PHCPI is a partnership dedicated to transforming the global state of primary health care, beginning with better measurement. While the content in this document represents the position of the partnership as a whole, it does not necessarily reflect the official policy or position of any partner organization.
Quality management includes three interlinked concepts, necessary to enhance quality across the health system: quality planning, quality control, and quality improvement [2].

- **Quality planning** includes aims, processes, and goals needed to create an environment for continuous improvement.
- **Quality control** entails monitoring established processes to ensure their functionality.
- **Quality improvement** is the action of every person working to implement iterative, measurable changes, to make health services more effective, safe, and people-centered.

### WHAT IT IS: WHAT IS QUALITY MANAGEMENT INFRASTRUCTURE AND WHY IS IT IMPORTANT?

Identification and implementation of appropriate quality interventions can have a significant impact on specific health services delivery and on the health system at large. Most approaches to national quality strategy development involve one or more of the following processes:

1. a quality policy and implementation strategy as part of the formal health sector national plan;
2. a quality policy document developed as a stand-alone national document, usually within a multi-stakeholder process, led or supported by the ministry of health;
3. a national quality implementation strategy - with a detailed action agenda - which also includes a section on essential policy areas;
4. enabling legislation and regulatory statutes to support the policy and strategy.

The predominant functions of governing quality of care at the national and subnational levels encompass leadership and management; the establishment of laws and policies; regulation; monitoring and evaluation; planning; and financing mechanisms [3]. A well-considered national quality strategy and operational plan are critical to institutionalizing quality management. It is important that quality management structures are developed with buy-in from stakeholders at every level: fostering a “culture of quality” is as important to the success of quality infrastructures as having a plan in place. Quality cannot be “inspected into” PHC systems if clinical staff are not committed participants - national mandates for quality improvement need supporters and champions. At the same time, that culture alone is not sufficient to guarantee safety, efficiency, and accountability [2].

Listed below are three central questions stakeholders should consider for strengthening the quality management infrastructure in their health system:

- What are the steps to quality management reform?
- What are some key pathways to developing quality management infrastructure that ensures quality and improves PHC functions and outcomes?
• What are some challenges to developing quality management infrastructure?

There are tools, guides, and example policy documents listed in the relevant resources section of the Governance and Leadership homepage and referenced below, which go into greater detail about the steps to planning and institutionalizing quality management structures, including potential challenges and how to meet them. Some are highlighted below; we encourage readers to make use of the resources compiled and described in the relevant resources section to assist with these efforts.

**WHAT ARE THE STEPS TO QUALITY MANAGEMENT REFORM?**

**Have an organizational infrastructure in place** *(national policy document)* that can plan, oversee, and shepherd the institutionalization of the quality management infrastructure. This should include people who represent all components of society (planners, practitioners, consumers) touched by PHC quality structures, and a designated leader with clear accountability [4].

**Ensure quality policy and quality implementation strategy** *(WHO, Health Finance & Governance Project)* are integrated *(WHO)* as part of the formal health sector national policies, programs, and strategies [2,3,5,6].

1. Develop a quality policy document *(WHO)* as a stand-alone national document, usually within a multi-stakeholder process, led or supported by the MOH [5].
2. Develop a national quality implementation strategy, creating intercountry, national, and regional partnerships with a detailed action agenda [2,3,5,6].
3. Elements that should be considered *(WHO)* in developing a national quality policy and strategy include [5]:
   - National health goals and priorities
   - Local definition of quality
   - Stakeholder mapping and engagement
   - Situational analysis
   - Governance and organizational structure
   - Improvement methods and interventions
   - HMIS and data systems
   - Quality indicators and core measures
4. Incorporate performance measurement *(national policy documents)* through collection, analysis, and reporting of information regarding health system performance [4,7].

**Prioritize interventions likely to have a high impact on quality** *(WHO)*, including: reducing harm to patients, improving clinical effectiveness, creating an enabling systems environment, and engaging patients, families, and communities [8].

1. Interventions around reducing harm include inspections of institutions for minimum safety standards, safety protocols and checklists, and adverse event reporting;
2. Interventions around improving clinical effectiveness include clinical decision support tools, clinical standards, pathways, and protocols, morbidity and mortality reviews, and collaborative and team-based improvement cycles;
3. Interventions around enabling systems environment include registration and licensing, external accreditation, clinical governance, and public reporting;
4. Interventions around engaging patients, families, and communities include formalizing community engagement and empowerment mechanisms, health literacy, shared decision making, peer support and expert patient groups, patient experience of care, and patient self-management tools [8,9].
Focus on strengthening areas (WHO) that are characteristic of a well-established quality program, including information collection and sharing, formal policy process in which partners at every level contribute to its development and long-term sustainability, and an executive function with autonomy within or outside government [2].

WHAT ARE SOME KEY PATHWAYS TO DEVELOPING QUALITY MANAGEMENT INFRASTRUCTURE?

Commit to legislation and regulatory statutes (WHO) to support the effectiveness of policy and strategy by: establishing guidelines, protocols, and standards for service delivery; requiring certification and licensing of health professionals using standards and guidelines; and using accreditation measures to make sure facilities and providers are delivering a minimum quality of service [2,3,5].

- Intentionally working across different health sector institutions and stakeholders outside the government such as health professional associations has the potential to achieve buy-in as well as gain additional resources for developing and implementing regulation [3].
- A clearly stated commitment from leadership to institutionalize quality of care throughout the health system is critical to strengthening the foundation of quality management infrastructure [9].

Establish well-designed health information and monitoring and evaluation systems (WHO, Health Finance & Governance Project) that routinely collect and publish data on quality health systems, as well as external assessment through peer review and accreditation [2,3,9].

- Develop mechanisms (WHO) to ensure that accreditation and licensing standards and standards of care are met across public and private sectors [2].
- External accreditation (WHO) of health services is one approach taken by many countries to disseminate national standards and maintain public accountability [2].

Ensure adequate financial and non-financial resources (WHO) for quality improvement [2]. Quality improvement practices can be resource-intensive, and it is important to consider the priorities and trade-offs, and plan for potential areas of resistance or challenge. A culture of learning on quality across the health system must be nurtured, including at the facility, sub-national, and national levels [9].

Some of the critical resource considerations include [2]:

- Time spent by clinicians and providers in trainings, records departments, and discussing standards, measurements, and action plans is time they are not spending in clinics.
- Data, information, and guidance: Clinical and management staff need access to standards, practical guidance on tested quality improvement methods, and examples of results - these must be gathered and developed for local use.
- Funding: The cost of staff time, and how to best use it, is a critical resource question at all times. Direct costs of quality improvement programs include quality support staff, training, data collection and access to information.

Coordinate quality systems (WHO) with national and/or local government to ensure valid standards, reliable assessments, consumer involvement, demonstrable improvement, transparency, and public access to quality criteria, procedures, and results [2].

Embrace a continuous process (WHO). Timelines of implementers and governments do not always line up - the process of institutionalizing quality management infrastructure can take as much as 5-8 years, while the people involved in the structures might change more quickly. “In using external technical assistance to set up quality systems, attention should be given to ensuring that transferred know-how becomes fully
institutionalized" [2]. Managing people and modifying culture are critical to succeeding with quality improvement processes - and it doesn’t all happen at once.

Involving communities in the process in meaningful ways (national policy documents) - they are a key stakeholder in quality service delivery [4,7].

- Strategies to solicit user and community perspectives include focus groups, key informant interviews, exit interviews, user satisfaction surveys, consumer advisory boards, needs assessments, community membership on hospital quality committees, and suggestion boxes [10].

WHAT ARE SOME CHALLENGES TO DEVELOPING QUALITY MANAGEMENT INFRASTRUCTURE?

Constrained financial, human, and infrastructure resources (peer-reviewed article) can hamper effectiveness of accreditation [11]. This can be overcome through efforts to establish leadership commitment and regulations to implement accreditation, to allocate sufficient financial resources, and to ensure the availability of data and facilitate its use [11].

Problems of managing change (WHO), and particularly failure to change the behavior of people and organizations [2]. Quality improvement is important - but hard. Its success or failure can often result from motivating, and modifying, behavior and culture.

- Strategies for managing change (WHO, Health Finance & Governance Project) to improve health service quality (national policy document) include focusing on [2,3,7]:
  - Information, including feedback on performance, benchmarking with peer groups, and collecting data to identify the need for change
  - Leadership management and staff support, including avoiding blame, providing training, and incentives to motivate for improvement
  - Re-configuring and re-engineering policy and organization systems towards population and patient needs
  - Public involvement: obtaining support for change through consultation and transparency.
  - Committing resources for quality improvement.

Health systems structure (WHO), for example a vertical, disease-focused system versus one with comprehensive targets. Often countries already have quality initiatives, which might be focused around specific technical areas or populations. Careful planning is necessary in order to successfully integrate these efforts with work on national quality [5,6].
WHAT OTHERS HAVE DONE: WHAT HAS BEEN DONE ELSEWHERE TO IMPROVE PRIMARY HEALTH CARE POLICIES

ETHIOPIA: STRENGTHENING REGULATORY CAPACITY

In Ethiopia, the Federal Ministry of Health is committed to developing a resilient health system that is accountable to all of its stakeholders, including government, communities, patients, service providers, and professional associations [12]. The government is the main health service provider in Ethiopia, and the autonomous regulatory body, the Health and Health-Related Services and Products Regulatory Agency, is funded by the Federal Ministry of Health to license and monitor health professionals, facilities, and delivery processes in both public and private sectors [13]. In addition, the Ethiopian Food, Medicine and HealthCare Administration and Control Authority is charged with performing quality assurance activities in both private and public sectors, with a particular focus on issuing licenses, registrations, and certifications for professionals, premises, practices, and products [14]. The National Health Care Quality Strategy aims to “consistently improve the outcomes of clinical care, patient safety, and patient-centredness, while increasing access and equity for all segments of the Ethiopian population, by 2020” [5,14,15].

Challenges to the country’s regulatory capacity have included a lack in uniformity of the regulatory structure at the local level, insufficient attention to health regulatory systems in some regions, and overly specific focus on limited areas within the health regulatory framework in others [16]. The Federal Ministry of Health and other federal agencies are key players in influencing many of the important aspects of quality delivery within health care. They have several levers to influence quality, primarily oriented around patient-focused interventions, regulatory interventions, incentives, data-driven interventions, organizational interventions, and health care delivery models [14]. Quality-focused regulations can set specific standards, requiring health providers to comply with certain policies, but there is flexibility built in to allow health care or professional organizations to prescribe their own rules [13]. This potential for flexibility allows regulators to monitor the perceived competence of provider institutions to produce the desired outcome of the regulation and provide more, or less, extensive oversight depending on their level of confidence [13].

According to Ethiopia’s Minister of Health from 2012-16, “accountability to communities and accountability to professional standards of care based on current evidence are both essential for resilient health systems” [12]. Health systems cannot be reformed or reshaped swiftly, so commitment to the time and persistence required to make important changes is essential [12], and Ethiopia’s health system strengthening efforts are an emblematic example.

KENYA: QUALITY IMPROVEMENT ACTIVITIES

In Kenya, efforts are underway to embed quality improvement approaches into the core of national health programs and community health practices [17]. Pathways to developing a systematic focus on quality include efforts to strengthen the national coordination of community health programs. They involve building the capacity of county-level decision makers to effectively prioritize and plan for equity-oriented community health programs. And they include improving the quality and performance of community health programs by generating demand through engagement with communities [17,18].

Locally, health service boards and health facility governing committees are two types of citizen-engagement programs being established to increase accountability through community participation [19,20]. In addition, in response to the need for greater sensitization of health managers and providers to the notion of quality and the benefits a quality focus could have in the work of health providers and the outcomes for their patients, the Kenyan Ministry of Health has created a Kenya Quality Model for Health that includes a training course to guide health staff and managers in strengthening quality management in every setting, from health service delivery to health policy development [21,22]. Nationally, the Ministry of Health anchors quality
improvement methodology and processes within regulation to receive licenses and rewards [3]. In order to receive licenses, and to have them renewed, facilities have to show evidence of quality improvement processes - for example, establishment of improvement teams, demonstration of clinical audits, and regular feedback loops [3].

Community engagement is critical to ensuring health services are designed, delivered, and monitored in such a way that they meet local health needs, but Kenya’s experience shows that work must be done throughout the whole system to ensure that quality in community health services reflects values demonstrated at service delivery, management, and policy levels as well [23,24]. In a context of institutional readiness - where community health programming and functions are in alignment with national guidance and managers are committed to supporting quality improvement activities - quality-oriented efforts are most likely to be successful and sustained [23].

MALAYSIA: FOCUS ON QUALITY MANAGEMENT

In Malaysia, the Ministry of Health is the main provider of health care, through an extensive network of hospitals and health facilities [25]. The population has historically had fairly equitable access to health services, but as private sector health services have increased, facilitated by Malaysia’s privatization policy, they have largely focused on more affluent urban areas [25,26]. The Ministry of Health began implementing quality improvement efforts in its hospitals as far back as the 1980s, ahead of the national government’s adoption of quality management directives [25]. Malaysia defined its Strategic Plan for Quality in Health in 1998, institutionalizing a regulatory structure which must prove a given level of progress or health improvements for both private and public facilities [3]. Malaysia’s accreditation body, the Malaysia Society for Quality in Healthcare, has certified 80% of government hospitals, and the private sector receives comparable oversight [27]. In addition, the private sector is represented in the patient safety council, committed to establishing a safe Malaysian health care system [3]. Benchmarking is a key component of the National Indicator Approach for monitoring, with a goal of encouraging MOH-overseen hospitals and health facilities to compare their performance [27]. At local levels, there is an expectation that hospitals and districts will discover, analyze, and take action to remedy problems even before they are informed of their performance at the national level [27].

In Malaysia public spending is oriented towards pro-poor practices, which has resulted in greatly reduced inequity in access to health care compared to many other countries [25]. In public hospitals, quality management components in regular practice include commitment to leadership and management, partnership with suppliers, continuous improvement, involvement and training of employees, strategic planning, teamwork, and quality assurance activities [25]. This institutionalized commitment to a culture of quality management means that even as the country’s health care practices are increasingly privatized, equity in quality of care will continue to be prioritized.
WHAT TO ASK: WHAT QUESTIONS SHOULD BE CONSIDERED TO BEGIN IMPROVEMENTS?

The questions below may be a useful starting place for assessing innovation and learning in your context and determining whether it is an appropriate area of focus and how one might begin to plan and enact reforms.

ARE COMPREHENSIVE PHC POLICIES IN PLACE OR BEING DEVELOPED? AND IS THE CURRENT LEGISLATIVE ENVIRONMENT PREPARED TO SUPPORT THE STRATEGY?

If so, opportunities might exist to work in tandem, or build off those existing or developing policy processes, to take advantage of momentum and lessons learned. Policy considerations for national quality strategy development include who the stakeholders in quality in health care are, whether there is a need for a national integrated program, who should be consulted in developing a program, what relevant legislation already exists, the government’s role in developing a program, and whether mechanisms should exist to integrate external support for quality, such as from WHO or the World Bank [2].

WHAT SUSTAINABILITY MECHANISMS SHOULD BE PUT INTO PLACE? IS THERE A PLAN FOR HOW THIS CAN BE A CONTINUING PROCESS THAT REGULARLY REVISITS THE DIFFERENT KEY STEPS, AND WHAT ARE THE OPPORTUNITIES TO EDUCATE USERS AND IMPLEMENTERS TO ENCOURAGE OPPORTUNITIES FOR IMPROVED PROCESSES?

WHO member states and working groups have convened periodically over the last two decades to discuss quality assurance in health care and make recommendations for facility-, national-, and international-level actors to promote acceptance, improve training activities, and improve linkages between countries and agencies [2]. Much of these learnings and recommendations have been consolidated in the appendix of the WHO report, Quality and accreditation in health care services: a global review. Taking the time to figure out what processes are feasible and what is appropriate in each country’s context is an important step in determining how to proceed with sustainable quality management activities.

IS THERE CLEAR ACCOUNTABILITY FOR QUALITY AT ALL LEVELS OF SERVICE DELIVERY? WHAT RESOURCES ARE NEEDED TO ENSURE ACCOUNTABILITY AND FEEDBACK SYSTEMS ARE IN PLACE AND USED?

Practical considerations for accountability resourcing includes what information is available about quality improvement methods, how this information could be made more accessible and exchanged, what data are collected locally that could be used to measure quality, whether clinical data are aggregated and made routinely available to clinicians, whether new information technology systems are designed to support quality improvement, and what kinds of funding and resources are needed to set up quality systems, such as for coordination, information, data management, and training [2].

ARE STAKEHOLDERS PREPARED FOR THE ONGOING, LONG-TERM INVESTMENT IN CHANGES TO CULTURE AND BEHAVIOR NECESSARY FOR SUCCESSFUL CHANGE MANAGEMENT?

Successful adoption of quality improvement mechanisms requires that individuals and organizations change behaviors. Change management includes the actions and steps that facilitate the transition of an individual, group, or organization from their present state to a future desired state of being [28]. This is an ongoing process and requires multiple steps and strategies, including assessing readiness for change, ensuring
environmental support - such as additional financial and human resources, developing and implementing pilots and plans, and anchoring change within an organization [7,28,29]. Health teams are encouraged to begin with simple changes in order to build success, improve morale, and create momentum to undertake more complex interventions [30]. Adopting change management practices and focusing on the individuals and groups involved can increase the likelihood that change will be successful: people, in organizations, are the ones who do, or do not, make change happen [28].

**HOW WILL THE SPECIFIC RESPONSIBILITIES OF EACH MAJOR BODY OR POSITION BE DEFINED?**

Organizational considerations should include which organizations are currently active in promoting quality improvement and how they relate to the Ministry of Health, whether a task force or committee is needed to establish a national program, and if so, who should represent what stakeholders and who should coordinate quality improvement at hospital/clinic level [2].

**HOW ARE COMMUNITIES, PATIENT ORGANIZATIONS, AND COMMUNITY- AND FAITH-BASED ORGANIZATIONS REPRESENTED WITHIN EXISTING HEALTH SYSTEM GOVERNANCE STRUCTURES?**

Differences in culture and attitudes are critical considerations that should be built into the processes of training and of management. While national plans often mention this, less common are the steps to actually identify where funding will come from and who will be responsible for ensuring these elements are actually considered [2]. Similarly, different organizations must have opportunities to connect, internally and between one another, to link quality activities and share policies and culture. Considerations of equity and inclusion must be factored into clinical decision-making, budgeting and financial systems, and the development of human and other resources [2].
HOW TO SUCCEED: WHAT ELEMENTS SHOULD BE IN PLACE TO SUPPORT EFFECTIVE IMPROVEMENTS?

PRIMARY HEALTH CARE POLICIES AND LEADERSHIP

Quality management infrastructures must be built upon, and by, appropriate and considered PHC policies and leadership. Good governance is a fundamental contributor to an environment that accommodates quality management. Because quality management is a continuous process it is reliant on sustainability planning that is built into strong PHC policies.

More information can be found in the PHC Policies Improvement Strategies module.

SOCIAL ACCOUNTABILITY

Transparency is an important aspect of social accountability, and a vital element for supporting quality assurance and improvement, mitigating corruption, and increasing effectiveness [3]. Social accountability mechanisms should be in place to ensure community members are able to monitor and react to health systems interventions and changes, as well as to engage community members in identifying barriers to care and interventions to improve access and quality. In terms of supporting quality management infrastructures, accountability mechanisms can involve explicit understanding of how services are supplied, financing to ensure adequate availability of resources to deliver essential services, information to monitor and evaluate these processes, and capacity to impose sanctions or provide rewards depending on performance [31].

More information can be found in the Social Accountability Improvement Strategies module.

HEALTH FINANCING: SPENDING ON PRIMARY HEALTH CARE

Countries contemplating national quality programs must commit the fiscal resources necessary for personnel and data systems to conduct effective quality management activities. This includes resources for communications and exchange of information; ongoing opportunities for staff and provider training in quality improvement activities; support from health and research institutions to district and local level providers to develop skills and knowledge in quality assurance; and the identification and funding of research priorities related to quality planning, control, and improvement [2].

More information can be found in the Health Financing Improvement Strategies module (forthcoming).

ADJUSTMENT TO POPULATION HEALTH NEEDS

This includes surveillance and routine information collection of information about population health status and needs in order to support priority setting, innovation, and learning. These are essential processes that feed back into strong quality management structures and processes, informed by accurate and up-to-date evidence.

More information can be found in the Adjustment to Population Health Needs Improvement Strategies module.


11. El-Jardali F, Hemadeh R, Jaafar M, Sagherian L, El-Skaff R, et al. The impact of accreditation of primary healthcare centers: successes, challenges and policy implications as perceived by healthcare providers and directors in Lebanon. BMC Health Services Research 2014, 14:86. [https://www.tandfonline.com/doi/full/10.1080/23288604.2016.1217966#aHR0cHM6Ly93d3cuMjQwMzA0MTMuaW1nL25vdGFuZGxvbmxpbm1lYnJrd29itaW5zdHJlZmFyLWZvZGUxYy1tdnBuZS1ub29sdmUuZ29vZ2xlLmNvbS90b29scy8yMTk4MjA2OTQuMDMwLjEwODMyNjY4MjU5MjIyNy8wLjI=/bmVlZEBAMA==](https://www.tandfonline.com/doi/full/10.1080/23288604.2016.1217966#aHR0cHM6Ly93d3cuMjQwMzA0MTMuaW1nL25vdGFuZGxvbmxpbm1lYnJrd29itaW5zdHJlZmFyLWZvZGUxYy1tdnBuZS1ub29sdmUuZ29vZ2xlLmNvbS90b29scy8yMTk4MjA2OTQuMDMwLjEwODMyNjY4MjU5MjIyNy8wLjI=/bmVlZEBAMA==)


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