

**Recommendation CM/Rec(2012)8
of the Committee of Ministers to member States
on the implementation of good governance principles in health systems**

*(Adopted by the Committee of Ministers on 12 September 2012
at the 1149th meeting of the Ministers' Deputies)*

The Committee of Ministers, under the terms of Article 15.b of the Statute of the Council of Europe,

Considering that the aim of the Council of Europe is to achieve greater unity between its members and that this aim may be pursued, *inter alia*, by the adoption of common principles in the health sector;

Recalling the Warsaw Declaration (2005) wherein it is stated that “effective democracy and good governance at all levels are essential for preventing conflicts, promoting stability, facilitating economic and social progress”;

Having regard to its Recommendation CM/Rec(2007)7 to member States on good administration and its Recommendation Rec(2000)10 on codes of conduct for public officials;

Having regard in particular to its Recommendation CM/Rec(2010)6 to member States on good governance in health systems;

Considering that the governance of a health system plays an important role in the planning, management and performance of health systems;

Considering that all member States face similar challenges regarding the performance of health systems;

Considering that one of the objectives of the Council of Europe is to find common solutions to the challenges facing European society;

Recognising that a good governance system should contain built-in mechanisms for monitoring and evaluation, as well as performance assessment, of the health system based on clear objectives;

Considering the advisability for member States to develop appropriate tools for monitoring, evaluation and performance assessment to assist in the implementation of the principles enshrined in Recommendation CM/Rec(2010)6;

Recommends that the governments of member States use and promote the tools described in the appendix to this recommendation as a basis for the development of their own monitoring tools to assist in the implementation of the principles enshrined in Recommendation CM/Rec(2010)6;

In order to adapt tools to improve governance and further develop them within a country's context, member States could consider the following actions:

- i. evaluate and monitor the implementation of the key principles of good governance, using Tool No. 1 in the appendix;
- ii. assess the level of prevention and management of conflicts of interest in health systems, using the checklist in the appendix (Tool No. 2);
- iii. review the level of development, implementation and monitoring of codes of conduct for different stakeholders and settings, using a checklist (Tool No. 3);
- iv. carry out a health governance monitoring survey, for self-appraisal and monitoring (Tool No. 4);

Recommends that governments of member States learn from and build on national and international experience, conduct periodic updates of the tools in the light of lessons learnt and support the exchange of good practices.

Appendix to Recommendation CM/Rec(2012)8

This appendix contains:

1. a monitoring tool to assist in the implementation of the principles and to assess and evaluate the outcomes in the field of good governance: accountability, transparency, institutional/organisational arrangements, participation, equity, quality, effectiveness, efficiency, sustainability, responsiveness, integrity (Tool No. 1);
2. a checklist to prevent and manage conflicts of interest in health systems (Tool No. 2);
3. a tool for developing and assessing codes of conduct for different settings and stakeholders in the health sector (Tool No. 3);
4. a prototype of a web-based tool for public use to survey opinions on the governance of health systems (Tool No. 4).

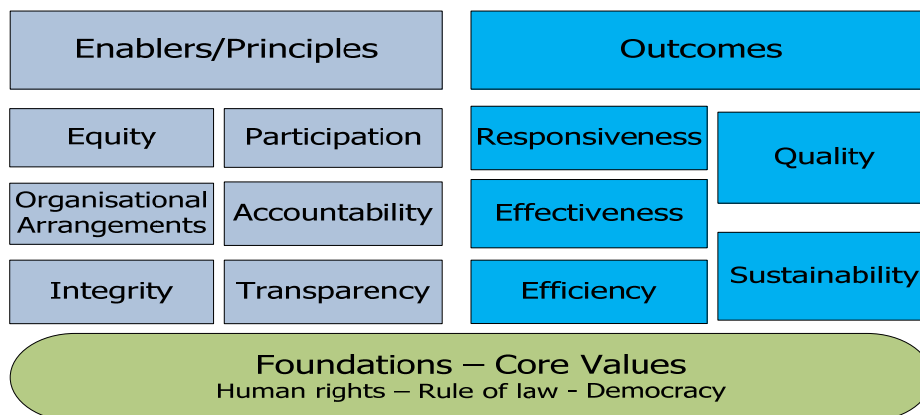
Introduction

1. Governance plays an important, albeit often unnoticed, role in all of our lives. Governance operates within and between countries and organisations and covers the economic, social, political and administrative spheres. Governance is a process of decision making that can exercise power and authority to steer actions, activities and behaviours.
2. Governance is an important dimension of the planning, organisation and performance of any area of economic and social activity. The way in which economic, political and administrative power is exercised affects a wide variety of individuals, communities, organisations and institutions across different areas, including health systems.
3. Governance in health systems is playing an ever more important role in dealing with the increasingly complex and heterogeneous nature of financing and providing health care; tackling fraud and corruption; managing the rising costs of many interventions and medicines; increasing efficiency; improving equity, effectiveness and quality; enhancing patient safety; addressing adverse events and responding to the needs and increasing demands of service users.
4. Governance plays an important role in all aspects of health systems: from the daily interactions between patients and health care professionals to funding decisions and policy making. Since many member States spend a significant proportion of their Gross Domestic Product (GDP) on health care, it is important that they take measures to lead, direct and control functions related to their health system. Governance plays a vital role in ensuring that adequate resources are correctly allocated in order to achieve the health systems' objectives.
5. In response to this, the Council of Europe has focused part of its work on contributing to a better understanding and implementation of governance in health systems. The Council of Europe regards effective governance as an essential contributor to high quality, equitable and safe health care. In contrast, the absence of effective governance is often at the heart of many health care service failures. Out of a growing concern for the effects of poor governance in health systems and recognising the potential positive impact of good governance, the Committee of Ministers adopted Recommendation CM/Rec(2010)6 and recommended its member States to take steps to implement good governance in health systems. Through its European Health Committee (CDSP), it also instructed a new committee of experts to examine how member States can effectively implement good governance.
6. The explanatory memorandum that accompanies Recommendation CM/Rec(2010)6 proposes a conceptual framework consisting of three components: fundamental values, principles and outcomes. The Committee of Ministers recommends that governments in its member States take appropriate steps to use and implement this conceptual framework.
7. The conceptual framework for good governance is based on a set of universal and fundamental values and principles: human rights, democracy, the rule of law, human dignity, equity, solidarity and professional ethics. Transforming these values and principles into meaningful and effective actions forms a real challenge, in particular in a difficult economic climate.

The conceptual framework

8. This recommendation is mainly concerned with the assessment of and advice on how to improve good governance of health systems by member States. In its preparation, particular account was taken of:

- i. knowledge of current and evolving (good) practice in the member States and internationally;
- ii. the conceptual framework for governance in health systems, as outlined in the explanatory memorandum to Recommendation CM/Rec(2010)6. The figure below illustrates how the values, principles (enablers) and outcomes of good governance interact with each other. These values, principles and outcomes are considered as “attributes” of good governance in the tools outlined in this recommendation;



iii. the fact that the tools presented in this recommendation may have to be adapted by member States to their respective country context and/or complemented by other mechanisms and methods suited to improve the governance of the respective health systems.

9. In the preparation of the recommendation, the following background documents were also prepared:

- conflict of interest;
- implementing good governance principles in health systems;
- monitoring good governance;
- improving governance: methods and tools;
- voluntary codes of conduct as an instrument of good governance in the health sector;
- equity and equality.

10. This recommendation should be implemented in line with Recommendation CM/Rec(2010)6 and the tools mentioned therein. They attempt to help member States to identify the strengths and weaknesses of their current health governance arrangements and ways in which they can improve them and monitor progress.

How to use the appendix to the recommendation

11. Recommendation CM/Rec(2010)6 recommends that member States take appropriate steps to ensure good governance of health systems, including capacity development measures. The actors involved in the governance of health systems are many and diverse, and may include policy makers, chief executive officers of hospitals, purchasing managers, physicians conducting clinical trials, pharmaceutical companies selling products, patients who wish to be seen first, etc. Since there are so many different interactions and encounters at any given time in the delivery and management of health care, leaders need to be aware of the challenges involved in ensuring good governance.

12. Actions taken by member States should provide new experience and evidence as a basis for monitoring policy analysis and practice that can contribute to national and international policy and practice reviews.

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TOOL No. 1

Introduction and instructions with regard to a computer tool to evaluate and monitor key attributes of good governance of health systems

Introduction

1. This tool is designed as a practical and applied instrument for evaluating and monitoring 11 key attributes of good governance of a health system and its constituent parts at all levels (regional health services, institutions such as hospitals, etc.).
2. It can be used for a Delphi-type exercise and as a survey instrument. If used regularly, it can help to track the evolution of these key attributes of good governance in a particular setting.
3. The instrument is not intended to provide a composite (or “scientific”) indicator of good governance in health systems; such tools can be found elsewhere in international literature on the topic. However, it can be used as a management instrument, highlighting different attributes and aspects of good governance.
4. The attributes selected are: 1. accountability; 2. transparency; 3. institutional/organisational arrangements; 4. participation; 5. equity; 6. quality; 7. effectiveness; 8. efficiency; 9. sustainability; 10. responsiveness and 11. integrity.
5. The tool is in a spread sheet format (Excel of MS Office), which is widely available, and can be easily used with non-proprietary formats such as Open Document.
6. The instrument is very flexible and can be easily customised to fit specific needs or contexts. If used for different social or interest groups, it can highlight different perspectives of the same attribute within a society.
7. The instrument is offered as a prototype, “as is”, without any commitment to further developing it or to providing a template for analysis of multiple users-respondents. Therefore, it can be complemented, shortened, modified or further developed by others.

Description of the tool

8. The instrument is built around the first page (Figure 1) which serves as an index with hyperlinks leading to each of the 11 attributes, a glossary page and a page of key references, whenever possible with web links.
9. Each attribute page has the following components and arrangement:
 - i. an operational definition of the attribute in question;
 - ii. cells for rating the importance of this attribute on a 1-10 scale (the relative weight with regard to other attributes);
 - iii. a non-exhaustive list of “examples of good practice”, or aspects of good governance that conform to or exemplify the attribute of good governance under consideration;

iv. a row of cells for assessment and rating of different aspects of each of the concrete examples of good practice related to the attribute under consideration:

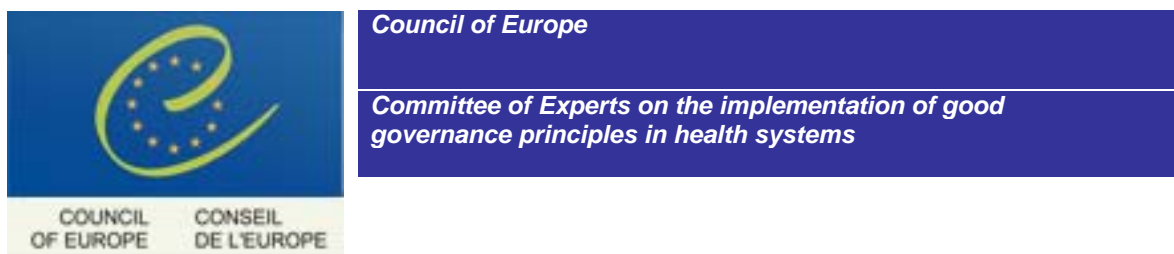
- a. rating of importance (very high, high, medium, low);
- b. level of achievement (1-10);
- c. stage of development:
 - "Plan": is the respective aspect planned for?
 - "Do": are planned activities implemented?
 - "Check": is the level of achievement evaluated?
 - "Act": are plans adapted to lessons learnt?
- d. remarks and comments.

Instructions for the tool

- 10. To begin, save the file with a different name.
- 11. For each attribute review the examples; take those that are relevant to your own situation/context and feel free to add any other as appropriate or necessary.
- 12. Review and evaluate each attribute and fill in the cells with the values reflecting your own assessment.
- 13. If you are using the instrument as a survey questionnaire, you should prepare a system for the development of a database to compile the responses.

		Is this aspect planned for?	Are planned activities implemented?	Is the level of achievement evaluated?	Are plans adapted to lessons learnt?	
Rating of importance	Level of achievement (from 1 to 10)	Stage of development PLAN	Stage of development DO	Stage of development CHECK	Stage of development ACT	Remarks/ Comments

Figure 1



Tool No. 1
Good governance of health systems
Evaluation and monitoring instrument

Links to:

- [Attribute No. 1: Accountability](#)**
- [Attribute No. 2: Transparency](#)**
- [Attribute No. 3: Institutional/organisational arrangements](#)**
- [Attribute No. 4: Participation](#)**
- [Attribute No. 5: Equity](#)**
- [Attribute No. 6: Quality](#)**
- [Attribute No. 7: Effectiveness](#)**
- [Attribute No. 8: Efficiency](#)**
- [Attribute No. 9: Sustainability](#)**
- [Attribute No. 10: Responsiveness](#)**
- [Attribute No. 11: Integrity](#)**

Links to:

- [Glossary](#)**
- [References](#)**

Attribute No. 1 – Accountability

Examples of good practice (non-exhaustive list)	
1.	The division of tasks and the assignment of responsibilities (chains/lines of accountability) are clearly defined, established and publicly available.
2.	The chain of accountability for financial performance is clearly defined, established and publicly available.
3.	The chain of accountability for performance and quality of services is clearly defined, established and publicly available.
4.	Existence of a system to measure, review and improve processes, results/performance, outcomes and impact, using different instruments such as quality management systems, peer reviews, etc.
5.	A system for redress, fair settlement of complaints and disputes, and compensation.
6.	Clear and transparent criteria for the allocation of financial resources taking into account health needs and addressing economic/social inequalities.

Attribute No. 2 – Transparency

Examples of good practice (non-exhaustive list)
1. Budgetary and financial information is publicly available, including the costs and pricing of health services.
2. Information about human resources (professional qualifications, licences, working hours, recruitment, etc.) is publicly available, clearly presented, easy to understand and regularly updated.
3. Information about results and outcomes of different health service providers and other important actors is publicly available, clearly presented, easy to understand and regularly updated.
4. Information about the quality and safety of health care and the performance of service providers is publicly available, clearly presented, easy to understand and regularly updated.
5. Patients have the right to access individual information about their own health (care).
6. Information about health care and health care related entitlements and benefits is understandable, available to the public and regularly updated.
7. Satisfaction surveys are regularly conducted and results are available to the public.
8. Information about waiting times and waiting lists is publicly available.
9. Information about decisions and decision-making processes (regulations, policies, procurement, contracting, etc.) is publicly available, clearly presented, easy to understand and regularly updated.

Attribute No. 3 – Institutional/organisational arrangements

Examples of good practice (non-exhaustive list)
1. Governing bodies to which management is accountable and administrative arrangements which must be respected are in place.
2. Appointment procedures for executives and persons in charge are clear, transparent and regularly reviewed.
3. Codes of conduct for different institutions, organisations and professional groups are established, disseminated and implemented.
4. Rules and procedures to deal with conflicts of interest are established and regularly reviewed.
5. Functions and responsibilities are clearly defined and delineated.
6. Policies and procedures for important processes are established (for example, induction for new staff members, quality management, risk management, handling of finances).
7. Provisions to combat fraud and corruption are established, disseminated, implemented and regularly reviewed.
8. Clinical protocols, guidelines and health technology assessments are established by independent, publicly accountable institutions based on transparent criteria and best available evidence.
9. Co-ordination, co-operation and consultation mechanisms between stakeholders and relevant actors are established and applied.
10. Provisions for regular internal and external audits (financial, clinical, quality) are established and applied.
11. Management information systems are established, regularly reviewed and adapted to the changing requirements and context.

Attribute No. 4 – Participation

Examples of good practice (non-exhaustive list)	
1.	Political office holders derive their powers from a democratic process.
2.	Members of governing bodies of health institutions are directly or indirectly appointed as the result of a democratic process (elections, nomination process, etc.).
3.	Provisions are established to ensure local community representation in governing bodies of health institutions.
4.	Meetings of governing bodies are regularly conducted in public and minutes of these meetings are publicly available.
5.	Professional advisory committees are in place at national, regional, local and institutional levels of the health system.
6.	There are provisions for the effective participation of patient, civil society and professional associations and organisations in policy and decision making.
7.	Effective public consultation systems for policy development are in place.
8.	Informed consent processes are in place for diagnostic and treatment procedures.

Attribute No. 5 – Equity

Examples of good practice (non-exhaustive list)	
1.	Public policies addressing socio-economic determinants of health are developed and implemented.
2.	Regular assessments of social distribution of health status, socio-economic gradients and barriers to equitable access of services are conducted and results are publicly available.
3.	Measures to improve equitable access to health care are developed and implemented.
4.	An inclusive approach to deal with specific health needs, including disadvantaged and vulnerable groups, is established and regularly reviewed.
5.	Resources, medical interventions, treatments and health care benefits are allocated and reviewed through a fair process, according to explicit criteria based on needs.
6.	Health statistics and information (management) systems provide disaggregated data and information including gender, age, socio-economic status, etc.

Attribute No. 6 – Quality

Example of good practice (non-exhaustive list)	
1.	Comprehensive quality management systems are established (legislation, regulations, implementation guidelines and monitoring systems, etc.).
2.	Compulsory safety standards are issued (blood safety, waste management, food safety, radiation protection, etc.) and implemented. Compliance is monitored and enforced.
3.	Results and outcomes of medical interventions and treatments are measured, benchmarked and reported through agreed indicators.
4.	Levels of achievement of high quality services are publicly acknowledged and rewarded.
5.	Rules and procedures for the detection of unsafe practices are established and implemented, and prompt action is taken when unsafe practices have been detected.
6.	Systems of proactive risk management to identify, document, manage and minimise risks are in place.

7. National quality objectives are developed in a participatory process, publicly communicated and regularly reviewed, including standard indicators per level and kind of services.

8. Health care quality management training and continuous education is established, controlled for quality and standardised (for different levels and types of staff, managers and decision makers).

Attribute No. 7 – Effectiveness

Examples of good practice (non-exhaustive list)

1. One or, where appropriate, two national, autonomous agencies/institutions should be established to review the effectiveness of clinical interventions, products, equipment and policies.

2. A system of clinical audits exists, the results are disseminated and actions necessary to improve clinical effectiveness are taken.

3. Objectives and targets of policies and programmes are set and evaluated, and levels of achievement are monitored at regional and national levels.

4. A strategy exists to evaluate the effectiveness of established and new clinical practices and interventions.

Attribute No. 8 – Efficiency

Examples of good practice (non-exhaustive list)

1. A national, independent institution (for example, an audit office) regularly conducts reviews on the economic behaviour and efficiency of health care financing, organisation and provision.

2. Specific studies on the best use of resources (“value for money”) for given objectives are commissioned, conducted and results are taken into account when formulating policies and strategies.

3. Cost accounting systems are in place and linked to the performance of health care provision (for example, cost per patient) and they are used for monitoring purposes.

4. Only medical health care technology (medical procedures, equipment, interventions, etc.) that has been scientifically proven to be beneficial is used.

5. Health care is delivered by appropriate staff members according to their professional competencies (subsidiarity level, delegated authority, nurses able to make prescriptions, etc.).

6. Training of health care professionals covers basic economics and practical guidelines to improve cost awareness, economic understanding and behaviour.

7. Budgetary and financial procedures provide for flexibility and incentives to encourage and improve efficient behaviour.

8. Health care staff members are held accountable for economic decisions and behaviour (value for money, efficiency measures, short- and long-term perspectives, etc.).

9. Regular feedback about efficiency is shared with relevant staff (for example, budget holders).

Attribute No. 9 – Sustainability

Examples of good practice (non-exhaustive list)

1. Core social principles of solidarity, equity and social sustainability are taken into account and reflected in the development and formulation of policies and strategies.

2. A comprehensive health financing strategy, including all sources of financing, and a long-term financing plan are established using the best available evidence and forecasts.

3.	A long-term strategy for health system sustainability is in place, with clear values, priorities, objectives and targets, and is reflective of needs and resources.
4.	Future recurrent and depreciation costs are considered when making important decisions with long-term implications (investments, new health technologies, etc.).
5.	Policies for safeguarding the availability of sufficient human resources are in place (staff retention, services in remote areas, etc.).
6.	Policies, strategies and guidelines for the prevention and control of the wasteful use of resources are established and enforced.

Attribute No. 10 – Responsiveness

Examples of good practice (non-exhaustive list)	
1.	Patient and general population health surveys are conducted and the findings are used for system improvements.
2.	User-friendly complaints systems that address patients' complaints and concerns in a timely manner are in place.
3.	Confidential reporting systems allowing patients to record adverse events, medical errors and malpractice, including mediation and compensation mechanisms, are in place.
4.	Systems to measure patient-reported outcomes are developed and used for improvement of services.
5.	Patient referral, transfer and prioritisation systems are fair and based on health needs.
6.	Targeted actions are taken to promptly and proactively respond to the specific demands and expectations of particular client groups.
7.	Health services are provided at the appropriate level in a holistic and integrated manner.

Attribute No. 11 – Integrity

Examples of good practice (non-exhaustive list)	
1.	Institutional arrangements (policies, structures, systems, legislation, etc.) are in place to detect, prevent and deal with fraud and corruption.
2.	An explicit policy on developing and promoting integrity, including awareness training for staff, is in place.
3.	Codes, policies and protocols to guide the integrity of professional judgment, ethics and behaviour exist and compliance is monitored.
4.	Submissions made by various interest groups during public consultation processes are made publicly available.
5.	A system to protect the integrity of medical research exists and is monitored (for example, research ethics committees).
6.	The source and level of funding and sponsorship for programmes (public health programmes, health promotion campaigns, clinical trials, etc.) are publicly available.
7.	Public awareness campaigns and actions to promote integrity exist (for example, a zero tolerance policy to breaches of integrity).
8.	There is a dedicated resource (person, network, committee, commission, ombudsman, etc.) that supports, advises and assists individual public and civil servants with questions and concerns in relation to ethics, values and conduct.

EXAMPLE

Attribute No. 11 - Integrity

Integrity involves adherence to ethical values framework and consistency and coherence between those values and behaviour/action.

Rating of this attribute (1-10) (Click the next right cell for a drop down menu)			Is this aspect planned for?	Are planned activities implemented?	Is the level of achievement evaluated?	Are plans adapted to lessons learnt?	
Examples of good practice (non-exhaustive list)	Rating of Importance	Level of achievement (from 1-10)	Stage of development PLAN	Stage of development DO	Stage of development CHECK	Stage of development ACT	Remarks/ Comments
1. Institutional arrangements (policies, structures, systems, legislation, etc.) are in place to detect, prevent and deal with fraud and corruption.							
2. An explicit policy on developing and promoting integrity, including awareness training for staff, is in place.							
3. Codes, policies and protocols to guide the integrity of professional judgment, ethics and behaviour exists and compliance is monitored.							
4. Submissions made by various interest groups during public consultation processes are made publicly available.							

5. A system to protect the integrity of medical research exists and is monitored (for example, research ethics committees).							
6. The source and level of funding and sponsorship for programmes (public health programmes, health promotion campaigns, clinical trials, etc.) are publicly available.							
7. Public awareness campaigns and actions to promote integrity exist (for example a zero tolerance policy to breaches of integrity).							
8. A dedicated resource exists (person, network, committee, commission, ombudsman, etc.) that supports, advises and assists individual public and civil servants with questions and concerns in relation to ethics, values and conduct.							

Glossary

1	Accountability	The state of being answerable for one's decisions and actions. Accountability includes financial and political accountability, as well as accountability for performance.
2	Transparency	Provision of accessible, usable, relevant and timely information to the public and the opening up of procedures, structures and processes to public assessment. Information needs to be disseminated effectively and made available on the Internet.
3	Institutional/ organisational arrangements	The institutional and organisational arrangements of the health system, and of any of its components, embody its governing and managerial structure, its decision-making and functioning processes, its formal and informal codes of conduct and procedures and the lines of accountability that determine overall performance and good governance.
4	Participation	Participation in health systems is generally referred to in a number of different ways. Firstly, participation relates to the involvement of patients in decision making concerning their own health care. Secondly, participation also concerns community involvement in health care, including policy making. Thirdly, it also relates to participation by professionals.
5	Equity	Equity (in health care and access to services) defines the extent to which the health system deals fairly with all those concerned regarding the allocation of resources or treatments. Equity, in this context, deals with the fairness in the financing and distribution of health care and its benefits among different individuals or groups.
6	Quality	The properties and characteristics of a product or service that render it capable of satisfying expressed or implicit needs. Quality of care is the degree to which the treatment dispensed increases the patient's chances of achieving the desired results and diminishes the chances of undesirable results, having regard to the current state of knowledge.
7	Effectiveness	Effectiveness is the extent to which planned outcomes, goals, or objectives are achieved as a result of an activity, strategy, intervention or initiative intended to achieve the desired effect. The perspective should not only be at an individual level but also at the health system level. The extent to which a specific intervention, when used under ordinary circumstances, does what it is intended to do.
8	Efficiency	Making the best use of available resources. Efficiency is the ratio of the output to the input of any system. An efficient system, or person, is one that achieves higher levels of performance (outcome, output) relative to the input (resources, time, money) consumed.
9	Sustainability	Sustainability is the capacity to endure. In a health system, sustainability has two dimensions: political, which refers to the capacity to enlist sufficient public support, and economic, which indicates the mid- to long-term prospect of keeping an adequate level of funding.
10	Responsiveness	One of the three goals of the health system is to meet people's legitimate expectations about how the system treats them. How a health care system behaves in relation to the expectations and needs of people.
11	Integrity	Integrity involves adherence to an ethical values framework as well as consistency and coherence between those values and behaviour/action.

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TOOL No. 2

A checklist to prevent and manage conflicts of interest in health systems

Explanatory note

Conflicts of interest arise when public officials have to make decisions at work that may affect their private interests, in other terms, a situation which creates the possibility of using one's professional position and/or assignment for personal purposes, with implications for the objectivity and/or rationality of decision making.

A conflict of interest is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest could be unduly influenced by a secondary interest. In the medical field, this could be a situation in which the professional opinion or decision concerning the principal interest (the patient's health, research, education) could be distorted by the influence of secondary or subordinate considerations (financial, prestige, power, career). The emphasis is on a "conflicting" situation, rather than on a specific action.

Secondary interests may include financial gain, but also the desire for professional advancement, recognition for personal achievement, as well as favours to friends and family or to students and colleagues. Policies that deal with conflicts of interest typically and reasonably focus on financial gain and financial relationships. The reason is not that financial gains are necessarily more corrupting than the other interests, but that they are more easily quantifiable. A financial interest therefore tends to be more effectively regulated than other secondary interests. Furthermore, for-profit companies exert influence primarily through their financial relationships with physicians and researchers.

Most secondary interests, including financial interests, are – within limits – legitimate and even desirable goals. The secondary interests are objectionable only when they have greater weight than the primary interest in professional decision making. For example, for a researcher or a teacher, financial interests should be subordinate to presenting scientific evidence in an unbiased manner in publications and presentations.

A financial interest does not have to concern a significant amount for it to have influence, gifts of small value may affect decisions.

Influence may operate without an individual being conscious of it. A conflict of interest exists whether or not a particular individual or institution is actually influenced by the secondary interest.

Institutions, professional organisations and governments establish policies, on behalf of the public, to address the problem of conflicts of interest. Conflict of interest policies seek to ensure that professional decisions are made on the basis of primary interests and not secondary interests. Such policies work best when they are preventive and corrective rather than punitive. They serve two overarching purposes: maintaining the integrity of a professional judgment and sustaining public confidence in that judgment. That professionals should promote these purposes constitutes the fundamental principle underlying any respectable conflict of interest policy.

Because a conflict is a set of circumstances or conditions involving a risk rather than a specific individual decision, the existence of a conflict of interest does not imply that an individual is improperly motivated. Conflict-of-interest policies are by their nature designed to avoid the need to investigate individual cases in this way.

Policies designed to reduce conflicts of interest and mitigate their impact provide an important foundation for public confidence in medical professionals and institutions.

	Tool No. 2 Conflicts of interest Evaluation and monitoring checklist
Links to:	Item 1: Main conditions conducive to the development of conflicts of interest in the health system
	Item 2: Situations which may lead to conflicts of interest in the health system
	Item 3: Policies and measures for the prevention and regulation of conflicts of interest in the health system

Item 1 – Main situations conducive to the development of conflicts of interest in the health system

1.	Lack of clarity regarding division of authority for the decision-making process.
2.	Lack of a systematic approach to the identification, early warning, monitoring, alerting and surveillance of conflicts of interest.
3.	Deficiencies of deontological regulation and professional self-regulation in terms of conflicts of interest.
4.	Gaps in the legal framework dealing with conflicts of interest.
5.	Public procurement processes are not fully transparent and results are not publicly available.
6.	There is a culture of tolerance for conflicts of interest.
7.	Lack of regulation concerning third-party influence, including lobbying activities.

Rating of importance (severity of potential harm)	Frequency	Likelihood that decisions will be influenced by secondary interest	Remarks/Comments
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Item 2 – Individual situations which may lead to conflicts of interest in the health system

1. Health care professionals are in secondary employment in an industry with interests in the health decision-making process.
2. Relatives and/or friends of health care professionals are employed by an industry with interests in the health decision-making process.
3. Public officials that leave to work for a company with interests in the health decision-making process (“gatekeeper turned poacher”).
4. Health care professionals have access to commercially sensitive private and confidential information.
5. Public officials have a financial or personal affiliation with organisations that have an interest in the health decision-making process.
6. Accepting gifts, entertainment or other favours without disclosure.
7. Personal or family relationships which could interfere with official duties or responsibilities.
8. Undeclared access to privileged information.

Rating of importance (severity of potential harm)	Frequency	Likelihood that decisions will be influenced by secondary interest	Remarks/Comments
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Item 3 – Policies and measures for the prevention and regulation of conflicts of interest in the health system

1. Comprehensive policies dealing with the prevention and regulation of conflicts of interest exist and are implemented.
2. Deontological codes, codes of conduct and good practice rules exist and are adhered to.
3. Open disclosure policies and standardised open disclosure forms exist and are implemented.
4. There are policies and measures that deal with conflicts of interest in the media.
5. Health care professionals receive training in how to identify and deal with conflicts of interest.
6. Regulation of medical research implying potential conflicts of interest exists and is enforced.
7. Potential conflicts of interest in the funding and provision of education and training for health care staff are identified and this information is made available to the public.
8. Governance arrangements at board level deal with conflicts of interest and information concerning board members’ conflicts of interest is publicly available.
9. Interactions between makers of pharmaceuticals, medical devices, food and other products and clinical personnel are controlled and information about funding is publicly available.
10. Industry funding for clinical practice guideline development is controlled and information about funding is publicly available.
11. A culture in public administration requiring public officials to be accountable and personally responsible is fostered.

Rating of importance (severity of potential harm)	Likelihood that decisions will be influenced by this policy or measure
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* * *

TOOL No. 3

Introduction and instructions

Checklists for monitoring and evaluating of codes of conduct in health systems

Introduction

1. This checklist tool is based on the general framework for codes of conduct in the health sector included in the appendix to Recommendation CM/Rec(2010)6 of the Committee of Ministers to member States on good governance in health systems.
2. The tool is designed as a practical instrument for appraisal and monitoring of key components of codes of conduct, as applied to actors in different sectors of a health system: health professions, industry, organisations, institutions, etc.
3. The tool can be used for a Delphi-type exercise and as a survey instrument. If it is used regularly, it can track the evolution of different aspects of codes of conduct across different health sector settings.
4. The items of the checklist have two groups of components related to codes of conduct:
 - a. general characteristics: existence, process of development and comprehensiveness of such codes, including provisions for compliance, periodic updating and publicity or diffusion;
 - b. implementation: enforcement of the codes of conduct which includes recognition of violations, the existence and composition of an enforcement body, monitoring mechanisms and sanctions for non-compliance.
5. The tool is in a spread sheet format (Excel of MS Office), which is a widely available and can be easily used with non-proprietary formats such as Open Document.
6. This prototype is offered “as is”, without any commitment to further development or the provision of a template for analysis of multiple users/respondents. Therefore, it can be complemented, shortened, modified or further developed by others.

Description of the tool

7. The tool consists of an index (Figure 2) with hyperlinks leading to its three sheets:
 - a. the first sets the context and recalls the general framework for codes of conduct in the health sector (Figure 3);
 - b. the second is a checklist with examples of the different sectors of a health system that are frequently regulated by codes of conduct (Figure 4). This sheet has a system of nested rows (“+” signs on the left border of the screen) that unfold into a list of items within each category; the categories and their internal lists are not exhaustive and therefore can be modified to suit any specific requirement;
 - c. the third (Figure 5) contains a checklist of examples of content (issues) included in codes of conduct of the health sector.

8. The two checklists (Figures 4 and 5) have the same configuration, consisting of two groups of columns: the left one, related to the general characteristics of codes of conduct (listed in paragraph 4.a above), and the right one with items related to the enforcement of codes of conduct (listed in paragraph 4.b above).

Instructions on the use of the tool

9. Save the file with a different name to be able to use it.

Figure 2

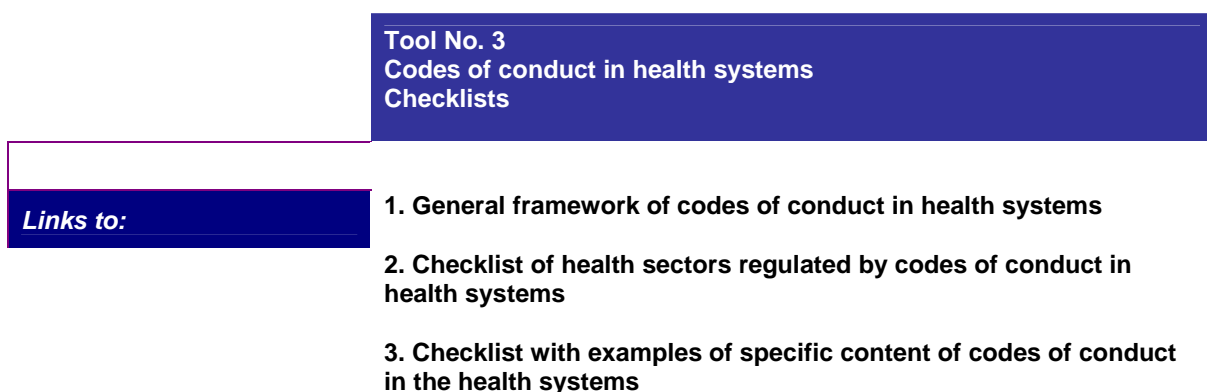


Figure 3

General framework for codes of conduct in the health sector	
1.	Introduction
2.	Values and ethical references
3.	Legal framework of reference
4.	Examples of areas in the health sector where a code of conduct may be put in place ¹
a.	Good professional practice:
i.	respect for the dignity of people (employees, patients, customers)
ii.	honesty and confidentiality
iii.	keeping professional competence up-to-date
iv.	use of the best scientific evidence
v.	compliance with accepted standards
vi.	compliance with regulations and legislation
vii.	awareness of the needs, demands and expectations of the population, patients and customers
viii.	co-operation with colleagues
ix.	spirit of moderation, reconciliation, tolerance and appeasement
b.	Use of resources of the service or system:
i.	cost-effectiveness practice in the use of resources
ii.	preventing the use of public resources for private gain
iii.	prevention of fraud and corruption

¹ Not all areas are applicable to all situations. The order of the items does not reflect priority ranking. The list is non-exhaustive and the items are for illustrative purposes only.

- c. Handling of conflicts of interest in the best interest of patients and population:
 - i. economic, or
 - ii. non-economic
- d. Proper access, sharing and use of information:
 - i. research of any information necessary for decision making
 - ii. duty to disclose all relevant information to the public and authorities
 - iii. duty to provide information to patients with respect to their needs and preferences
- e. Handling of gifts and benefits:
 - i. existence of an explicit policy concerning gifts
 - ii. transparency regarding gifts received from interested parties
- f. Research-related topics:
 - i. clinical trials (Helsinki Declaration)
 - ii. truthful claims of research potential
 - iii. patient consent with full disclosure of risks
- g. Relationships with other actors in the health sector:
 - i. colleagues and other health professionals
 - ii. patients and their families
 - iii. insurers, third-party payers
 - iv. health-related industries (pharmaceuticals, food, advertisement, cosmetics, medical devices, etc.) and other interest groups
 - v. government officers of health and other sectors (e.g. police)
 - vi. patients and self-help organisations, NGOs, etc.
 - vii. media
- h. Good corporate governance of health institutions, services or centres
 - i. Issues of multiculturalism, tolerance and respect
- 5. Enforcement of the code of conduct:
 - a. Recognition of violations
 - b. Composition of the body responsible for dealing with enforcement
 - c. Transparency of procedures and public scrutiny
 - d. Complaints system
- 6. Updating, monitoring and development of the code of conduct:
 - a. Process of development of codes of conducts: initiative, ownership, legitimacy
 - b. Comprehensiveness
 - c. Limitations of codes of conduct
 - d. Codes of conduct and legislation

Figure 4

CODES OF CONDUCT IN THE HEALTH SECTOR

		Checklist												
		Development, existence, comprehensiveness, compliance, updating, publicity						Enforcement						
		Existence	Comprehensiveness	Provisions for compliance	Provisions for updating	Process of development	Publicity (transparency)	Provisions for enforcement	Recognition of violations	Enforcement body (existence, composition)	Procedure transparency (public scrutiny)	Complaints system	Monitoring mechanisms	Application of sanctions
Health professions														
	Medicine													
	Dentistry													
	Nursing													
	Pharmacy													

Examples of different sectors in the health system where a code of conduct may be put in place

g.	Relationships with other actors in the health sector													
i.	Colleagues and other health professionals													
ii.	Patients and their families													
iii.	Insurers, third-party payers													
iv.	Health-related industries (pharmaceutical, food, advertisement, cosmetic, medical devices, etc.), and other interest groups													
v.	Government officers of health and other sectors (e.g. police)													
vi.	Patients and self-help organisations, NGOs, etc.													
vii.	Media													
h.	Good corporate governance of health institutions/services/centres													
i.	Issues of multiculturalism, tolerance and respect													

NB. Not all areas are applicable to all situations. The order of the items does not reflect priority ranking. The list is non-exhaustive and the items are for illustrative purposes only.

* * *

TOOL No. 4

Prototype of a web-based tool to survey opinions on the governance of health systems

Introduction

1. This web-based tool reflects the “attributes” of good governance in health systems, as outlined in the explanatory memorandum to Recommendation CM/Rec(2010)6.
2. The tool is designed as a practical instrument to survey opinions on the governance of health systems.
3. The tool can be used with a randomised sample of stakeholders, as a public opinion survey instrument or as part of a focus group.
4. The items of the survey are divided in two groups:
 - a. opinion statements indicating how strongly the respondent agrees or disagrees with the statement, between 0 (I strongly disagree) and 5 (I strongly agree);
 - b. questions regarding whether a particular measure is available or present in a given country or region.
5. The tool is in a spread sheet format (Excel of MS Office), which is widely available and can be easily used with non-proprietary formats such as Open Document.

Instructions

6. The online survey is confidential; respondents do not have to give their name or contact details.
7. The survey takes about 10 minutes to complete. Each attribute has 3 indicators (for a total of 33 indicators) and 3 statements (in total 33 statements).
8. Each respondent is asked whether he or she thinks that the 33 indicators are present and then is asked to rate the corresponding statements to indicate a level of agreement.
9. If you plan to use the tool as a survey questionnaire, you should organise a database system for collecting and analysing the responses.

Attribute	Indicators	Is measure available?			Statements	Rating (1-5)
		Yes	No	Don't know		
Accountability	The division of tasks and the assignment of responsibilities (chains/lines of accountability) are clearly defined, established and publicly available.				Individuals and organisations are held to account when underperformance or poor performance is detected.	
	The performance of health care managers and leaders is closely monitored in my country/region.				Overall, the right people are in charge of health care services.	
	There is an overall plan that outlines the vision, priorities and actions for the health care system in my country/region.				Individuals and organisations are rewarded for good performance.	
Transparency	Annual accounts of health care spending are available to the public.				Health care providers share important information about their spending and the quality of care freely and openly.	
	Information about the performance of health care services is publicly reported.				It is easy to find information about the quality and performance of health care services in my country.	
	Information about health- and health care-related entitlements and benefits is understandable, publicly available and regularly updated.				A clear and fair process exists if I want to make a complaint about the quality of a health care service.	
Institutional/ organisational arrangements	Organisations representing the interest of health care professionals exist.				There is an effective system in place to deal with the detection and tackling of fraud and corruption.	
	An autonomous audit system exists to monitor, enforce and encourage high-quality and safe health care.				The process for appointing people to positions within health care organisations is fair, transparent and clear.	
	Rules and procedures to deal with conflicts of interest are implemented.				Executive and legislative functions and powers are clearly defined and delineated.	

Participation	A designated agency exists to advocate and support patients, such as an ombudsman.				Health care organisations, such as hospitals, clinics or pharmacies, are interested in my views and feedback.	
	Meetings of governing bodies are regularly conducted in public and minutes of these meetings are publicly available.				Patients can access individual information about their own health care (where appropriate).	
	Informed consent processes are in place for diagnostic and treatment procedures.				Patients are involved in decisions about their health care.	
Equity	National guidelines for inclusive consultation with patients exist.				All patients are treated equally, regardless of their income, social status, etc.	
	Proactive measures are taken to improve the health status of disadvantaged and vulnerable groups.				The government has taken adequate steps to deal with the specific health needs of disadvantaged and vulnerable groups.	
	Health statistics and (management) information systems provide disaggregated data and information including gender, age, socio-economic status, etc.				The allocation of resources is fair and based on explicit criteria of health needs.	
Quality	National or regional measures have been developed to monitor outcomes.				Levels of achievement of high-quality services are publicly acknowledged and rewarded.	
	A mandatory professional licensing and certification process is in place to ensure that professional standards are met.				Prompt action is taken when unsafe practices are detected.	
	National/regional quality objectives and priorities have been set.				Health care professionals working in my country/region are competent to deliver high-quality and safe care.	

Effectiveness	There is a national or regional health policy/strategic plan stating objectives with a time frame and resources allocated.				In general, the best possible patient outcomes are achieved.	
	A system of clinical audits exists. The results are disseminated and necessary actions to improve clinical effectiveness are taken.				New clinical practices and interventions are evaluated before being implemented.	
	There is a national or regional agency to review the effectiveness of medical procedures, products, equipment and health policies.				The clinical performance of health care professionals is regularly audited to make sure the best clinical outcomes are achieved.	
Efficiency	A dedicated resource (team, institution, organisation) is responsible for conducting reviews on economic behaviour and efficiency of health care financing, organisation and provision.				Suspected fraud in health care is actively and quickly dealt with.	
	A national or regional audit office is in place to make sure public money is spent wisely.				The leaders responsible for the management of the health care system in my country/region make sure that the best value for money is achieved.	
	Cost accounting systems are in place and linked to the performance of health care provision (for example cost per case) and are used for monitoring purposes.				I believe that the current system of allocating resources achieves the best results for the money spent.	
Sustainability	A long-term health financing strategy exists, with clear objectives and targets, based on current and future needs.				Leaders make every effort to retain staff working in health care services.	
	Policies, strategies or guidelines for the prevention and control of the wasteful use of resources are established and enforced.				In my opinion, adequate future recurrent and depreciation costs are considered when making important decisions with long-term implications (investments, new health technologies, etc.).	
	Policies for safeguarding the availability of sufficient human resources are in place (staff retention, services in remote areas, etc.).				Spending on health care is under control and does not pose a threat to the economic stability of the country/region where I reside.	

Responsiveness	Waiting times for different services are monitored at national and regional levels.				Patients are not faced with unnecessary delays to receive treatment.	
	A user-friendly complaints system that addresses patients' complaints and concerns in a timely manner are in place.				Patients' complaints are addressed and resolved quickly and satisfactorily.	
	Targets have been set for acceptable waiting times.				Waiting times are decreasing.	
Integrity	Major public contracts are awarded following a public tendering process.				Managers and leaders working in the health care organisations in my country/region have integrity.	
	A fair and transparent system exists to compensate patients for medical errors and malpractice.				Leaders and managers put patients' interests first.	
	A code of conduct to govern the ethics and behaviour of all staff involved in health care management and delivery exists.				The conduct and behaviour of health care professionals are exemplary.	