these settings, further risking the misinterpretation of correlation as causation.

This evidence base must therefore be interpreted cautiously and any conclusions must be evaluated in context. When assessing accreditation, it may be useful to ask "What aspects of accreditation might work in my context?" rather than solely "Does accreditation work?".

Quality and standards in accreditation programmes

Evidence on the quality and standards of accreditation programmes themselves again reveals an incomplete picture. One review identified no published material on the process of accreditation standard development and only one paper on implementation, highlighting the lack of evidence in this space *(28)*. Another review points to notable concerns about accreditation programmes owing to their perceived low quality of standards, discrepancies between their results and those of quality audits, and the reality that in clinical practice there are often complex events that are not reflected in accreditation standards *(10)*. This further underlines the limitations of evidence on efficacy, because most research does not concurrently evaluate the quality of the assessment itself; it also underlines the importance of developing reliable, valid accreditation processes, discussed further below.

Bearing these limitations in mind, the following section briefly summarizes key findings from the literature and identifies outcomes that accreditation may seek to improve. These outcomes are related to process and outcome measures, organizational changes, health workforce, consumer and patient views, and costs. This overview of evidence explicitly considers a broad definition of accreditation (i.e. systematic assessment of hospitals against accepted standards by an external organization) with possible overlap with other forms of external evaluation discussed earlier in this paper.

Quality measures

The quality outcomes contained in the papers discussed here include clinical and patient outcome indicators (e.g. mortality, length of hospital stay and patient safety). Overall, the evidence for impact on measures of quality is mixed; for example, a large narrative review from 2012 incorporating evidence from 122 studies from a variety of global settings[4] presented inconsistent results, with the authors warning that no strong claims on effectiveness can be drawn from this evidence *(10)*. A systematic review from 2015, albeit one that identified only two qualifying studies,[5] similarly highlighted the lack of reliable evidence to support the effectiveness of accreditation programmes *(21)*. A further review from the same year identified prior reviews and only one qualifying study, reiterating the scant and mixed evidence, and highlighting that studies rarely include context, implementation or cost *(9)*. A 2021 review looking at the effect of accreditation, public reporting and inspection found no papers reviewing this triad and limited evidence for each of these on patient outcomes *(29)*. Two older systematic reviews cautiously suggest positive correlations. The first, in 2011, incorporated evidence from 11 countries[6] and suggested a positive correlation between accreditation programmes and clinical outcomes, although the methodological rigour of the original studies included in this review was not clear *(24)*. The second review, in 2020, similarly suggested a positive correlation between accreditation and quality measures (including efficiency, safety, effectiveness, timeliness and patient-centredness) although it concluded that methodological weaknesses in the original studies resulted in challenges interpreting the reliability of this evidence *(30)*.[7] Some single country studies again found mixed evidence of positive impact on quality outcomes *(see, for example: 31, 32–42)*.

This evidence demonstrates the difficulty in understanding the impact of accreditation on quality of care. Also, all of these studies focused on *hospital* accreditation.

Organizational changes

The changes discussed in the identified papers included the extent to which hospital accreditation programmes promote standardization of care processes, increase compliance with external programmes or guidelines (e.g. clinical best practice) and promote the development of organizational cultures conducive to quality and safety.

Again, systematic reviews and individual country-based studies revealed ambiguous results. The large 122 study narrative review (2012) discussed above found mixed results *(10)*. Two studies undertaken in 73 and 89 European hospitals, respectively, concluded that quality and safety structures and procedures were more evident in hospitals that were either accredited or certified than in those that were neither *(43)* but found limited evidence on clinical practice *(44)*. A further multicountry review

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[4] Australia, Egypt, India, Jordan, Kenya, Lebanon, Liberia, Saudi Arabia, South Africa, Thailand, the United States of America (USA), Zambia and a number of European countries.

[5] South Africa and the United Kingdom of Great Britain and Northern Ireland.

[6] Australia, Canada, Denmark, Egypt, Japan, the Philippines, Republic of Korea, Singapore, South Africa, the USA and Zambia.

[7] Belgium, Brazil, China, China, Hong Kong SAR, Czechia, Denmark, France, Germany, Indonesia, Ireland, Iran (Islamic Republic of), Jordan, Lebanon, Poland, Portugal, Republic of Korea, Türkiye, Saudi Arabia, Serbia, Spain, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland and the USA.

used a "strengths, weaknesses, opportunities and threats" (SWOT) analysis format to understand factors affecting implementation of accreditation programmes, identifying the variability of implementation and how that affects organizational (and other) outcomes *(45)*. The 2021 study discussed above, which reviewed the triad of accreditation, public reporting and inspection, found that accreditation improved adherence to processes of care, although with no associated improvements to patient outcomes *(29)*.

Impact on health workers

The evidence on the views of health workers is equally varied. No literature reviews focused on this dimension. Findings from smaller studies included that health workers have positive views on the impact of hospital accreditation on the delivery of patient care, development of professional skills, cost management and job satisfaction *(10, 46–48)*. Other studies highlighted concerns regarding the human and financial resources that accreditation programmes require, and the increased stress levels these might induce *(10, 49–51)*. A qualitative study from Australia found a favourable view of accreditation by health care staff to be a "critical enabler" for an effective programme *(11)*.

Patients, public and communities

As with any quality improvement process, accreditation ultimately aims to improve the health and well-being of patients and the wider public, and their involvement, satisfaction, decision-making and outcomes related to accreditation should be a key area of consideration. However, there is little research in this area, and the few empirical analyses that do consider this relationship indicate an undefined impact of hospital accreditation on the views and satisfaction of consumers and patients, pointing to findings that accreditation is not linked to measurably better quality of care as perceived by patients *(10, 52)*.

Cost-benefit

There are two key elements to consider in relation to cost-benefit. The first is whether accreditation programmes contribute to cost savings at the facility level (e.g. through more efficient and higher quality processes resulting in fewer medical complications). The second is whether accreditation programmes represent value for money at a national or subnational level, recognizing the opportunity cost that accreditation represents in relation to other activities to address quality of care. There is little research on either element. Where evidence is available, it outlines concerns that participation in accreditation programmes consumes considerable financial resources, with an undetermined return on investment *(53, 54)*.

Primary care

Most of the research looks at hospital accreditation or does not sufficiently identify the types of facility included, yet accreditation is increasingly of interest in primary care facilities. Although not as extensively used or studied, and with a relatively short history when compared with hospital accreditation, primary care accreditation programmes are nonetheless widespread, with examples from Australia, Canada, countries in the WHO Eastern Mediterranean Region, Europe, New Zealand and the United States of America (USA) *(55–57)*. A 2019 review of accreditation standards used across

different primary care settings globally found a large variation in accredited domains, with more developed and mature programmes having a focus on people-centred care *(57)*. A 2011 survey of European programmes also highlighted the variety of approaches used; most programmes at the time were found to be voluntary, to have associated costs for primary care practices, to be devised by national bodies with public reporting and to often (but not always) include benchmarking *(55)*. Neither of these papers made any systematic assessment of effectiveness. A 2013 review of effectiveness that looked solely at Australia, Canada, western Europe, New Zealand and the USA found a lack of evidence and mixed results on any associations with improved patient outcomes, and provider and patient perspectives *(56)*. In relation to costs, the significant financial burden of accreditation is noted and, despite some evidence that accredited practices may be more cost-effective, it is not clear whether the costs recovered equal (or exceed) those spent *(56)*.

2.2.2 Legal matters

There are various legal frameworks for national accreditation programmes, and these can be embedded in complex and varying legal infrastructures and political environments. There are also important legal implications for any national accreditation programme under consideration *(58)*. This section outlines some of the legal implications of accreditation, looking first at the legal status and independence and responsibilities of the accrediting body and second at how accreditation may overlap with other health care related laws.

The legal status of accrediting bodies

Any accreditation body must be set up as a legal entity (or part of one) with clear legal responsibilities on assessing and assuring standards. This is especially important if the accreditation body is part of a government department or ministry, because independence is key to ensuring validity and accuracy, and avoiding conflicts of interest; it is also a defining feature of an *external* evaluation *(3)*. This may be additionally complicated in primary or community care, where the health authorities who have a board function may also play a role in accreditation (this is in contrast to hospitals, which often have a board of directors with oversight over strategy and mission). Research from the USA demonstrates how complicated this relationship can sometimes be, when a 2008 change of law required the Joint Commission on Accreditation of Healthcare Organizations (a nongovernmental accrediting body with an international presence) to formally apply to the Government for authority to determine a hospital as eligible for participation in its programmes (Medicare/Medicaid), significantly changing the relationship between – and the independence of – the Government and the accrediting body *(59)*.

Although independence is important, it may be necessary (or desirable) for data to be shared between the accrediting body and the national government to reduce duplication of data gathering processes, allow ministries of health to use these data for other (or complementary) quality improvement or monitoring interventions, and promote the multisectoral changes required to comprehensively improve quality of care. Thus, data protection laws must also be considered, maintaining the balance between protecting and sharing sensitive information, ensuring any accreditation data collected align with those laws. Also, important here, is the use of public reporting as a strategy for improving accountability and transparency, itself a quality improvement

intervention *(8, 13)*. This should be considered when planning data protection and sharing from accreditation processes.

Accreditation and other laws

Existing laws pertaining to minimum standards, scope, quality, professional registration or licence to practice, health care administration and leadership may need to be examined to understand how accreditation aligns with these frameworks. Facility regulations – for example, on fire safety, radiation, medicine and health care products, building safety, employment health and safety, equipment safety and mandatory governmental licensing (organizational or individual, public or private facilities) – need to be understood, and the relationship between these assessments and assessors established. Although it is preferable for accreditation programmes to focus on continuous improvement rather than providing a binary pass or fail, if information is gathered on an issue that may have a legal basis for intervention, a process and lines of communication need to be in place.

Any assessment of laws may also need to be reviewed at national or subnational levels depending on the existence of decentralized laws and health system management. Beitsch et al. (2007) highlight how a "patchwork quilt of laws and authorities" across different states in the USA has provided space for innovations in accreditation programmes, while recognizing that the consistency brought by a standardized national system could yield benefits *(60: p. 384)*. This context is likely to differ by country and degree of regional autonomy. One of the least recognized challenges for a national accreditation system may be varying subnational laws supporting public health practice across a country *(60)*.

2.2.3 Financial matters

Accreditation programmes can be developed nationally, by government, by independent agencies authorized to do so by governments, or by independent (commercial or not-for-profit) national or international agencies contracted by health care organizations. Regardless of the model, accreditation programmes are necessarily linked to financial management because of the myriad implications for costs and incomes.

Cost considerations of accreditation programmes

Sufficient funding, especially in low-resource settings, is a major challenge to ensure that accreditation processes are sufficiently staffed, of high quality, effective and sustainable *(61)*. The aims of the accreditation process can often differ between higher and lower resource settings, with the former often focused on issues such as patient satisfaction, public accountability and staff development, and the latter on better or equitable access and assuring basic quality and safety standards *(61)*.

Sustainable funding plans must be clearly linked to feasible aims and must be considered across the spectrum – from accreditation body processes to support for facilities or organizations that undergo accreditation processes and are found to require development. In many settings, a binary pass or fail is not conducive to providing accessible, quality, equitable, sustainable health services, because it risks closing services that are vital to provide population health coverage.

The support organizations may require if they are to reach minimum standards and implement continuous quality improvement cycles to maintain accreditation standards could be considerable and will require medium- and long-term financial planning. Without funding considered or allocated for each stage, accreditation may have limited value and could result in overall losses of time and resources.

The breadth and extent of cost implications are considerable and should include an assessment of the following costs (among other costs):

- costs of start-up and programme development including, developing standards, multilevel and multisectoral consultation, assessment of data quality and availability, legal alignment and consideration;
- sustainable resourcing of "accreditation machinery", including staffing, overheads, field visits, surveys, follow-up, report processing, monitoring and evaluation;
- health system impact and costs of the accreditation process to the health facility's or the organization's governance and leadership and workforce (e.g. opportunity costs to patient care); and
- costs for implementing improvements and supporting the health facility or organization to achieve and maintain accreditation standards, which may be complex and considerable.

Conversely, potential cost savings from improving quality of care can be considerable (see reference 62, for instance), although attribution to accreditation programmes is challenging (see Section 2.2.1), incremental and fragmented.

Financial implications of being an accredited organization

A further financial consideration is potential incentives for organizations or facilities to participate in voluntary accreditation. There are some examples of explicit strategic linkages between health financing mechanisms and accreditation programmes.

Incentives could be through one or more of the following:

- competitive advantage;
- patient demand leading to increased fee collection or government funds;
- purchasing bodies specifying accreditation requirements for participating providers (e.g. health insurance schemes);
- links to performance-based incentives;
- links to government subsidies – financial incentives can, in some cases, be so significant that programmes that initially appear to be voluntary actually become "quasi-mandatory" *(7)*; and
- mandatory accreditation to be a publicly funded service.

Conversely, accreditation may be costly at facility level, putting less resourced, public facilities at risk of disadvantage, for example:

- accrediting bodies may charge a fee, which can be significant;
- there may be significant costs and resources associated with the accreditation process, with associated additional burden on the time and workload of health workers;

- there may be significant costs associated with achieving accreditation standards, which may have significant opportunity costs for other quality improvement processes.

These financial flows and the implications for facilities should be considered when assessing, designing or modifying an accreditation programme (see Section 3).

2.2.4 Illustrative country experiences

Across the world, different models of accreditation are being implemented in diverse settings. The examples briefly described here, derived from peer-reviewed articles and grey literature on country-specific experiences, have not been included to reflect best practice; rather, they illustrate a range of models along the external evaluation spectrum outlined above, and highlight some key lessons from design and implementation. Many of these examples are not explicitly called accreditation, yet they fall under the definition cited in this paper and thus demonstrate the variations that exist globally.

The examples given here reference national programmes. Not represented here are the many voluntary programmes sought by health organizations and undertaken by (usually commercial) international accreditation bodies.

United Republic of Tanzania

In 2015, the Ministry of Health of the United Republic of Tanzania implemented the Star Rating System, an external evaluation programme aimed at providing support for improvement in quality of care tailored to the national context. The system was designed through a multistakeholder process and included selection of 12 key assessment areas representing common health system challenges (e.g. health facility management, client satisfaction, and infection prevention and control). A scoring system was developed, building on existing assessment tools, and minimum standards were agreed. Scoring was to be completed on a five-star scale, with a target of 80% of primary health facilities to be rated with at least three stars by 2017–2018 *(63)*.

Although there was an initial planned assurance mechanism by which any facilities scoring zero stars would be closed, this was revised when initial results showed that more than one third of facilities scored zero, and many of these were in disadvantaged and hard-to-reach areas. In the initial phase, the threat of closure was therefore replaced with targeted support and funding for improvement *(63)*.

Features of implementation considered valuable included formal participation in facility assessment by a member of the council health management team; generation of facility quality improvement plans based on immediate feedback of data from assessments; mechanisms to ensure consideration of results by managers and policy-makers at local through to national levels; and integration with other improvement processes, such as supportive supervision *(63)*.

Ghana

In Ghana, an accreditation system has been integrated into the National Health Insurance Scheme (NHIS). All private health providers who wish to provide services to NHIS members should be accredited to meet a defined set of standards that depend

on the type of facility and level of care. Linking facility accreditation to the NHIS has been cited as a useful mechanism for expanding access to quality services *(64)*. Despite not specifically focussing on supporting facilities to make improvements, this system incorporates a financial incentive for accreditation and mandates development of a facility quality assurance programme as a prerequisite *(65)*. Also, accreditation has been framed as an intervention within Ghana's national health care quality strategy, demonstrating the linkages with other aspects of the strategic direction on quality of care. Finally, the strategy makes clear the need to link accreditation efforts with facility quality management teams and improvement efforts *(66)*.

Rwanda

In the early 2000s, to improve quality and shift demand to public hospitals, Rwanda implemented a performance-based financing initiative, which highlighted the need for further quality interventions *(67)*. A directive from the Ministry of Health saw a tertiary referral hospital gain accreditation via the Council for Health Service Accreditation of Southern Africa (COHSASA), a not-for-profit international accreditation body that works across sub-Saharan Africa *(68)*. A decision was made to extend accreditation to the further 43 district hospitals and a national accreditation service was developed *(67)*. This accreditation was linked to the performance-based financing initiative, providing a clear financial incentive for participation. Although the links between accreditation and other governmental initiatives has been useful, oversight from a nongovernmental, external entity has been sought, to reduce the risk of conflict of interest and provide the independent, external evaluation required for these processes *(67)*.

Australia

In Australia, several accreditation agencies are authorized to assess health facilities against a common set of standards. There are also mechanisms for performance data gathered in the accreditation process to be fed back to senior health system officials and policy-makers, so that they are aware of key challenges and can effectively plan improvements in quality. There is a strong focus on people-centredness, with one of the eight main standards focusing on partnerships with consumers. A recent review of the Australian system identified opportunities to strengthen the assessment procedure and build in resources and support for provider organizations *(69)*.

Islamic Republic of Iran

In the Islamic Republic of Iran, accreditation is a mandatory aspect of the assurance system for hospitals *(70)*. The accreditation system currently in place built on a longstanding programme of hospital evaluation in which a small team of assessors scored facilities against predominantly structural standards and assigned a grade that was linked to the payment tariff. In 2012, this was expanded to incorporate improved measurement of process and outcome measures. Although this complex and large-scale initiative aimed to improve quality and responsiveness of services, significant challenges have been noted around adequate resourcing of hospitals, effective governance and provision of support to hospitals *(70, 71)*.

Mexico

To expand coverage of health services to those not already covered by social security, Mexico implemented a new health financing system, Seguro Popular, in 2003. Mexico

also introduced a new system of mandatory accreditation for all facilities providing services under the Seguro Popular. The aim of this accreditation programme is to ensure that people accessing services under this scheme receive care that meets at least the minimum standards for quality. However, it has been emphasized that accreditation is only one intervention within a much broader set of governance mechanisms in the Mexican system that work together to promote quality care *(72, 73)*.

Tunisia

In Tunisia, with a background of an expanding medical tourism industry across the past decade and motivated by a need to complement health insurance funding, there has been increased interest in accreditation of facilities as a competitive measure to attract prospective patients. With the formation of a national accreditation body, the focus has now evolved to incorporate continuous improvement of quality of health services for the population of Tunisia. The initial roll-out is intended to include both public and private facilities, with a particular focus on primary care *(74)*.

Oman

In 2016, an initial cohort of 11 hospitals in Oman commenced roll-out of the Patient Safety-Friendly Hospital Initiative (PSFHI), an external evaluation system that is overseen by the WHO Regional Office for the Eastern Mediterranean and is focused on supporting implementation of evidence-based practices for improving patient safety *(75)*. The PSFHI is a voluntary, hospital-driven programme that combines self-assessment with guidance and evaluation from external experts. Assessments consider 139 standards and score against four levels of compliance, aiming to encourage benchmarking and public accountability, facilitate monitoring and improvement of performance, and help to build a comprehensive patient safety system *(76)*. The Oman experience demonstrated the use of external evaluation standards as a catalyst for broader hospital programmes on patient safety and has been identified as a foundation for a possible future national accreditation system *(75)*.

England

In England, the Care Quality Commission is an independent regulatory body that performs external evaluation as part of its statutory role to monitor, inspect and regulate health services *(77)*. The evaluation process uses both continuous monitoring of data and regular expert inspection visits to all health facilities. Alongside specialists on the inspection teams are "experts by experience" – those who have personal experience of care services. Of note is the comprehensive nature of the Care Quality Commission, which incorporates external evaluation of the full primary health care system alongside hospitals, such that it includes first points of contact (e.g. general practitioner practices, walk-in centres and out-of-hours services). Reports are prepared detailing the results of the inspection process, and recommendations are made on how care can be improved. The Care Quality Commission also acts as a regulatory agency; hence, external evaluation results also inform the exercise of regulatory powers to protect patient safety and enforce actions to improve care. Alongside the use of external evaluation to drive provider improvements, detailed ratings are also made available to the public to inform decisions on accessing care.

3. Strategic considerations: using a health systems lens

Section 2.2.1 highlighted the complex and varied nature of international evidence on the impact of accreditation on quality of care. It also highlighted the lack of evidence from low-resource settings, and on effects on health workers, involvement of the public and cost-benefit. Most studies consider individual hospitals as the unit of analysis. Demonstrating a positive impact (whether direct or indirect) of accreditation programmes on the overall performance of individually accredited facilities should be a crucial factor in the development and maintenance of accreditation programmes. However, this is not sufficient. Other potential impacts at the system level and on equitable access to quality health services need to be considered when deciding on the development of and investment in accreditation programmes, setting nationally relevant standards and allocating resources to support facilities to participate (and to sustainably improve to meet quality standards, where necessary).

The country illustrations in Section 2.2.4 highlighted the variety of approaches and models used to develop and implement accreditation programmes, adapted to different contexts. If a decision to proceed and develop a national accreditation programme is made (considering the points discussed below), health system decision-makers should think carefully about how to progress this in a contextually appropriate manner. This should involve asking key questions on coverage, equity, scope, incentives, stakeholders and opportunity costs, and looking at how to make best use of existing assessments and programmes while taking into account the need for continuous adaptation of standards and methods, regulatory mechanisms, institutional settings, funding and incentives.

The performance of the system as a whole is more than the sum of the performance of individual facilities; hence, as health system stewards, decision-makers will need to ensure balanced development in the different parts of the system. Such development could be between primary care facilities and hospitals, between affluent and poorer

areas or between public and private sectors, and could consider the short-, medium- and long-term risks and impacts across the system.

The rest of this section expands on and discusses these points, providing some key considerations when aiming to design and redesign optimal accreditation programmes.

Demand, trust and care-seeking behaviour

Accreditation programmes are primarily designed to impact the "supply" of health services, but their impact on the "demand" of services should not be underestimated. In the absence of a mandatory nationally established programme, facilities might still be interested in gaining accreditation from international organizations to improve their reputation or revenue sources (or both). Accreditation status may provide a strong competitive advantage in attracting and retaining patients, and hence have an impact on financial flows, as outlined above. This is particularly obvious in the frame of international health tourism, where hospitals seek accreditation by international programmes to attract patients across borders or those with private health insurance coverage. This observation can be extended to the national context, when private facilities, in particular, can also financially benefit from such a competitive advantage.

Accreditation is seen as a medium- to long-term investment by these health care organizations. Only those with significant resources and already well-established quality standards would be able to achieve this status, and this is most likely to be in larger private facilities. If national policy-makers do not implement measures to support quality initiatives for all public facilities, the situation is likely to further exacerbate inequalities by improving facilities that already have high demand and higher quality of care; in turn, this will increase the imbalance in demand and potentially increase any quality divide between public and private sectors, or between primary and secondary or tertiary care. This is particularly true because facilities serving international or affluent patients are generally concentrated in larger cities, concurrently exacerbating the urban–rural quality divide. The imbalance also shifts demand from public facilities and promotes higher costs for individuals seeking health care, exacerbating poverty and catastrophic out-of-pocket spending.

Policy-makers may wish to implement national accreditation programmes proactively to increase population trust in public health care organizations, or for specific types of services. For instance, prioritizing accreditation programmes for primary care facilities could send a strong signal to restore the trust of the population and increase demand for primary care. This move to assure quality in primary care facilities can also contribute to making this setting more attractive for health workers. Hence, setting up an accreditation programme for primary care may be considered a key step in transforming health systems to become truly primary care oriented, which in turn is key to UHC; it might also help to counter the perception still dominant in many countries that primary care is "poor care for poor people".

Considering the supply side: what about the impact on quality services and equity?

Accreditation traditionally involved the voluntary participation of facilities in a programme, and this often remains the case. As discussed in Section 2.2.1, this can bias any data because these facilities may have already made some commitment to quality improvement mechanisms, including safety and accountability, and the data

will miss any facilities that are not inclined to submit themselves for review or able to afford or engage in quality improvement processes.

Thus, accreditation can increase the quality divide between facilities if only those that are "better-off" are able to participate in the programme and benefit from its associated incentives. This situation is likely to be compounded if there are costs associated with participation in accreditation. Conversely, properly managed accreditation programmes can reduce this divide by setting a common standard for all to achieve and providing additional support if needed. In this situation, the programmes are helping to level out the quality provided across the country and to improve equity. Therefore, mechanisms should be established to help less well-off facilities to meet the accreditation standards. For instance, an assessment of resource gaps to meet standards can guide additional resource allocation to complement existing evidence-based modalities. Also, costing a national package of essential health services can take into account minimum requirements set by certification or accreditation programmes, to establish the conditions for these essential services to be delivered with sufficient quality. With this perspective of accreditation as an intervention to level the playing field and support equitable access to quality services, a key challenge is to set standards that are realistic enough to be met by those facilities that are worse off (with some additional support) but are ambitious enough to drive system-wide improvements. A related challenge is to balance support, rewards and penalties linked to the accreditation status (which carry a risk of further exacerbating inequalities within the health system).

Mandatory or voluntary accreditation?

The two points outlined above on the potential impact of voluntary or non-universal accreditation (e.g. not including aspects of the health system such as primary care) provide valuable lessons on demand and supply and therefore on inequalities and public trust. However, the question of whether accreditation should be mandatory or voluntary is not a straightforward one, and each context needs to be carefully evaluated before progressing.

A process that is mandatory, externally authorized, fair, supportive and driven may promote change in any organization, irrespective of the organization's inclination to be inspected *(21)*, and crucially the process can link with other health system interventions to improve quality of care. Here, it is important to reflect on whether accreditation is considered as an outcome (in the sense of "something to be achieved") or a process ("an ongoing, supportive improvement intervention"). There is a strong case for the latter. However, mandatory programmes may risk skewing perceptions towards achieving an "outcome" rather than continuous quality improvement if accredited organizations see the process as a regulatory requirement as opposed to a supportive, iterative, holistic, inclusive continuous process to improve quality outcomes and organizational systems *(19)*. These issues need to be recognized and balanced to optimize the effectiveness and efficiency of accreditation, with attention given to the resourcing of quality improvements alongside evaluation processes.

Accreditation should be understood as a supportive, funded system to continuously track performance of health care organizations, collecting and evaluating data on indicators upon which quality can be assessed and improved.

Multi-level planning and integrated approaches

Country health systems of course operate in different contexts, with consequences for the speed at which quality of care interventions are developed, adapted and implemented. Indeed, accreditation and external evaluation mechanisms often do not flow from national strategic directions on quality health services but rather emerge from autonomous activities from health institutions (e.g. large hospitals) or through district-based efforts to assess the quality of health services. Thus, multiple levels – national, subnational and facility – need careful attention when considering the role of external evaluation and accreditation within a health system.

A crucial component of well-functioning systems that is often undervalued is the coordination and integration of care providers to ensure continuous patient care. This has implications for the content of accreditation programmes and level of accreditation. Recently, some accreditation programmes have added specific standards aimed at strengthening people-centredness; for example, standards reflecting people's participation (both users and community non-users but also staff representatives), and coordination and integration within facilities and with other health and social care providers. This could involve, for example, accreditation of clinical pathways (i.e. following the patient on a journey, potentially from community to secondary or tertiary care, for the management of a clinical condition) and of disease packages (e.g. linked to insurance payments and incorporating all elements of care for a specific disease). No matter how this is realized, the needs of patients, families and communities must be considered crucial in the design of people-centred accreditation and external evaluation approaches.

Exploring the role of accreditation within primary health care

The primary health care approach is a cornerstone of UHC. There are two main considerations when considering the role of accreditation in supporting this approach. First, implementing accreditation of primary health care services may have a role in supporting quality of care and increasing the level of community trust. Second, there may be value in incorporating this approach in accreditation standards, such as the inclusion of hospital accreditation standards on referral and on collaboration with primary care providers, or the development of processes to assess standards related to public health functions. Both of these considerations require simultaneous attention when aiming to use accreditation programmes to strengthen primary health care.

Understanding linkages with existing or planned health system measurement: coordinating the data landscape

Section 2.1 outlined how accreditation processes differ from other facility assessments and routine data collection. Here, we discuss further how these assessments and others could be used to enhance or collaborate with accreditation programmes. Those designing accreditation programmes can map different data collection and assessment mechanisms nationally to reduce duplication and identify potential links.

Three potential ways in which other routine or periodic assessments may be used are as follows:

- in the decision-making or design phase of accreditation programmes, data collected in other assessments could be used to identify issues or gaps requiring

further evaluation in an accreditation programme or to assist the generation of accreditation standards;

- to meet local needs related to quality of care, other quality improvement interventions could be considered (e.g. previous assessment and evaluation initiatives or those that have been used in place of an accreditation programme, although these will differ in scope or process); and
- data collected in other assessments could be shared, to formulate or inform that element of the accreditation process, and accreditation and data collection instruments could be aligned to minimize the assessment burden on health service staff.

For the last point, legal aspects of data sharing and the independence of the accreditation body must be considered (see Section 2.2.2). Another important relationship to be explored in the design of accreditation is the one with health financing. Several health financing schemes (e.g. contracting, performance-based financing, health insurance, health equity funds or health vouchers) link their payment arrangements with the results of quality and performance measurement using different formulae. Certain schemes set minimum standards, measured by external facility evaluations, as a condition for participation, as shown by the examples in Section 2.2.4.

The WHO *Operational framework for primary health care* is accompanied by the *Primary health care performance measurement for improvement: framework & indicators*. The primary health care monitoring framework is a cross-cutting concept, and contains a set of quality-relevant indicators, including some that focus on the use of regulatory mechanisms (e.g. licensing, certification, external evaluation and accreditation) in primary care and other facilities. These indicators merit careful consideration by countries as they track progress towards improved health system performance.

Quality interventions: the importance of complementarity and alignment

WHO's key technical documents on quality of care clearly outline the need for comprehensive and integrated quality interventions that span the health system and the need to consider national, district, local, community and facility level interventions.[8]

Accreditation should be seen not as a standalone intervention but as one piece of an ongoing, iterative, comprehensive process to monitor health system performance, improve quality of care and assure public accountability of the health sector. It should be carefully planned and implemented alongside other interventions, recognizing opportunities for complementarity and ensuring that its implementation is sequenced to maximize positive impacts. There is evidence that complementarity in the quality approach is important, and that it is best to use several approaches in tandem *(81)*.

As discussed in Sections 1 and 2, accreditation lies on a spectrum of external evaluation processes and, in practice, the distinctions between registration and licensing, certification and accreditation are blurred. However, it is useful to consider

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[8] Three key technical documents are the *Handbook for national quality policy and strategy (8)*, *Quality health services: a planning guide (78)* and *Quality of care in fragile, conflict-affected and vulnerable settings: taking action (79)*. Further documents are available from the publications page of the WHO website *(80)*.

the sequencing of these initiatives when planning external evaluation processes. The spectrum can be placed into wider quality planning, to consider whether other interventions would best precede or coincide with this process. Foundational tools and resources (e.g. trained staff, water and sanitation, and access to basic equipment) may be more useful as *precursors* to more complex interventions such as accreditation. It is essential to coordinate the planning and implementation of a comprehensive set of quality interventions (before or alongside accreditation).

Involving the health system: multisectoral engagement and networking

When considering how accreditation programmes can be framed and embedded within the health system, it is important that stakeholders from across that system are involved in the accreditation process – from planning, to development, implementation and review cycles. At the system level, this includes working with other bodies and stakeholders to understand the current data or measurement and quality improvement landscape, to understand the added value of accreditation and how accreditation can complement existing or planned initiatives. Particularly important is multistakeholder involvement in developing quality guidelines and standards that are designed to both assess quality and stimulate quality improvement.

Stakeholders to consider for engagement in these processes include government departments or agencies, communities and civil society, non-governmental organizations (NGOs) and other agencies across the health, data, legal and financial systems. They should include bodies and funders involved in health care financing, licensing, health care law, and monitoring and evaluation, and across vertical disease programmes at national, district and local levels. It is vital to include health care organization leadership at district, local and facility level in this process, in addition to the broader health workforce and the public. A quality or accreditation oversight or coordinating body may be required, linked to national quality governance structures and comprising the key stakeholders.

Evaluating accreditation: understanding complex interventions in complex environments

Section 2.2 above outlines the challenges inherent in interpreting evidence and outcomes on accreditation; for example, comparing different accreditation programmes and standards, voluntary involvement resulting in biased data, the importance of context, and issues around finding the "active ingredient" for success. These issues apply equally to evaluating individual accreditation programmes or understanding facility results and outcomes.

It is paramount to differentiate the various facets that accreditation programmes encompass. Thinking about their impact requires consideration of more than just clinical and patient outcome indicators, because these programmes may affect a broad array of organizational and process aspects, including staff satisfaction, patient perceptions and overall finance, cost-benefit and opportunity costs. In practice, this implies that establishing causal links between accreditation and outcome measures emerging from adaptive services in health care organizations requires careful examination. When assessing accreditation programmes, rather than asking "Does accreditation work?" it may be more useful to ask "What aspects of accreditation might work in my context?". When it comes to implementing and evaluating

accreditation programmes, the focus may be on how to optimize each of the steps in an accreditation cycle *(13)*.

Central to an external evaluation are high-quality, contextualized accreditation standards and instruments that make it easier to determine whether a facility or organization has achieved the standard or what to do if the standard is not achieved *(19)*. Many countries have developed specific measurement tools and performance assessment instruments to support the accreditation process. These tools often draw from a range of data sources (e.g. patient records, facility registers and national statistical systems) to ascertain adherence to standards of care and performance. Globally, there is a need for a rapid review of existing efforts, tools and methods to identify good and best practices, and to inform the development of global standard survey instruments and evaluation methodology to support accreditation processes.

One potential way to guide the design and operational thinking is to use the key questions summarized in Section 5. Decision-makers on different levels in countries may take these as starting points for strategic dialogue on planning and evaluating accreditation activities.

Alongside assessing the quality and impact of accreditation programmes at facility level, governance and accountability at national or organization level is crucial. Clear structures, accountability pathways, potential conflict of interest, and relationships between the accreditation body and the ministry of health must be clearly and transparently outlined. For a programme to be successful, the accreditation body must have sufficient capacity and resources, as well as a clear mandate and the capability to recommend change.

Involving people: taking account of health workers, patients and communities

As countries move towards implementing or re-assessing accreditation programmes, it is important to address the human and relational aspects that go beyond the reporting of clinically measured patient outcomes. Although the role of patients and consumers within accreditation processes remains unclear, there is empirical evidence of health workers' concerns with accreditation programmes and their consequences (intended or unintended). These factors should be included in the design or modification of any accreditation programme.

Achieving effective and meaningful involvement of health workers in accreditation programmes requires consideration and planning on actions that will help health workers to cope with increased levels of job strain (e.g. due to accreditation surveys), minimize potential psychological consequences, preserve job satisfaction and prevent adverse effects of any accreditation activity. Ideally, accreditation programmes should be integrated into health systems as a supportive intervention, where health workers benefit from participation and where their importance as a valuable resource and as custodians of quality health care is recognized and protected. This requires better engagement of health workers in accreditation programmes and associated improvement initiatives, to ensure that support for improvement activities is built into programme design and that efforts towards meeting accreditation standards do not constitute an unjust burden on health workers.

Despite not focusing on individuals – the remit of health worker regulation, discussed elsewhere *(1)* – the accreditation of facilities or organizations may nonetheless assess and make recommendations on workforce (e.g. on quantity, skill mix and competence). Where workforce recommendations are made, they should be implemented in a way that provides opportunity and support for the affected health workers. One approach that merits consideration is supportive supervision as a facilitative process that is designed to improve health workers' performance through joint problem-solving and communication between supervisors and supervisees; incorporating such supervision requires careful design *(82, 83)*. With its explicit focus on using data for the monitoring of staff performance towards goals, and its continuous feedback loops to align tasks and expectations, supportive supervision shares features with accreditation assessments, which may be leveraged *(82)*. This can be particularly beneficial in low-resource settings, where supervision is critical to health workers' performance, and is thus a pivotal determinant of the quality of services provided *(84, 85)*.

The role of patients, the public and communities is an underrecognized and underreported element of accreditation programmes. The perspectives of these groups and the experiences of quality of care in accredited facilities should be paramount when understanding, evaluating and improving quality. Accreditation should be designed to facilitate and improve people-centred health services, defined as "an approach to care that consciously adopts the perspectives of individuals, families and communities, and sees them as participants as well as beneficiaries of trusted health systems that respond to their needs and preferences in humane and holistic ways" *(86)*. The design and delivery of accreditation programmes should align with this approach. Finally, public reporting of health care data is a core element of health system accountability and transparency, and such reporting can improve quality through benchmarking and public scrutiny *(8, 13)*. This should be considered for the outputs of accreditation programmes, while bearing in mind regulations on data sharing and independence of accreditation bodies (see Section 2.2.2).

Money matters: accreditation must be evaluated considering the wider opportunity costs and value for money

Analyses of whether the benefits gained through accreditation programmes represent value for investment is pivotal. There is scant empirical guidance demonstrating the cost-effectiveness of accreditation programmes, which often require substantial financial and human workforce resources. There is a need for rigorous costing of the resources invested and benefits accrued for health organizations through accreditation programmes if an evaluation of a programme's effectiveness is to contribute to informed and rational decision-making about health policy, assessments of opportunity cost to the health system and appraisal of options for quality interventions.

The literature demonstrates a lack of clarity on the relationship between accreditation programmes and a range of outcome measures, making an appraisal of the costs and benefits of this intervention difficult, and a comparison with other methods aimed at improving quality of care almost impossible *(53, 54)*. More focused and robust research on these explicit areas (i.e. voluntary versus mandatory schemes, health workers' perceptions of accreditation and cost-effectiveness) is critical to improving the understanding and application of accreditation across different health systems.

The human resources and financial burden of accreditation programmes on health organizations must be factored into any decision on adoption. When considering their potential implementation, it is essential to weigh the human, financial and opportunity costs of accreditation programmes against other investments in quality improvement interventions, although doing so can be challenging *(9, 10)*. This applies in all settings but may have particular relevance in LMICs, where available resources in the health sector are commonly even more restricted. Box 3.1 highlights what can be done in relation to accreditation in fragile, conflict-affected and vulnerable (FCV) settings.

Box 3.1 A spotlight on FCV settings

Sustained efforts to systematically assess and improve health care quality in FCV settings are challenging. There is often major disruption to data collection and assessment initiatives, as outlined in WHO's *Quality of care in fragile, conflict-affected and vulnerable (FCV) settings: taking action (79)*. In general, actions for information systems and quality measurement involve more foundational elements, such as ad hoc assessments of service delivery, encouraging transparency and data sharing among stakeholders and developing basic quality indicators *(79)*. Sequencing of different quality interventions is an important consideration, and this is particularly evident in FCV settings, where progress on even the most foundational quality activities will be required before more complex endeavours such as accreditation can be usefully considered.

A 2019 literature review on health financing in fragile or post-conflict states identified a lack of evidence on accreditation in these settings, but highlighted one example from Liberia where a government-sponsored mandatory accreditation system was developed as part of the country's basic package of health services *(87, 88)*. This programme aimed to assess the degree to which facilities met the package's clinical standards and met the management services required to deliver the package. It did not explicitly track or measure quality of care *(88)*. A review written by the project funders concluded that accreditation in this setting allowed data gathering on service provision, provided useful feedback to facilities on performance and improvement, and promoted stakeholder engagement and harmonization of priorities *(88)*.

Attempts have also been made to standardize accreditation processes for international emergency or humanitarian medical teams, with much variability on how this occurs in practice *(89, 90)*.

These experiences may be helpful to consider when understanding the health provider landscape in FCV settings and the potential role of accreditation initiatives.

4. WHO perspective

Accreditation (or related external evaluation processes) is often seen as a cornerstone of country efforts to improve and assure quality of care. However, accreditation is costly, the evidence of effectiveness is not straightforward and a move to develop accreditation programmes may leave out other crucial foundational quality improvement measures. This document does not aim to outline a position for or against accreditation. Rather, it suggests that any decisions on accreditation need to be made cautiously, carefully evaluating quality interventions that may need to precede or complement accreditation, evaluating costs and securing resources to support sustainable quality improvement in accredited facilities, making important decisions on scale and coverage, and including the people working in these organizations and the communities benefiting from the care they provide.

Standalone accreditation programmes are probably insufficient to drive comprehensive quality changes that will improve population health. Instead, they should be seen as one option in a suite of interventions that must be carefully planned and integrated within each context.

WHO proposes the following 10 key points to help national decision-makers or policy-makers to understand how or whether to implement an accreditation programme in their setting:

1 Due care should be taken when considering, planning or implementing accreditation programmes to ensure that they are aligned with commitments to universal health coverage (UHC) and quality essential health services with a people-centred approach. Accreditation can risk skewing demand and supply, and exacerbating inequalities in standards of care; this should be considered before making any decision to implement. All accreditation processes should place improvement in the quality of care for patients and the overall population at the heart of efforts.

2 Accreditation is a lengthy, expensive and recurrent process that requires funds to be allocated, especially in low-resource settings, to support quality improvements and the achievement of standards at target facilities. Attention should be given to careful assessment of costs and opportunity costs in relation to potential benefits from accreditation versus other quality improvement processes. Thus, those responsible for health financing need to be involved in decision-making related to accreditation.

3 Decision-makers will need to understand how the accreditation programme fits into the wider health system, ensuring integration into other national or subnational initiatives focused on quality of care. This involves a careful appraisal of alternative or complementary interventions. This may involve sequencing interventions, starting at basic assessments and improvements to essential functions and infrastructure (e.g. water, sanitation and hygiene, and trained workforce) and moving up the external evaluation spectrum, potentially starting from the simpler option of licensing before moving towards accreditation. Any external evaluation or accreditation programme should either incorporate the more foundational processes further down this spectrum or ensure that these are otherwise fulfilled before developing more complex interventions. Accreditation may need to be considered in longer-term plans once short-term foundational goals have been achieved.

4 Accreditation should be viewed as one intervention to support the continuous process required to improve quality of care and processes in the target facility or organization, as opposed to a "one-off" achievement of accreditation status. Standards should be set that outline improvement goals and steps, and re-accreditation cycles should measure successive improvements over multiple cycles.

5 Accreditation programmes should involve health workers and the public from their inception, valuing and carefully considering their views and concerns as the potential beneficiaries of programme implementation. Health workers of all cadres are central gatekeepers and drivers of quality of care, and should be supported before and throughout accreditation cycles. Likewise, patients, the public and communities hold critical information on quality of care and should be involved before and during decision-making.

6 Accreditation programmes themselves must comprise high-quality, independent structures and processes. Given the significant variation worldwide, accreditation programmes are only as useful and effective as the processes and standards used in each case. These should be context-specific, with tools and standards tailored to each setting's need and capacity, and developed within and for unique health systems. However, a careful balance must be made between local adaptation and standardization, ensuring optimal accreditation standards that both allow assessment and recommend improvements, and that align with national or global standards.

7 Accreditation should be a supportive process, not a punitive one. The health workforce should be supported throughout any external evaluation process, and their engagement and satisfaction should be monitored and maintained. Facilities or services found to be below required standards should be provided with optimal support to sustainably achieve the necessary improvements.

8 People-centred primary health care, community engagement, health emergency preparedness and effective wider public health functions are critical to UHC, and they warrant a rethink of traditional accreditation processes. New accreditation models may wish to focus on primary care, user experience of health services, care packages for clinical pathways of certain conditions, community or public health services, or health facility preparedness and resilience.

9 The global body of research on external evaluation or accreditation is incomplete. Notably, evidence is lacking on accreditation in LMICs; the impact on health workers, patients, the public and communities; and cost-benefit or cost-effectiveness. Evaluation and research on accreditation programmes, with a focus on these and other gaps, are required for an evolving global knowledge base on the subject.

10 Further systematic learning from country experiences on design, redesign and implementation of accreditation programmes and its linkages to quality of care is vital. This paper calls for learning to be generated and shared throughout the global community working to improve quality of care.

5. Questions for health system policy-makers and decision-makers

This section aims to support discussions with and within ministries of health on how, when and whether to implement an accreditation process for their health services. This is neither a complete tool nor a prescriptive process, but instead should be used as a guide to start considering key policy questions in relation to accreditation. These questions are all interrelated and link to the discussion in Section 3 on strategic considerations. The questions may be adapted to specific country settings and can be used to inform a situational analysis, guide policy or strategic dialogue, or help set local research and learning agendas.

1 Understanding the health system assessment and evaluation landscape

a. Do health services or organizations partake in voluntary accreditation programmes? How is that affecting patient demand, equitable access and funding to those facilities? Is it exacerbating a two-tiered (or multitiered) health system in which accredited facilities are not accessible to all and receive a disproportionate amount of funds?

b. What health services monitoring and assessments are currently undertaken in or about your health services? Are these data currently effectively used for quality improvement processes?

c. What other national external evaluation processes exist (e.g. periodic health facility assessments, facility supervisions, licensing, certification)? Are these used to their maximum benefit and are they explicitly linked to efforts to improve quality of care?

d. Could a national accreditation (or broader external evaluation) programme bring together the processes listed above? Would this be of sufficient additional benefit to warrant the extra cost?

2   Integration into a coherent and comprehensive quality improvement plan

a. Is there a national quality strategy or policy and associated quality leadership at the ministry level? How are existing external evaluation or accreditation processes linked to or embedded within that strategic effort?

b. Is accreditation being considered in a suite of quality initiatives and interventions that are appropriate for the context and linked to sustainable funding?

c. What are the strategic and operational linkages between accreditation and quality of care efforts at various levels of the system (facility, district and national)?

d. Are foundational quality interventions being undertaken; for example, related to water and sanitation, basic infrastructure and equipment, workforce competencies, training and supervision, and equitable health service coverage?

e. Are sustainability and continuous improvement considered and embedded within accreditation programmes?

3   Understanding costs and money flows

a. Is your health financing system involved in an accreditation process?

b. Is any funding linked to accreditation equitable or does it risk exacerbating a quality divide (e.g. between primary and secondary care or public and private services)?

c. What are the direct and indirect costs of accreditation? Have the full financial implications, including potential support to facilities requiring (continuous) actions to meet and maintain standards, been recognized?

d. Are the costs and opportunity costs of accreditation fully understood and has an options appraisal weighing up costs and benefits of alternative interventions been undertaken?

e. What policy decisions will be made based on accreditation decisions regarding, for example, whether facilities remain open and how funding flows?

4   Quality and standards within the external evaluation processes

a. Does the country have up-to-date national clinical guidelines, quality of care and other standards necessary to inform the planning and accreditation standards?

b. What external evaluation processes already occur nationally?

   i.   Have these processes been quality assured? Is the impact on quality, workforce, organizations and the public known? Are cost-benefits understood?

   ii. Is there a process to report and understand any adverse impacts of accreditation?

   iii. Are bottlenecks or challenges in previous or current initiatives understood?

c. Are methods to understand and measure costs and impacts built into the accreditation process from the start?

d. Are accreditation standards appropriate and contextualized? Are they appropriately comprehensive (e.g. do they include health resilience and preparedness elements)?

e. Are accreditation standards linked to other monitoring and evaluation processes such as primary health care? If not, could they be?

f. Has a stakeholder analysis been undertaken? Have the required multisectoral stakeholders been involved in the programme?

g. Have all levels of the health system (primary to tertiary) and models of care been considered; for example, could a novel framework for accreditation (e.g. focusing on patient pathways) be more effective?

h. Have the views and needs of health workers, communities, patients and the public been taken into account? If so, is this sufficient?

i. Has the independence of the external evaluation organization and process, and individuals involved in this process, been assessed? Are there any potential conflicts of interest?

j. Is accreditation data publicly shared? If not, could it be?

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