

HEALTH CARE QUALITY AND ACCREDITATION CONFERENCE BOOKLET

Foreword from State Secretary Ministry of Health

Foreword from Director of the Agency for Accreditation of Healthcare Institutions

Foreword from Team Leader of the Project

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Belgrade, Serbia

Friday March 18th 2011

Foreword from State Secretary, Ministry of Health Republic of Serbia

Quality and safety assurance in health care is at the top of international and European health system agendas. It has been recognised for some time that, in the increasingly fast changing, complex and pressured health care environment, much can and needs to be done to ensure universally high standards of health service quality and safety, which all users of health care systems are entitled to expect. However, quality, safety and effectiveness are not the only issues. International industry and commerce has long recognised the connection between effectiveness and efficiency, the latter being an equally important issue in the difficult health system resource climate. The philosophy of 'getting it right first time' has long been the centrepiece of Total Quality Management, which has dominated industrial and commercial development since the middle of the last century and has more recently been embedded into the principles of evidence-based health care and evidence-based medicine.

The Public Agency for Accreditation of Health Care Institutions in Serbia was established in 2008 to lead the development of a number of related areas of health care continuous quality and safety improvement and is a 'youthful' addition to the long established health sector in Serbia. Its proposed role and functions lie at the heart of Serbia's own efforts and commitment to keep pace with best European practice in assuring quality and safety, in both the private and public health care sectors. Major performance management systems such as accreditation and certification, the core business areas of the Agency, are increasingly common features of European health systems, representing rigorous systemic and systematic efforts to ensure that all citizens, wherever they live in Europe in general or Serbia in particular can be confident that primary care centres, hospitals, pharmacies laboratories etc. and their staff are offering and providing evidence-based diagnosis and treatment in a way that conforms to what are considered best practice standards.

This project, "Establishment of the Public Agency for Accreditation and Continuous Quality Improvement of Health Care in Serbia" is an EU-funded (1.5 M EUR) was designed to assist and support the Agency in the early stages of its development. It formed part of the European Union's assistance to healthcare in Serbia. Through project activities, which are described in detail in this booklet, the Agency and its staff have been well supported in the development of its role and functions by experienced experts from across Europe and North America, who have been able to bring experience and models of best practice from across the international health care arena, and have joined with the Agency and the Ministry of Health in evaluating international developments in the context of the particular needs of the Serbian health care system. The project has also provided recognised international and European expertise and practical experience, which has assisted and supported the Agency in designing key systems and processes for Serbia. This experience and insight has enabled the Agency to learn, not only from good practice, but also to try to avoid developmental and implementation mistakes made in other countries, which are further down the road in system development. Specific support has been provided by the Project in key areas of legislation and governance development, accreditation system development, standard setting, indicator development, quality strategy improvement, safety strategy development, Health technology Assessment capacity building, clinical practice development and many other aspects of activity. All support received from the Consortium, its team leader and the team of experts has been highly appreciated and highly valued and has contributed to significant progress being made over the past two years, towards Serbia's wish and clear intention to incorporate systematic quality and safety performance monitoring and management into its health care system.

My own and the Agency's deep thanks are expressed here for the support provided over the past two years which has proved invaluable in setting down strong foundations for a continuous quality and safety assurance and improvement system and process, to compare with the best in Europe. Much still needs to be done by the Agency, but the foundations laid with the Project's support should serve the people of Serbia well in the difficult years ahead.

Dr. Nevena Karanovic, PhD
STATE SECRETARY
MINISTRY OF HEALTH REPUBLIC OF SERBIA

Foreword from Director of the Agency for Accreditation of Healthcare Institutions

Agency for Accreditation of Health Care Institutions in Serbia was founded in October 2008 to perform professional, regulatory and development activities in the process of accreditation of health care institutions. It started its operations in July 2009, aiming to fulfill its designated duties that include establishment of health care accreditation standards, evaluation of quality of health care provided to general population, decision making in health care accreditation management issues, awarding accreditation status and issuing public accreditation certificates, and keeping records of accreditation certificates issued.

Funds for the establishment of the Agency for Accreditation were provided from the Budget of the Republic of Serbia. Project "Establishment of the Agency for Accreditation and Continuous Quality Improvement of Health Care in Serbia", funded by the European Union, was launched in July 2009, and in two years of its duration it ensured capacity building of the Agency for Accreditation of Health Care Institution through technical assistance it provided. All throughout the Project duration, Agency staff and External Surveyors were in continuous training.

Establishment of the Accreditation Program is a long and difficult process that demands engagement of large material and human resources. Availability of worldwide renowned international consultants, who led and assisted us to create a credible national program according to international principles and standards, was of the utmost importance for the future of the accreditation of the health care institutions in Serbia and of the Agency itself.

Approach to our common working activities was based on extensive consultations with all project key stakeholders, applying strategic definition of health care quality and patient safety through proposals for revision of Strategy for Continuous Improvement of Health Care Quality and Patient Safety. Through these activities we tried to determine the right place of the Agency for Accreditation in the overall map of health care institutions who deal with recording and improvement of health care quality.

One of the Project activities was to ensure the viability of the Agency through self-financing, but unfortunately with no results. Agency financing remains one of the most important issues for the Agency to deal with in future.

European integrations and relevance of the activities related to improvement of health care quality and patient safety on that road are integrated into accreditation process. National interest in patient safety area is recognized by the Agency and emphasized through its dedication to activities in this field.

Providing proposals for redefining the Strategy for Continuous Improvement of Health Care Quality and Patient Safety shows best our dedication to improvement of quality of health care services through promotion, development and implementation of Good Clinical Practice Guidelines.

Project activities are described in detail in this booklet. Results of the Project are great and significant for both Serbian Health Care System and Serbian Citizens that are using it. I would like to extend my gratitude to Ms. Annette Katrava and all members of the Project Team for their exquisite cooperation and dedication to their work. I would like to also thank the Ministry of Health, Institute of Public Health of Serbia "Dr Milan Jovanović - Batut", National Expert Committee for Continuous Quality Improvement and Patient Safety, Health Professionals Chambers, Chamber of Healthcare Institutions of Serbia, National Expert Committee for development and implementation of Good Clinical Practice Guidelines, Ministry of Health Projects funded by The World Bank loans, health care institutions that helped us test the accreditation program, namely: General Hospital Užice, General Hospital Zrenjanin, BelMedic Hospital, Primary Health Care (PHC) Centre Kragujevac, PHC Centre Leskovac, PHC Centre Dr Ristić, Pharmacy Subotica, Pharmacy Farmanea, Laboratory Biomedica and all pilot institutions from other Projects that were engaged in testing of quality indicators that will be included in the accreditation process.

I certainly hope that the Project results will be used in the best possible way and be of use to all stakeholders of health care system in further development and reforming of health care system.

Director of the Agency for Accreditation
of Health Care Institutions in Serbia
Dr Snežana Manić

Foreword from Team Leader of the Project

Access to high quality healthcare is a basic right which is increasingly recognized and valued by the European Union and its Institutions. Citizens expect that health systems make every effort to ensure the quality and safety of health care services provided.

In 2005, the Government of Serbia embarked on its own reform programme designed to improve efficiency and quality, contain escalating costs and strengthen the financial sustainability of its health care system. A key reform element was the establishment of a Public Agency for Accreditation of Health Care Institutions in Serbia (Article 214 of the Health Care Law) in October 2008 to support healthcare organizations in improving the quality of care “through the application of a variety of quality tools and approaches and through a range of activities.” A key responsibility of the Agency being the design and implementation of a ‘best practice’ accreditation program to assure the safety and quality of health care services provided by Serbian health care institutions.

This project, “Establishment of the Public Agency for Accreditation and Continuous Quality Improvement of Health Care in Serbia” was an EU-funded (1.5 M EUR) from IPA (Instrument for Pre-Accession Assistance) 2007 program, formed part of the European Union’s assistance to healthcare in Serbia. The project’s main objective was to support the Agency during the early stages of its development and in the design and testing of an accreditation process, to ensure a safe, equitable, viable and high-performance oriented health care system, with health care providers stimulated to achieve continuously increasing standards of efficiency, effectiveness and quality. Project objectives, were closely linked to Serbian Health Policy, the European Partnership and the SAA requirements. It aimed to respond to the needs of key stakeholders, the Agency, Health Care Institutions (HCI) and Ministry of Health (MoH), and wider target groups, such as the Health Insurance Fund (HIF), Institutes of Public Health (PHI), professional associations, health care providers and, above all, patients.

The project was implemented by a consortium led by EPOS Health Management with NHS NICE, CHKS and HD-ECG as members of the consortium. It lasted for 22 months (June 2009 to April 2011). The team of consultants included 3 long term experts and over 30 short term experts representing Canada, France, Greece, Hungary, Ireland, Italy, New Zealand, Republika Srpska, Serbia, Slovenia, UK, and USA.

Accreditation (and similar systems of external assessment against standards) has been introduced in many countries world-wide, as part of an overall strategy for continuous improvement of healthcare institutions, systems and outcomes with benefits to consumers, regulators, financiers, managers, and other stakeholders. But, the effectiveness, sustainability and affordability of an accreditation programme, depends ultimately on the healthcare environment of the host country, the type of programme selected, and how it is implemented. The rationale for setting up a National agency for healthcare accreditation is to assist health care organizations to improve the quality of their health and health care services and outcomes. The Agency aims to accomplish this through setting standards, measuring performance, providing consultation and education where needed, and ultimately awarding accreditation to those organizations which meet the required standards.

The project has supported the Agency in identifying and introducing quality and patient safety standards in Serbia as part of an accreditation process designed as a blueprint for achieving excellence in everyday clinical and management practice. With the support of the project the Agency has begun to *transform traditional approaches into a CQI effort* that encourages health care institutions to use *accreditation standards as operational tools* for routinely assessing and documenting their strengths as well as identifying and correcting their weaknesses, making accreditation the by product of sound management performance and practice.

In reality, health system improvement will be limited, not by the capacity of the Agency to identify institutional compliance with standards, but by the capacity of institutions - and municipalities and the Ministry of Health - to absorb and develop more effective systems for planning, operational management and performance management, and delivering services, which should be visible in a National strategy for continuous quality and safety improvement

The project team extends its profound thanks to the Director of the Accreditation Agency, Dr. Snezana Manic and her team with whom we have had a great pleasure and privilege to work collaboratively. Also to the Ministry of Health, former Minister Prof. dr. Milosaljevic, and Dr. Nevena Karanovic, State Secretary and President the Project Steering Committee, members of the Project Steering Committee: Dr Snezana Manic - Director of Agency for Accreditation of Health Care Institutions of Serbia; Dr Maja Vuckovic-Krcmar - Project Manager Health and Social Affairs, Delegation of the European Union to the Republic of Serbia; Prim. Dr Tatjana Radosavljevic - Director of Serbian Medical Chamber; Prim. Dr Ilija Tripkovic – President of the Governing Board of Chamber of Health Care Institutions; Prim. Dr Tanja Knezevic – Director of Institute of Public Health of Serbia “Dr Milan Jovanovic Batut”; Ms. Svetlana Vukajlovic former Director of Republic Institute for Health Insurance, and Prof. Snezana Simic and Dr. Vesna Korac, Ministry of Health Quality Commission, for their guidance and support. Thanks are also due to Mr. Sasa Rikanovic, Director Ministry of Health World Bank Project – DILS, SHP-AF and his team for his help in pursuing an integrated approach to overlapping project activities.

This project could not have succeeded without the generous participation of countless professionals who shared their time, knowledge and expertise in project activities. A special thank you to the project team (listed below) which implemented the project with professionalism and dedication to improve the health care system in Serbia. To all of you, I extend my deep appreciation.

Equipped with the results of the project, and their undoubted energy and enthusiasm for progress, we wish the Accreditation Agency great success in supporting health care institutions, and ultimately patients, a safe environment for the delivery of high quality health care services.

In this booklet, presented at the Project Closing Conference, you will find a summary of project activities and results.

Annette Katrava

Team Leader/ Health Accreditation Expert

PROJECT TEAM

Key experts	
Annette Katrava (Greece/Canada)	Team Leader and Health Accreditation Expert
George Boulton (Great Britain)	Health Policy and Systems Expert
George Purvis (USA/Ireland)	
Brane Dobnikar (Slovenia)	Health Legislation Expert
Short term experts International	
Akos Peter Mayer (Hungary)	Accreditation Programme Evaluator
Andrea Gardini (Italy)	Accreditation Programme Evaluator
Biserka Simcic (Slovenia)	Accreditation Programme Evaluator
Charles Shaw (Great Britain)	Accreditation Programme Expert
Dorjan Marusic (Slovenia)	Models of Payment and Incentives to Providers Expert
Elma Heidemann (Canada/USA)	CQI Expert
Francis Joseph Ruiz (Great Britain)	Technology Appraisal Expert
Francoise Cluzeau (France)	CPG Expert
James Coles (Great Britain)	Indicators Expert
Marion Snowden (USA/New Zealand)	Standards Development Expert
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Ivana Ivakic Markovic	Translator/Interpreter
Marina Drakic	
Miroslava Narancic	Office Manager

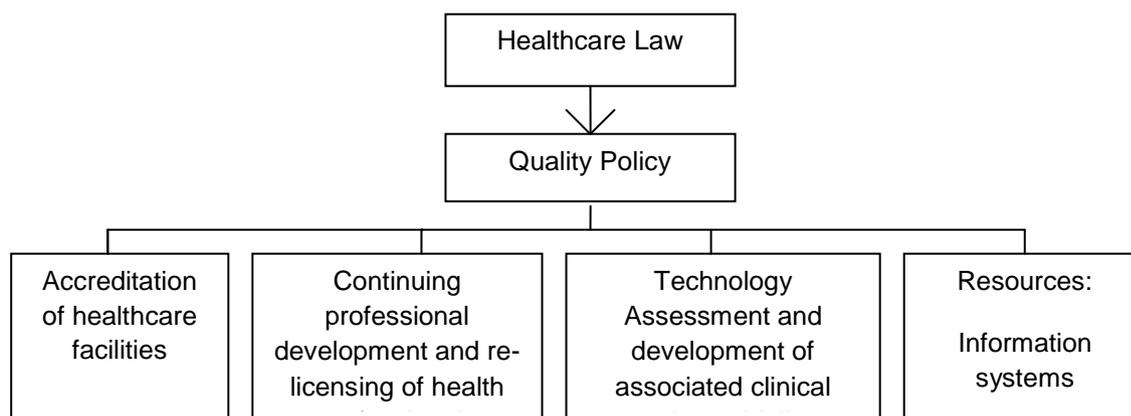
INTRODUCTION AND BACKGROUND

This booklet is a summary of the EU-funded project (1.5 M EUR, June 2009-April 2011) from IPA (Instrument for Pre-Accession Assistance) 2007 program, as part of the European Union's assistance to healthcare in Serbia.

The Republic of Serbia plans to improve the quality of healthcare for the population. Within a comprehensive health system reform strategy in Serbia, quality of health care and patient safety is a key strategic priority for the Ministry of Health. The main project objective is to contribute to the quality and safety improvements by promoting a safe, equitable, viable and high-performance oriented health care system, in which providers of care are stimulated to achieve continuously increasing standards of efficiency, effectiveness and quality. This was achieved mainly by supporting the National Agency for the Accreditation of Health care Institutions during its early development stages in stimulating a culture of continuous quality improvement and in designing and introducing an accreditation process and program. The following paragraphs describe project achievements, next steps and conclusions.

Based on the Law on Health Care from 2005 (see figure 1), the Agency for Accreditation of Health Care Institutions in Serbia was established (October 2008) for the purpose of health care quality improvement and patient safety. The Agency was established to perform professional, regulatory and developmental affairs in the process of accreditation of health care institutions.

Figure 1: Framework for Quality stems from 2005 Healthcare Law¹



The project built on groundwork laid by previous international donor sponsored projects over a number of years. Prior to the commencement of the project the Agency was established by law, with a Managing Board; an Agency Director appointed and staff hired; an office location secured, and a budget allocated. The Agency was therefore able to take full advantage of the EU funded project to develop and strengthen its programmes and activities.

The development of accreditation programmes of Serbia started in 2005 with the Project "Serbia Health Project", financed by World Bank (WB) credit. During this Project the accreditation process and standards were further progressed by:

¹ Crisp Helen, HQS Consulting, *National Healthcare Quality Improvement Strategy, Republic of Serbia*, February 2007

- Evaluating the accreditation standards and process tested in a previous WB project
- Developing of laboratory, pharmacy and diagnostic & imaging standards;
- Developing education standards for teaching hospitals;
- Developing patient safety standards;
- Testing all aspects of accreditation content and processes against ISQua principles.

This resulted in revision of the proposed National Accreditation Programme which is now being applied and tested in a number of selected EU project and WB project pilot sites. EU project has used 9 pilot sites (5 public and 4 private sector institutions) for testing purposes.

Establishing accreditation and the Agency in a broader multi-faceted quality and safety improvement and assurance strategy is critical. A National Quality Improvement Strategy² was developed in 2009 with implementation Action Plan³. This sets out the broader framework within which the quality of healthcare services delivered to the population will be improved. The project held a series of workshops with key stakeholders to develop the Agency's Strategic and Business Plan and to identify its specific contribution, in terms of functions, products and services, to the overall Quality Improvement Strategy.

² Strategy for Permanent Improvement of Quality of Health care Protection and Safety of Patients, According to Article 45 paragraph 1 of the Government Act ("Official Gazette of RS" No. 55/05, 75/05 – correction, 101/07 and 65/08), February 2009

³ Quality Strategy Action Plan 2009-2015, Official Gazette RS ", issue 40/10, June 2010

PROJECT OBJECTIVES

This project's main purpose is to support the initial activities in development of the Agency for Accreditation of the Health Care Institutions of Serbia (AZUS) so that appropriate institutional, organizational and management arrangements as well as system capacities are in place in order to perform accreditation program in Serbia in a competent and self-sustainable manner. The Project's objective was to improve the health care system in the Republic of Serbia so as to create a safe, equitable, viable and high-performance oriented health care system where providers of care are stimulated to achieve continuously increasing standards of efficiency, effectiveness and quality.

The specific objectives of this Project

1. to support development of the Agency for Accreditation of Health Care Institutions and assist it in the determination and development of its role, functions, approach and processes within the overriding legal framework and the broad Serbian health system quality improvement strategy
2. to assist the continuous improvement of quality of health service delivery in the Serbian health sector by creating a balance between the professionally and/or institutionally driven internal quality improvement processes with the external assessment mechanisms

Accreditation objectives

The objectives of Accreditation are improvement of health care quality and patient safety and establishment of trust of health care service users in health care system.

Accreditation represents a process of assessment of health care institutions performance quality based on the application of optimum level of established standards for health care institutions operation in given health care area or medical branch (Health care Law, article 213).

Additional objectives of accreditation are: improvement of health care management, ensuring of efficient and worthwhile provision of health care services, and establishment of equal or approximately equal conditions of provision of health care services for the entire health protection system.

Based on the Law on Health care and the Law on Public Agencies, the Agency will assume responsibility for the establishment of standards for accreditation of health care institutions, the evaluation of quality of health care services provided to general population, the efficient and effective management of the accreditation process, the awarding of accreditation certificates and keeping all appropriate records(Health care Law, article 215).

PROCESS

The project methodology included reviewing healthcare accreditation standards within Europe and internationally with a view to make proposals for the Serbian model. Healthcare accreditation standards within Europe are generally similar in content and aim for active improvement, but there is wide variation in emphasis, assessment criteria, internal quality control and use of statistical measures⁴.

The impact of external standards based assessment models varies according their purpose, standards, procedures and incentives. The MARQuis study⁵ showed that, for individual hospitals, higher levels of patient safety were associated with accreditation than with ISO certification but both systems were significantly better than none. Mandatory accreditation programmes have a higher impact on the health system if only by involving a greater proportion of hospitals⁶ (Figure 2).

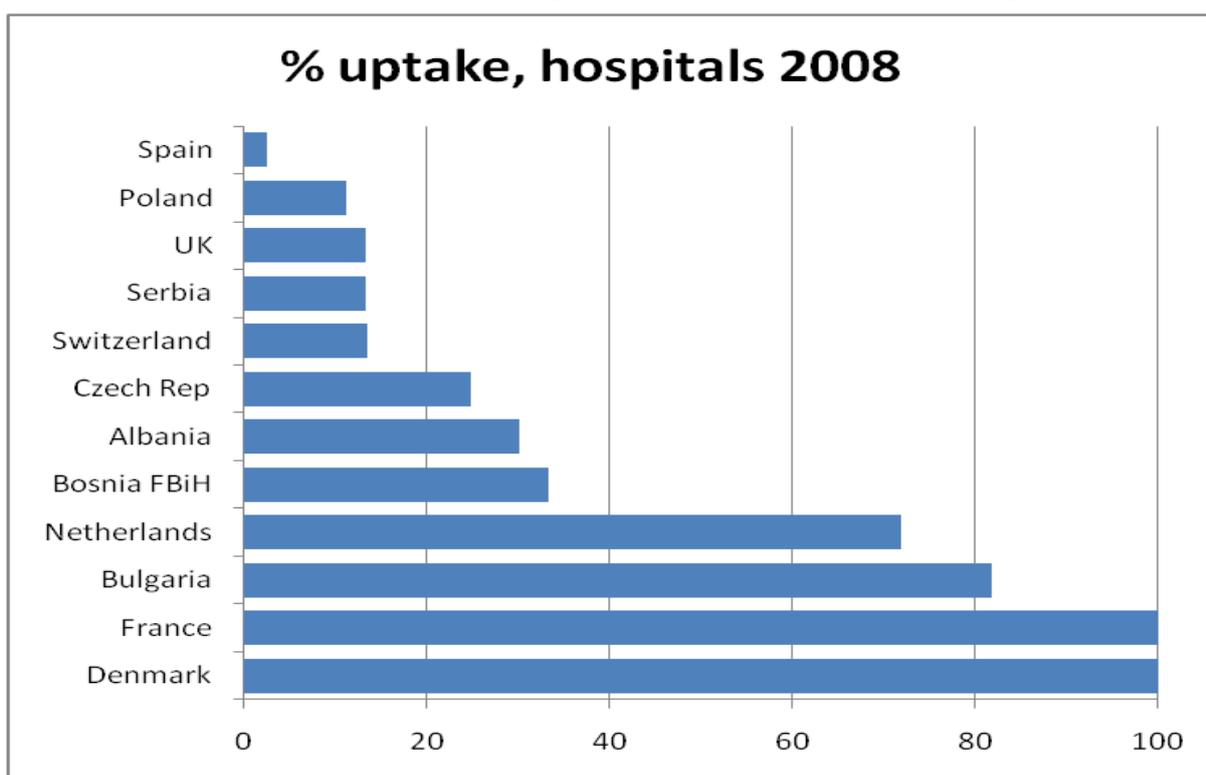


Figure 2 Percentage hospital coverage, national accreditation/certification 2008

The Project started by reviewing the existing proposed national accreditation programme (for hospitals and primary care centres) developed and pilot tested in 2005 through a WB project and by reviewing international approaches. ISQua standards were adopted as the benchmark for the design of the Serbian accreditation system.

Most EU countries have some form of National accreditation programme with varying degrees of stakeholder governance, of compulsion and of national uptake. Sub-national programmes, such as in

⁴ Shaw Charles, Bruneau Charles, Kutryba Basia, DeJongh Guido, Sunol Rosa "Towards Hospital Standardization in Europe", International Journal for Quality in Health Care Advance Access, June 24, 2010

⁵ Groene O, Klazinga N, Walshe K et al, Learning from MARQUIS: future direction of quality and safety in health in the European Union. Quality Safety Health Care 2009;18:i69-74

⁶ Shaw Charles, Bruneau Charles, Kutryba Basia, DeJongh Guido, Sunol Rosa "Towards Hospital Standardization in Europe", International Journal for Quality in Health Care Advance Access, June 24, 2010

Spain and in Italy, are mostly run by regional government. Some 60 hospitals in Europe have been accredited by the Joint Commission International (JCI), which forms part of a world-wide programme, using published international standards⁷.

In Europe, there is no simple tool to assess compliance with common national and European directives, guidance and professional advice on the management of health care institutions. Despite evidence of unacceptable variations in the protection of patient and staff safety little attention has been given to harmonizing the way services are organized and managed⁸. In the past 10 years, several studies have explored the potential of health care accreditation to reduce variations in the quality and safety in hospitals in Europe^{9 10 11} and internationally^{12 13}

EC-funded research project on external peer review techniques (ExPeRT) identified ISO certification and organizational accreditation as the most prevalent standards-based assessment systems for healthcare in Europe). The study did not include statutory licensing and inspection, or the accreditation of training institutions.

In a 2007 survey for the Belgium health ministry found that 11 out of the 17 programmes in Europe are already committed to harmonize by meeting the principles and standards defined by the International Society for Quality in Healthcare (ISQua) for standards development and for standards-based assessment^{14 15}. Several accreditation programmes – such as JCI, France, Ireland, Denmark, the Netherlands and some programmes in the UK – have already been independently accredited and accessed.

The successful transfer of quality improvement methods, which have proved effective in other countries, depends more on culture and environment than on the technical competence of the intervention. “Solutions” such as performance indicators, clinical guidelines and accreditation have little impact unless accompanied by management and information systems, decentralized authority, professional self-regulation, clear accountability and responsibility, national coordination – and financial incentives for improving performance.

Using the broader international context and experience for quality and accreditation, a total of 67 educational workshops, training sessions and conference events were implemented with over 3431 participants (see figure 3 below and annex 1) to obtain the project results summarized in the next chapter.

⁷ Joint Commission International. *Accreditation Standards for Hospitals (standards only)*, 3rd edition. Ann Arbor: Joint Commission Resources, 2007

⁸ Shaw Charles, Bruneau Charles, Kutryba Basia, DeJongh Guido, Sunol Rosa “*Towards Hospital Standardization in Europe*”, International Journal for Quality in Health Care Advance Access, June 24, 2010

⁹ Shaw CD, Kutryba B, Braithwaite J, et al. Sustainable Healthcare Accreditation: messages from Europe in 2009, Submitted to IJQHC November 2009 Manuscript no. INTQHC-2009-11-0297

¹⁰ Pomey MP, Contandriopoulos AP, Francois P et al. *Accreditation: a tool for organizational change in hospitals?* International Journal for Quality in Health care 2004;17:113-24

¹¹ de Walcque C, Seuntjens B, Vermeyen K et al. Comparative study of hospital accreditation programmes in Europe, KCE Health Services Research 2007-2022.

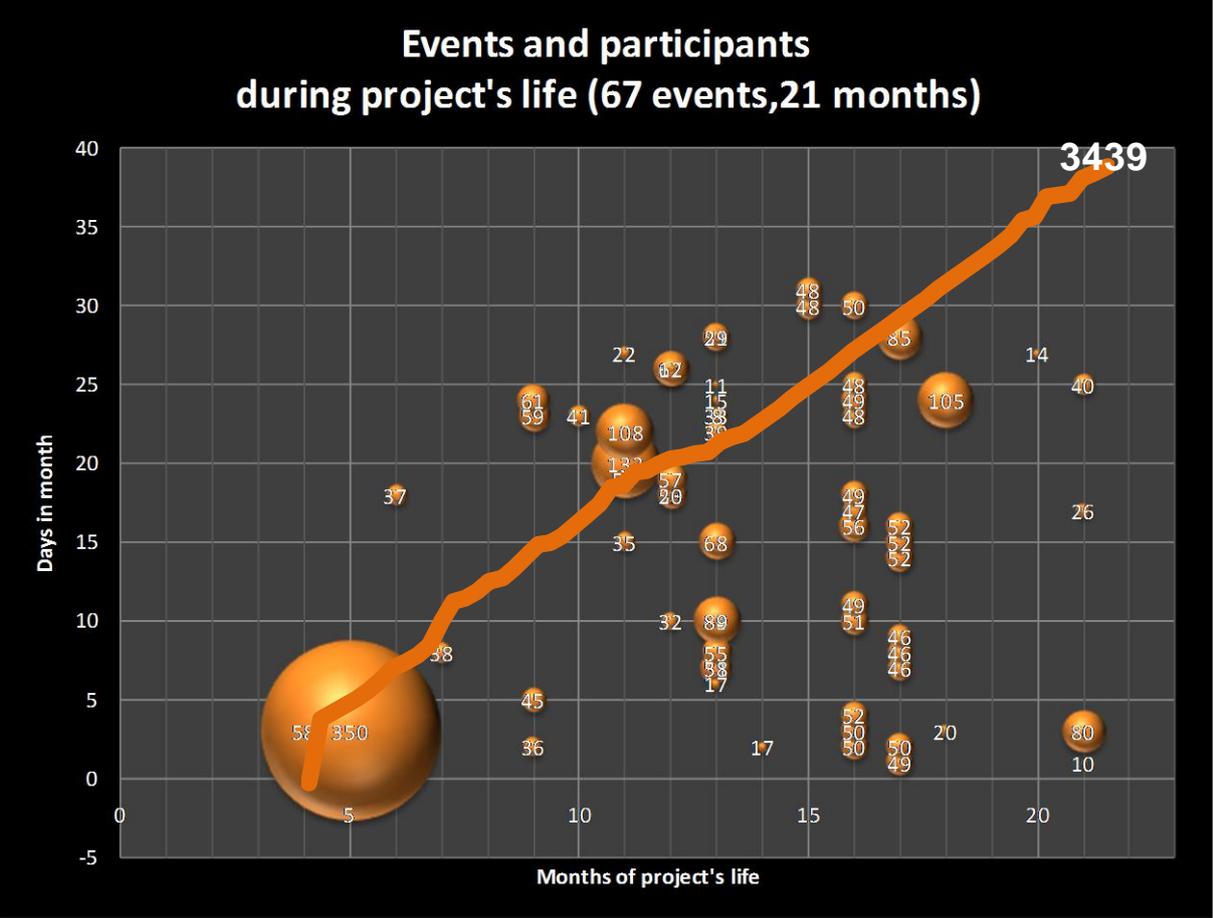
¹² Greenfield D, Braithwaite J. Health sector accreditation research: a systematic review. International Journal for Quality in Health care 2008;20 (3): 172-183

¹³ Lutfya MN, Sikka A, Mehta S et al. Comparison of US accredited and non-accredited rural critical access hospitals. International Journal for Quality in Health care 2009; 21:112-8

¹⁴ International Society for Quality in Healthcare. *Principles for Standards for External Assessment Bodies*. 3rd edition. December 2007

¹⁵ International Society for Quality in Healthcare. *International Accreditation Standards for Healthcare External Evaluation Organizations*, 3rd edition December 2007.

Figure 3: Events and Participants



RESULTS

Result 1.1: The identification and preparation of the full legal framework for the successful functioning of the Agency.

A modern and comprehensive set of regulations was developed/reviewed for the accreditation legal framework to ensure that Serbian accreditation legislation is consistent with the EU legislative framework. Specifically, the project assisted the Agency by:

- Mapping of the Serbian legal regulations on the quality and safety in health care
- Mapping of the relevant Serbian bodies and their competences related to the quality and safety in health care
- Mapping relevant institutions involved in healthcare quality and safety
- Contributing to the decision on establishment of the Republican professional commission for drafting and implementation of the clinical practice guidelines
- Contributing to the rule book on work of the Commission for drafting of the clinical practice guidelines
- Making and justifying proposals for changes and amendments of the Health Care Law
- Designing an Agency code of professional ethics external surveyors involved in accreditation processes
- Agreeing a cooperation arrangement with health care institutions for external surveyors
- Contract design for the engagement of the external surveyor in the process of accreditation of the health institution
- Developing a rule book on certification of the health care providers

Result 1.2: The necessary structural, organizational and managerial arrangements for the successful operation of the Agency.

The Agency was supported to develop a strategic plan and 3-year business plan including proposed functional and structural developments. This included a proposed organogram, information systems strategy and communication and marketing plan. The business plan was constructed at a difficult time in the history of the Agency with decisions pending on the proposed introduction of a 'mandatory' system of certification and other related uncertainties. The business plan was therefore based on the possibility that the following developments might be added to the Agency role during the course of the plan period and the plan should set out the minimal organisational and resource requirements for sustaining all potential developments:

- The introduction of a mandatory system of certification for all 4,383 public and private health care institutions commencing 2013
- The establishment of a Health Technology Assessment (HTA) function to support health system regulation, planning operations and performance management functions
- The establishment of a clinical practice support unit to promote good practice developments in clinical and medical audit
- The establishment of a clinical practice support unit to support the Quality Commission work in the design, promulgation and compliance monitoring of clinical guidelines, protocols and pathways

Additionally, an internal policy and procedure manual was produced. Various capacity building and knowledge transfer activities were undertaken with Agency staff.

Result 1.3: The Agency is supported in developing new technical processes and systems and sustains the accreditation processes and functions.

The development of accreditation occurred as part of broader health reforms in Serbia and in the context of the Government's Quality Strategy. The Agency is the main National centre for the definition, measurement and improvement of standards. The proposed national accreditation programme for hospitals and primary health care centres was further enhanced to meet ISQua (International Society for Quality in Healthcare) principles by enhancing existing accreditation standards, and by developing new standards for clinical support services – laboratories, pharmacies and diagnostics imaging – through workgroups of key stakeholders.

Field testing in 9 pilot sites (5 public and 4 private health care institutions – General Hospital in Uzice, General Hospital in Zrenjanin, Dom zdravlja in Leskovac, Dom zdravlja in Kragujevac, Pharmacy in Subotica, General Hospital Bel Medic, Dom zdravlja Dr Ristic, Pharmacy Farmanea, Biochemical laboratory Biomedica) occurred between May and September 2010, with self-assessment of health care institutions. In September and October 2010 over 90 external surveyors were trained for standards interpretation, survey process, documentation review, specific or specialized areas (safety, infection control, etc) and report-writing skills. The training programme for external surveyors was jointly developed by the Agency, the Belgrade School of Medicine/School of Public Health and the project. Eleven (11) CME training courses on quality and accreditation were approved by the Belgrade School of Medicine and Serbian National Health Council to be delivered to over 90 external surveyors (see annex 2 and 3). External assessment of 9 pilot sites was undertaken in November and December 2010. Survey teams were drawn from the pool of trained surveyors. Evaluation of pilot site accreditation process occurred between January and March 2011.

Patient safety is high on the EU policy agenda and is a relatively new component of accreditation World-wide. In 2005, Member States established a mechanism to discuss and take forward patient safety issues. A working group was set up under the High Level Group on Health Services and Medical Care through which the European Commission aims to facilitate and support its Member States in their work and activities. The World Health Organization (primarily through the World Alliance on Patient Safety), the Council of Europe, the OECD and European associations of patients, doctors, nurses, pharmacists, dentists and hospitals are also active members of the group.

The Accreditation and Quality Agency is the natural “home” for these initiatives and it coordinates efforts in this area and establishes itself as a provider of information, training and advice on aspects of patient safety to healthcare facilities in Serbia.

The Agency, with the support of the project, has designed a Patient Safety Strategy incorporating action in five specific patient safety areas: hand hygiene, safe surgical practices, safe medication practice, patient identification and minimizing adverse events. The implementation manual provides information on each of these five areas, as a specific and individualized strategy for each will be required.

A sub-set of the national quality indicators was selected and tested in 37 pilots sites (Dom zdravlja: Lucani, Bela Palanka, Knic, Osecina, Indjija, Vozdovac, Knjazevac, Sjenica, Dimitrovgrad, Ruma, Vlasotince, Zagubica, Svilajnac, Topola, Kladovo, Sabac, Ada, Velika Plana, Novi Pazar, Lebane,

Leskovac, Kragujevac, Valjevo, Kraljevo, Savski venac, Stari grad, Novi Sad, Dr Ristic; Hospital: Zrenjanin, Uzice, Valjevo, Kraljevo, Piroat, Vrbas, Bel Medic; Clinical Hospital Centre “Dr Dragisa Misovic”; Clinical Centre of Kragujevac) in order to establish targets. These quality indicators will be used during the accreditation process for health care institutions self-assessment and by the external surveyors during the accreditation visit from 2012.

The following documentation was prepared to support and guide the accreditation process:

- National accreditation programme of standards for primary care, secondary care and tertiary care institutions
- Guidebook for Self-Assessment (for Health care Institutions)
- Guidebook for External Surveyors
- Patient Safety Strategy and Patient Safety Standards Manual for Healthcare Institutions
- Quality Indicators Data Definitions Guidebook

Result 2.1: *Within the constraints of the legal framework, the role, function and alternative approaches to accreditation are clearly assessed, evaluated and agreed, taking account of international evidence and experience of best practice.*

Voluntary accreditation programmes, modelled on systems from USA, Canada and Australia have grown steadily throughout Europe. Uptake and coverage of accreditation is strongly associated with direct or indirect financial advantage in being accredited. Even where accreditation programmes are available in Europe, they often do not provide a comprehensive view of hospitals in either public or private sector. The statutory position of the Haute Autorite de Sante (HAS) in France has generated rapid uptake and now has the widest national coverage in Europe (the Danish programme has yet to be fully implemented).

Accreditation, as defined in the Serbian 2005 Healthcare Law, is voluntary and involves an assessment of the quality of work against pre-determined optimal standards. The process is paid for by a fee payable by the institution. This may pose problems for institutions in an increasingly pressured financial climate and the impact of accreditation may be negated. A decision has been taken in principle to introduce mandatory ‘certification’ of health care institutions, to operate alongside accreditation, but focused on a more limited range of patient safety indicators. Safety of the patients is one of the basic objectives of the National Strategy for continuous quality improvement and patients’ safety, adopted in 2009.

By meeting certification standards, public and private healthcare institutions will be stimulated to establish systems of quality and patients safety, that should have a considerable impact on the quality of work of the health system and contribute to the restoration patients’ confidence in the health care system (see figure 4).

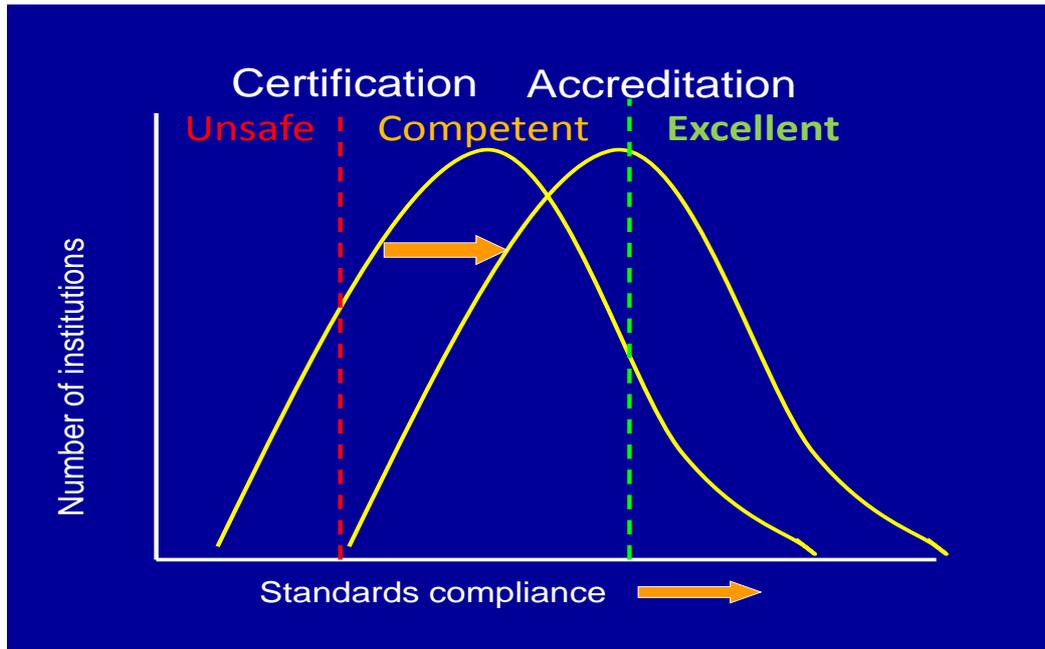
Harmonization with the EU regulation is another target for the introduction of the mandatory certification and, in that sense, the basis for the compliance with the EU regulations¹⁶.

¹⁶ European Commission. Together for Health: A Strategic Approach for the EU 2008-2013. COM(2007) 630 Final. Brussels, 2007

Council of the European Union. Recommendations on patient safety, including the prevention and control of healthcare associated infections (2009/C 151/01) Luxembourg, 9 June 2009

European Parliament. Legislative resolution of 23 April 2009 on the proposal for a directive of the European Parliament and of the Council on the application of patients’ rights in cross-border healthcare.

Figure 4 Conceptual model of certification and accreditation



These regulations define a set of common values for health systems, and include the proposition that “...patients can expect from every EU members’ health system to ensure the systematic approach to the provision of the patients’ safety, including the monitoring of the factors of risk and non-adequacy”. The Council of Europe issued the recommendations that each member state should determine an independent body, to perform the activities related to the patient safety, including

1. The definition of clear standards of quality and safety for health care providers,
2. The implementation of quality and safety standards,
3. The exercise of continuous control and implementation of any corrective measures that should be undertaken.

Through its Resolution from 2002, WHO recognized patients’ safety as a fundamental and basic principle for all health systems and in 2004 invited EU member states to direct the highest possible attention to the issue. The introduction of certification should facilitate the achievement of key EU and WHO recommendations related to the patients’ safety. Furthermore, the introduction of mandatory certification would considerably assist the sustainability of the Agency, and the development of a viable Business Plan 2011 – 2013.

Result 2.2: *The Agency is supported in the development of the necessary skills and capacities to enable it to ensure high quality healthcare services by efficiently and effectively developing and performing its accreditation activities and moving towards self-sustainability.*

Agency staff capacity improved in the key areas through participatory approaches, “learning by doing”, training, and study tours. All workshop content was jointly prepared by project consultants and Agency staff to ensure knowledge transfer. Furthermore, the project supported the Agency staff and key beneficiaries in attending the following conferences in order to obtain the most current and state-of-the-art knowhow internationally.

- 26th Annual International ISQua Conference in Dublin, Ireland, held from 11th to 14th October 2009, 6 persons attended;
- European Accreditation Network Workshop in Utrecht, Netherlands, held from 16th to 17th March 2010, 2 persons attended;
- EHMA Annual Conference – Managing Radical Change in Health: Quality, Efficiency, Equity, in Lahti, Finland, held from 30th June to 2nd July 2010, 2 persons attended;
- 27th Annual International ISQua Conference in Paris, France, held from 10th to 13th October 2010, 3 persons attended;
- Study Tour – visit to the National Institute for Health and Clinical Excellence in London, UK, 26th to 30th September 2010, 6 persons attended;
- European Accreditation Network Workshop in Prague, Czech Republic, held from 10th to 11th February 2011, 1 person attended.

A study tour to NHS NICE was also organized for training in implementation packages for clinical practice guidelines (CPGs). The Agency currently supports the newly reinstated Ministry of Health Commission for CPGs. NICE staff also assisted the Agency to prepare a national framework for Health Technology Assessment (HTA). While progress has been made in the development of CPGs in Serbia and the accreditation of healthcare providers, the institutional framework for undertaking of HTA and the linked economic evaluations remains unclear. Responsibilities for undertaking HTA seem to be split across several institution/governmental department including the Ministry of Health and the Health Insurance Fund. The Business Plan 2011-2013 provides for an HTA coordinating function to be provided within the Agency, initially with World Bank financial support.

Result 2.3: *The Agency is supported in developing linkage with other existing aspects of the Ministry's quality assurance strategy, thereby providing coherence to the healthcare overall quality improvement effort in Serbia healthcare system.*

The project promoted revision of the national quality policy in order to strengthen the strategic goals with special reference to clinical practice, audit, governance, institutionalisation and change management.

Furthermore, the project mapped and clarified the legal basis, responsibilities, activities and capacity of the various committees and institutions concerned with quality improvement in the healthcare system. Effective quality management relies on effective management systems at all levels, including planning, organization, direction and control. A step towards building functional links and collaboration between the contributing bodies (see figure 5 and 6) would be to identify for each:

- Line and mechanisms for upward accountability; reporting procedure
- Formal relationship with related bodies
- Functional status; advisory or executive
- Legal status: relevant laws, regulations, by-laws, instruments
- Source of funding, income generation
- Management control systems: planning and reporting cycle
- Scope and limits of responsibilities for staff and functions within the health system
- Provision of products or services related to quality and safety in healthcare
- Information flow: generation, analysis, aggregation and exchange of quality data

Additionally, the project collaborated with the Ministry of Health World Bank Project & Quality Commission to develop and “integrated Quality Improvement Plan” (figure 7) tool for Healthcare institutions to monitor and improve quality.

Figure 5 Mapping of institution relevant to quality and patient safety in health system of the Republic of Serbia

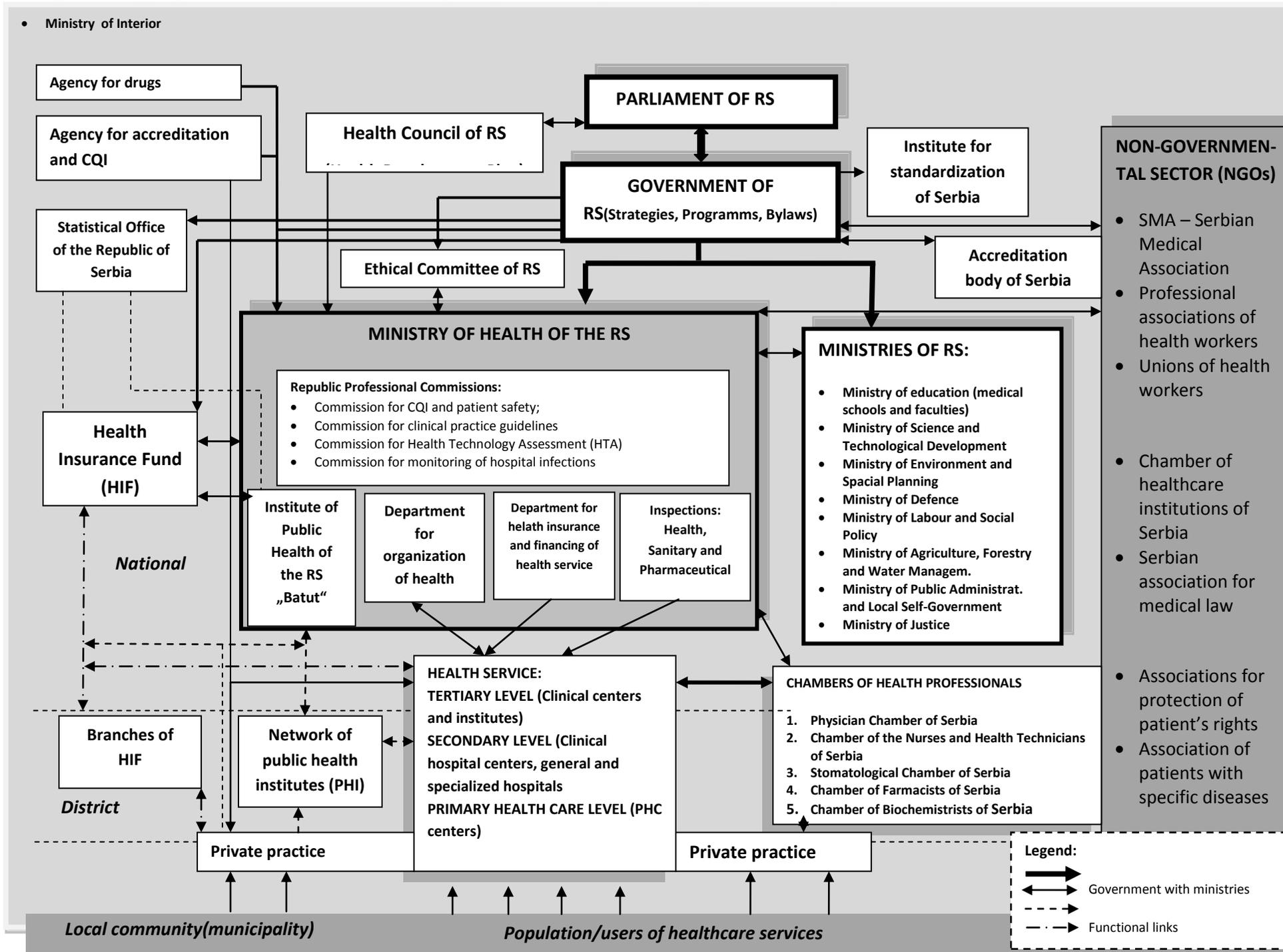
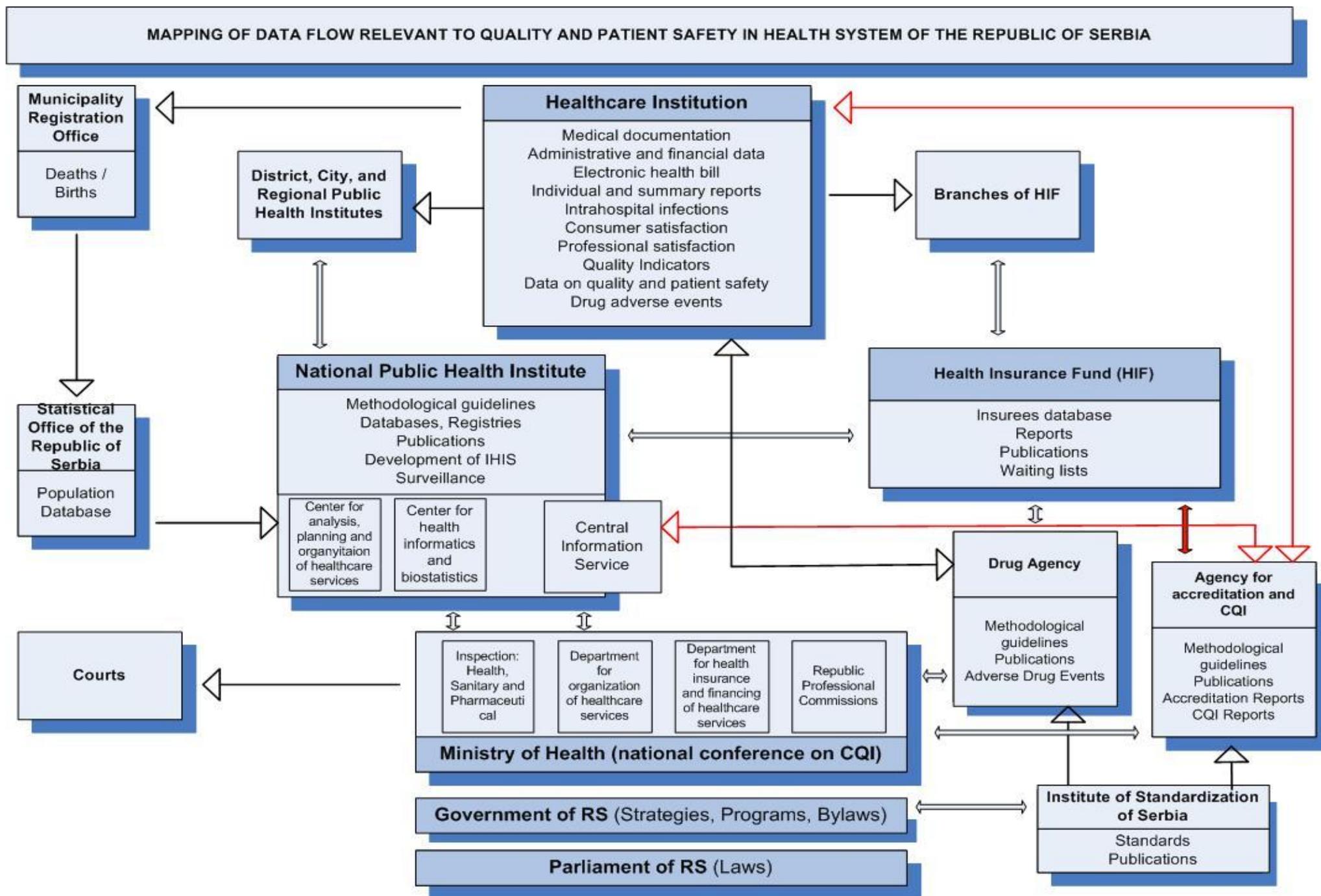
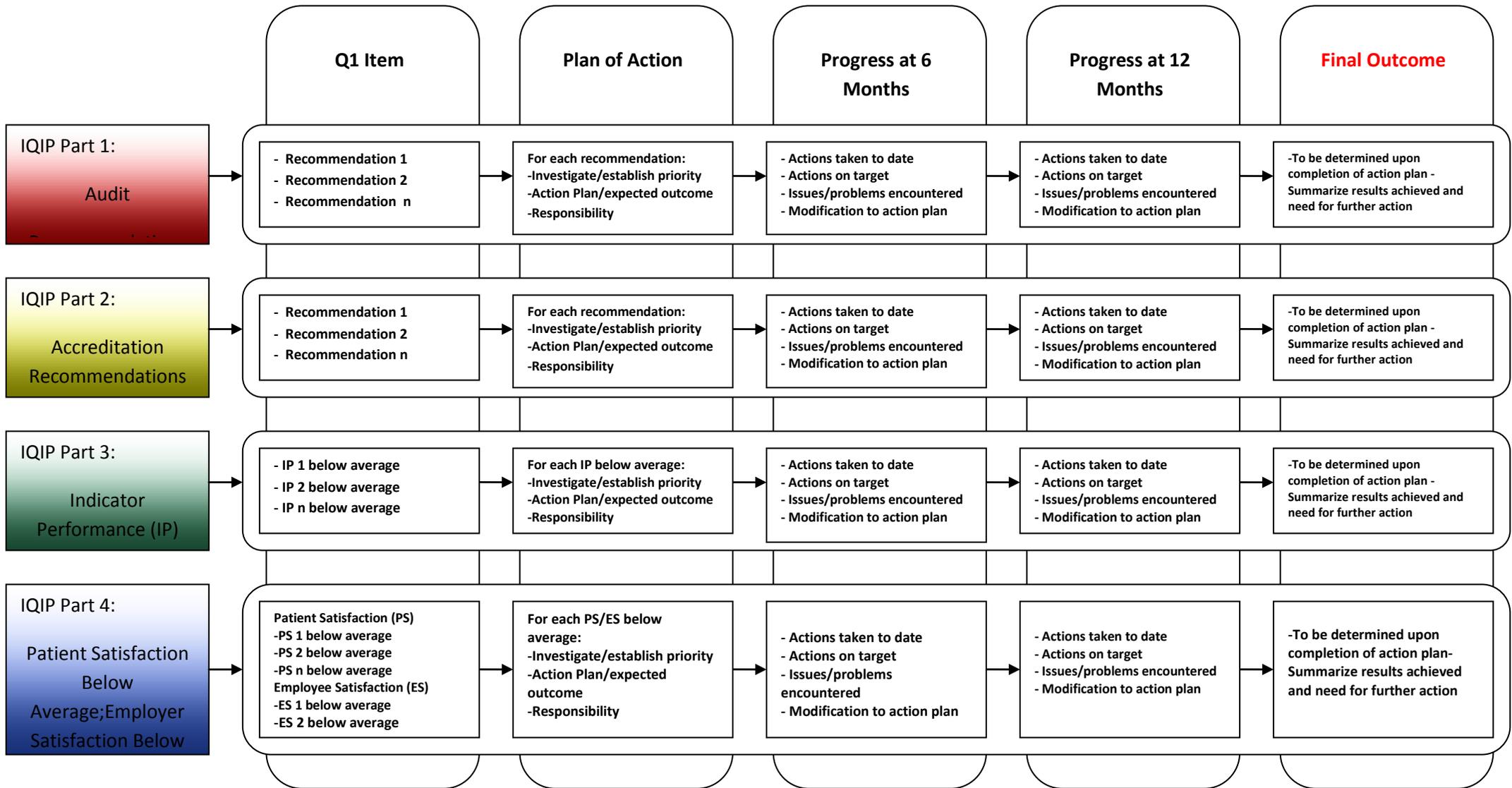


Figure 6 Mapping of data flow





NEXT STEPS

One of the important keys to healthcare reform, and to quality improvement, is performance related funding. The commitment of the Health Insurance Fund to implement the national quality plan, particularly active service planning and commissioning, performance benchmarking of provider institutions, purchasing outcomes for certain services and reporting of the impact of public funding on health system outcomes - remains unclear.

Effective systematic improvement of quality and safety requires a balance of accountability, responsibility and authority for managing change. The Accreditation Agency is the best suited organization in Serbia to promote a “quality culture” and to instil new leadership skills for healthcare managers towards a shared vision of continuous quality improvement (CQI) and to contribute to the necessary and extensive human resource development task.

In reality, continuous improvement of the health system will be limited not by the capacity of the Agency to identify institutional compliance with standards, but by the capacity of institutions - and municipalities and the Ministry of Health - to respond by developing more effective systems for planning, organization, general and professional management and performance management. What is required is deep cultural change which can only be achieved and sustained by a multi-faceted change strategy in which the Agency can make a significant contribution. However, such a comprehensive change requires the active participation of and contribution from all key stakeholders working to a common policy and common direction.

Some of the most difficult areas of quality and safety assurance have yet to be tackled – the quality and safety of medical care and clinical practice. This is at the core of the quality and safety assurance issue in health care, yet it is a minimally developed field of activity in Serbia. It is also the most difficult area to tackle as it often challenges traditional and historical conventions and roles and provides difficult challenges to professionals and patients alike in terms of evidence-based practice, transparency and openness, patient centeredness, human resource development etc. The real test of the success of a quality strategy will be its contribution to the quality and safety of medical care and clinical practice and the ‘new’ Agency functions of HTA, evidence-based health care and clinical practice development will be key supports for change in this key area of activity.

A useful developmental approach for Serbia will be to continue to harmonize its approaches to continuous quality improvement and patient safety with European guidelines where they exist and benchmarking standards and assessment disciplines with the proven approaches advocated by the International Accreditation Programme of the International Society for Quality in Healthcare (ISQua).

CONCLUSIONS / LESSONS LEARNT

Much effort has gone into the development and implementation of technical processes and systems for a national accreditation programme for the public and private sectors in Serbia. Significant deliverables were produced and intensive involvement of key stakeholders occurred in the form of consultative and educational workshops. The project has supported the Agency with a number of legislative revisions to the Healthcare Law, creation of by-law, and various contracts recommendations. Increased awareness and involvement among different stakeholders concerning the importance of on-going interventions on quality and safety in health has occurred with field testing of national accreditation standards in 9 pilot sites (5 public, 4 private) and various project workshops and training sessions involving over 600 key stakeholders. (read more about all project activities on www.accreditationproject.rs).

Project progress reports indicate evidence of need for changes throughout the health system. These changes are well beyond the capacity of the current project led by EPOS but are essential to the improvement of quality and safety in Serbia.

It is suggested that the European Commission, World Bank and international agencies to coordinate projects which relate to improvement of the Serbian health system. Attention should focus on the political, financial and organizational environment to support and integrate technical interventions such as the introduction of payment, data, management and clinical systems.

Funding for the improvement of quality and safety of healthcare should be related directly on an authoritative national quality strategy which is based on stakeholder consultation and scientific evidence. The current plan – national quality strategy - does not meet these requirements. The design and evaluation of projects should measure the impact on the health system, as well as on pilot sites, consistent with implementation specified elements of the national quality plan.

The government, ministries and international community should work together on a coherent strategy for changing the healthcare system. Quality improvement in healthcare is not something that can be done in isolation, alongside the strategy that is specifically labelled “quality improvement”. There are a number of other healthcare development strategies focusing on particular patient groups, segments of society, disease types or specific delivery methods for healthcare. All of these are aiming to improve quality within their specific field and the national strategy needs to be aware of these and to aim to coordinate joint approaches whenever feasible.

Experience from many countries confirms that all accreditation programmes face threats to their sustainability, including:

- Unrealistic business planning and timescales
- Delay, or failure of financial incentives for institutions to participate
- Premature or untapered end of core funding by international donors
- Resistance from academic institutions to participation
- Change of government, minister or policy

Consideration should be given to reconfiguring the five proposed strategies of the national quality strategy or to adding two new ones to include:

- Development of clinical practice and clinical systems (technology assessment, practice guidelines, clinical governance – organization, data, audit, accountability)
- Systematic institutionalization of quality and safety

The project resulted in some important, improvements within the health care system, and understanding the role and contribution of the Agency to continuous health system quality and safety improvement. It is likely that changes to the Health Law will impose a regime of mandatory certification on health institutions, which will help further reinforce the position and institutional role of the Agency within the health care system. The role of Agency in continuous improvement of quality and safety of health services is already evident and this role will become even more prominent in the future.

In conclusion, the quality of Serbia's healthcare system has major socio-economic benefits. Health care reform is positioned within the wider Public administration reform framework and the second has been pioneering new developments in terms of service quality/value for money that serve as an example to other branches of the public sector. This project has assisted to further develop and define the culture of health care quality and the role of patients and medical professionals in quality assurance. Furthermore, the project assisted to promote the objectives of accreditation: improvement of health care quality and patient safety - and establishment of trust of health care service users in health care system.

ENVOI

Some citizens may never need to visit health care institutions. Our conviction is that all will benefit from quality and patient safety in health care. The introduction of quality and patient safety standards in Serbia with accreditation has the aim to provide a blueprint for achieving excellence in clinical and operational practice and a way of actually day-to-day living by that practice. The Accreditation Agency has begun to transform traditional habits into a CQI effort that allows health care institutions to use accreditation standards as operational tools for routinely assessing and documenting their strengths as well as identifying and correcting their weaknesses, making accreditation the essential and complimentary partner in good practice professional and general management regimes.

Annex 1: Project Workshops and Conferences

LIST OF WORKSHOPS AND CONFERENCES ORGANIZED BY THE PROJECT								
Event No	Date	Event's title	Number of participants	Month of the project	Day of the month	Type of event (enter 1)		
						Workshop	Training	Conference/ Visibility Event
1	03.09.2009	Health Care Accreditation Project Presented	58	4	3			1
2	03.10.2009	Future of Accreditation of Health Care Institutions in Serbia	350	5	3			1
3	18.11.2009	Special workgroups established for development of new standards	37	6	18	1		
4	08.12.2009	Meeting of Special workgroups for development of new standards	38	7	8	1		
5	02.02.2010	Meeting of Special workgroups for development of new standards	36	9	2	1		
6	05.02.2010	Workshop Development of Strategic and Business Plan for the Agency for Accreditation of Health Care Institutions in Serbia	45	9	5	1		
7	23.02.2010	Evaluation of Pilot Sites Workshop	59	9	23	1		
8	24.02.2010	Second workshop on the Development of a Strategic and Business Plan for the Agency for Accreditation of Health Care Institutions in Serbia	61	9	24	1		
9	23.03.2010	Meeting of Special workgroups for development of new standards	41	10	23	1		
10	15.04.2010	Workshop on the Accreditation for Clinical Centres and Clinical Hospital Centres	35	11	15	1		
11	19.04.2010	Indicator Development Workshop	53	11	19	1		
12	20.04.2010	Patient Safety Strategy Information Session	133	11	20			1
13	22.04.2010	Management of External Surveyors Workshop	108	11	22	1		
14	27.04.2010	Meeting of Special workgroups for development of new standards	22	11	27	1		
15	10.05.2010	Workshop for Lead Surveyor Training was held in Valjevo	32	12	10		1	

16	18.05.2010	Training on self assessment (testing of national accreditation standards) in pilot sites - DOM ZDRAVLJA LESKOVAC	53	12	18		1
17	18.05.2010	Training on self assessment (testing of national accreditation standards) in pilot sites - PHARMACY SUBOTICA	20	12	18		1
18	19.05.2010	Training on self assessment (testing of national accreditation standards) in pilot sites - DOM ZDRAVLJA KRAGUJEVAC	57	12	19		1
19	26.05.2010	Training on self assessment (testing of national accreditation standards) in pilot sites - HOSPITAL ZRENJANIN	67	12	26		1
20	26.05.2010	Training on self assessment (testing of national accreditation standards) in pilot sites - HOSPITAL UZICE	62	12	26		1
21	26.05.2010	Training on self assessment (testing of national accreditation standards) in pilot sites - HOSPITAL BEL MEDIC	12	12	26		1
22	07.06.2010	Training on self assessment (testing of national accreditation standards) in pilot sites - PHARMACY SUBOTICA	31	13	7		1
23	07.06.2010	Training on self assessment (testing of national accreditation standards) in pilot sites - DOM ZDRAVLJA LESKOVAC	58	13	7		1
24	08.06.2010	Workshop on quality indicators	55	13	8	1	
25	10.06.2010	Training on self assessment (testing of national accreditation standards) in pilot sites - DOM ZDRAVLJA KRAGUJEVAC	64	13	10		1
26	10.06.2010	Training on self assessment (testing of national accreditation standards) in pilot sites - HOSPITAL ZRENJANIN	89	13	10		1
27	10.06.2010	Meeting Private Health Sector Pilot Sites Management	17	13	6	1	
28	15.06.2010	Training on self assessment (testing of national accreditation standards) in pilot sites - HOSPITAL UZICE	68	13	15		1
29	21.06.2010	Training on self assessment (testing of national accreditation standards) in pilot sites - DZ DR RISTIC	7	13	21		1
30	22.06.2010	Patient Safety Standards Education Workshop	39	13	22	1	
31	23.06.2010	Regulators & Inspectors Workshop	33	13	23	1	

32	23.06.2010	Training on self assessment (testing of national accreditation standards) in pilot sites - PHARMACY FARMANEA	8	13	23		1
33	24.06.2010	Training on self assessment (testing of national accreditation standards) in pilot sites - PHARMACY FARMANEA	15	13	24		1
34	25.06.2010	Training on self assessment (testing of national accreditation standards) in pilot sites - LABORATORY BIOMEDICA	11	13	25		1
35	28.06.2010	Training on self assessment (testing of national accreditation standards) in pilot sites - DZ DR RISTIC	51	13	28		1
36	28.06.2010	Training on self assessment (testing of national accreditation standards) in pilot sites - LABORATORY BIOMEDICA	29	13	28		1
37	02.07.2010	Training on self assessment (testing of national accreditation standards) in pilot sites - HOSPITAL BEL MEDIC	17	14	2		1
38	30.08.2010	Continuous Medical Education Programme (CME)	48	15	30		1
39	31.08.2010	CME	48	15	31		1
40	02.09.2010	CME	50	16	2		1
41	03.09.2010	CME	50	16	3		1
42	04.09.2010	CME	52	16	4		1
43	10.09.2010	CME	51	16	10		1
44	11.09.2010	CME	49	16	11		1
45	16.09.2010	CME	56	16	16		1
46	17.09.2010	CME	47	16	17		1
47	18.09.2010	CME	49	16	18		1
48	23.09.2010	CME	48	16	23		1
49	24.09.2010	CME	49	16	24		1
50	25.09.2010	CME	48	16	25		1
51	30.09.2010	CME	50	16	30		1
52	01.10.2010	CME	49	17	1		1
53	02.10.2010	CME	50	17	2		1
54	07.10.2010	CME	46	17	7		1

55	08.10.2010	CME	46	17	8		1	
56	09.10.2010	CME	46	17	9		1	
57	14.10.2010	CME	52	17	14		1	
58	15.10.2010	CME	52	17	15		1	
59	16.10.2010	CME	52	17	16		1	
60	28.10.2010	Workshop on quality indicators	85	17	28	1		
61	03.11.2010	Workshop on Future Directions of Health Technology Assessment and Clinical Practice Guidelines in Serbia	20	18	3	1		
62	24.11.2010	External surveyors awarded certificates	105	18	24			1
63	27.01.2011	Health Technology Assessment Workshop	14	20	27	1		
64	01.02.2011	Workshop on quality indicators	10	21	1	1		
65	03.02.2011	Workshop on quality indicators	80	21	3	1		
66	17.02.2011	Evaluation of Pilot Sites Accreditation Survey Results Workshop	26	21	17	1		
67	25.02.2011	Evaluation of Pilot Sites Accreditation Survey Results Workshop	32	21	25	1		
TOTAL PARTICIPANTS			3431			22	41	4
TOTAL EVENTS 67								

Annex 2: Surveyor Training Programme Courses

<u>No. of course</u>	<u>Title of Continuous Medical Education (CME) course</u>	<u>No of Credits</u>	<u>Volume</u>	<u>Course Coordinators</u>
1	Continuous quality improvement and patient safety	7	6 hours	Prof dr Snezana Simic, Mr. George Boulton
2	Team work		6 hours	Prof dr Dejana Vukovic, Dr Snezana Manic
3	Strategic planning and institutions	8	6 hours	Prof dr Vesna Bjegovic Mikanovic, Dr Snezana Manic, Ms. Annette Katrava
4	Patient role in continuous quality improvement and provision of health care services	8	6 hours	Prof dr Snezana Simic, Mr. George Boulton
5	Basics of accreditation evaluation and institutions (theory and practice)	8	6 hours	Prof dr Sandra Sipetic-Grujjicic, Dr Snezana Manic, Ms. Annette Katrava
6	Accreditation standards - clinical	8	6 hours	Prof dr Sandra Sipetic-Grujjicic, Dr Snezana Manic
7	Accreditation standards – non clinical	6	6 hours	Prof dr Ljiljana Markovic-Denic, Dr Snezana Manic, Ms. Annette Katrava
8	Accreditation standards –clinical support : Laboratory ,Pharmacy and Diagnostic Radiology	7	6 hours	Prof dr Ljiljana Markovic-Denic, Dr Snezana Manic, Ms. Annette Katrava
9	Accreditation planning	8	6 hours	Asis. Prof. dr Bojana Matejic, Dr Snezana Manic, Ms. Annette Katrava
10	Accreditation methods for evaluation of institutions	8	6 hours	Prof dr Jelena Marinkovic, Dr Snezana Manic, Ms. Annette Katrava
11	Preparation of accreditation report with recommendations	8	6 hours	Prof dr Dejana Vukovic, Dr Snezana Manic, Ms. Annette Katrava

Annex 3: List of trained Surveyors

List of health care professionals trained to become surveyors for the Agency for Accreditation of Health Care Institutions of Serbia:

No	Name and Surname	Occupation	HCI	City
1	Aleksandar Kefer	Economist	Hospital	Sremska Mitrovica
2	Ana Pavlovic	Medical Nurse	DZ Vračar	Belgrade
3	Andjelo Beletic	Medical Biochemistry Specialist	CCS Centre for Biochemistry	Belgrade.
4	Anka Vesic	Medical Nurse	Hospital	Valjevo
5	Biljana Lopičić	Medical Nurse	DZ	Kraljevo
6	Biljana Lukic	In House Lawyer	Hospital	Valjevo
7	Dr Bisenija Radivojevic	General Medicine Specialist	DZ	Kragujevac
8	Dr Branka Stamatovic Gajic	Psychiatrist	Hospital	Valjevo
9	Dr Časlav Miladinovic	Medical Doctor	DZ	Doljevac
10	Dr Danka Zivanovic	General Medicine Specialist	DZ	Valjevo
11	Dr Sci Med Dejan Nikolic	Surgeon	CHC Bezanijska kosa	Belgrade
12	Desanka Radulovic	In House Lawyer	DZ Stari Grad	Belgrade
13	Dr Dragan Kaljevic	Clinical Pharmacology Specialist	Hospital	Kraljevo
14	Dr Dragan Radojevic	Medical Doctor	DZ	Uzice
15	Dragana Kostadinovic	Medical Nurse	DZ	Novi Sad
16	Dragana Mardešić	In House Lawyer	DZ Palilula	Belgrade
17	Dr Dragana Zegarac	Specialist in Neuropsychiatry	Hospital	Zrenjanin
18	Dragica Škundric	Medical Nurse	DZ	Zrenjanin
19	Dragica Vnučec	Medical Nurse	DZ Savski Venac	Belgrade
20	Prim Dr Dušica Mladenovic	General Medicine Specialist	DZ Palilula	Belgrade
21	Goran Nikolic	Medical Nurse	DZ	Uzice
22	Prof dr Goran Videnovic	Maxillofacial surgery	Medical Faculty	Kosovska Mitrovica
23	Prim Dr Gordana Dragašević	Specialist in Occupational Medicine	DZ Stari Grad	Belgrade
24	Dr Gordana Đorđević	Gynaecologist	Hospital	Vranje
25	Prim Dr Gordana Palic Jevremovic	General Medicine Specialist	DZ Vozdovac	Belgrade
26	Gordana Simic	Medical Nurse	DZ	Valjevo
27	Dr Gordana Stankovic	General Medicine Specialist	DZ	Niš
28	Prim. dr Ilija Tripkovic	Surgeon	Hospital	Valjevo
29	Ivana Zelenovic	Medical Nurse	DZ	Sečanj
30	Jadranka Zdravkovic	Medical Nurse	CC	Kragujevac
31	Jagoda Lukic	In House Lawyer	CHC Dragisa Misovic	Belgrade

32	Prim Dr Jasmina Jovanovic	General Medicine Specialist	DZ	Leskovac
33	Dr Jasmina Mihajlovic	Paediatrician	DZ Vračar	Belgrade
34	Jasmina Peulja Vukobratovic	Economist	DZ	Novi Sad
35	Jasna Bjelanovic	Medical Biochemistry Specialist	CCS Centre for Biochemistry	Belgrade
36	Jelena Osap	Medical Biochemistry Specialist	DZ	Novi Sad
37	Jovanka Franeta	Pharmacist	Pharmacy	Novi Sad
38	Lidija Lazovic	In House Lawyer	Hospital	Kraljevo
39	Dr Livia Varga	Paediatrician	DZ	Backa Topola
40	Dr Ljiljana Dugic	Internal Medicine Specialist	DZ	Kragujevac
41	Ljubica Radovanovic	Medical Nurse	DZ	Kragujevac
42	Marija Mijajlovic	Medical Nurse	Hospital	Kraljevo
43	Marija Panovski	Medical Nurse	Hospital	Pozarevac
44	Dr Sci Med Marko Folic	Medical Doctor	CC Kragujevac	Kragujevac
45	Dr Milena Djukic	Ophthalmologist	DZ	Niš
46	Dr Milena Papic	Specialist in Occupational Medicine	DZ	Sečanj
47	Milica Jovanovic	In House Lawyer	Hospital	Pozarevac
48	Dr Sci Med Milovan Dimitrijevic	Maxillofacial Surgeon	CCS ENT Clinic	Belgrade
49	Dr Mirjana Krčevinac	General Medicine Specialist	DZ	Kraljevo
50	Prim Dr Mirjana Perovic	Medical Biochemist	General Hospital	Vrbas
51	Dr Mladena Kalajdzic	General Medicine Specialist	DZ	Kraljevo
52	Dr Nada Bačić	Paediatrician	DZ	Zrenjanin
53	Dr Nataša Stojcevic Radulovic	Gynaecologist	Hospital	Sremska Mitrovica
54	Prim Dr Nebojša Maksic	Medical Biochemistry Specialist	CCS Centre for Biochemistry	Belgrade
55	Dr Nenad Sretenovic	Plastic Surgeon	General Hospital	Pozarevac
56	Nenad Veljovic	In House Lawyer	DZ	Obrenovac
57	Olgica Sekelj	In House Lawyer	DZ	Zrenjanin
58	Dr Radivoje Lazic	Urologist	Hospital	Pozarevac
59	Prim Dr Radmila Mihajlovic	General Medicine Specialist	DZ	Valjevo
60	Prim Dr Radmila Obrenovic	Medical Biochemistry Specialist	CCS Centre for Biochemistry	Belgrade
61	Dr Radoslav Milošević	Emergency Medicine Specialist	DZ	Obrenovac
62	Radoš Topalovic	In House Lawyer	DZ	Uzice
63	Ruzica Nikolic	Pharmacist	Pharmaceutical Company Galenika	Belgrade
64	Sandra Selthofer	Medical Nurse	DZ	Vranje
65	Sanja Stankovic	Medical Biochemistry Specialist	CCS Centre for Biochemistry	Belgrade
66	Dr Slađana Kaurin Miletic	Statistician in Medicine	DZ	Sabac

67	Slavica Zaviša	Medical Nurse	Hospital	Zrenjanin
68	Dr Snezana Despotovic Kušljevic	General Medicine Specialist	Palilula DZ	Belgrade
69	Dr Snezana Jankovic	General Medicine Specialist	DZ	Obrenovac
70	Dr Srđan Tomic	Dermatologist	DZ	Vranje
71	Stana Arsenijevic	Economist	DZ	Kragujevac
72	Dr Svetlana Sovrlic	Medical Doctor	DZ	Sečanj
73	Mr ph spec Svetlana Stojkov Rudinski	Pharmacist	Pharmacy	Subotica
74	Tanja Erdeljanovic	Medical Nurse	CCS ENT Clinic	Belgrade
75	Tatjana Bokic	Medical Nurse	DZ	Nis
76	Tatjana Crnjanski	Pharmacist	Pharmacy	Subotica
77	Mr sci Tatjana Vodnik	Medical Biochemistry Specialist	CCS Centre for Biochemistry	Belgrade
78	Dr sci Vera Celic	Internal Medicine Specialist	CHC Dragisa Mišovic	Belgrade
79	Dr Verica Milatovic Jezdic	Clinical Biochemistry Specialist	DZ Savski venac	Belgrade
80	Verica Seničić	Medical Nurse	CHC Dragisa Mišovic	Belgrade
81	Dr Vesna Bernobic Popovic	Social Medicine Specialist	DZ	Stari Grad
82	Vesna Krstic	Medical Nurse	Hospital	Vranje
83	Prim dr Vesna Vujičić	General Medicine Specialist	DZ	Savski Venac
84	Dr Vesna Zlatanovic Mitic	Emergency Medicine Specialist	DZ	Doljevac
85	Dr Zoran Dimitrijevic	Specialist in Neuropsychiatry	DZ	Uzice
86	Dr sci Zoran Vlahovic	Social Medicine Specialist	CHC Dragisa Mišovic	Belgrade
87	Zorica Blagojevic	Medical Nurse	Hospital	Sremska Mitrovica
88	Mr ph Zorica Marinic	Pharmacist	DZ	Sečanj
89	Zorica Popovic	In House Lawyer	DZ	Doljevac
90	Prim mr ph Zorica Šumarac	Medical Biochemistry Specialist	CCS Centre for Biochemistry	Belgrade.
91	Dr Zvonimir Veselinovic	Surgeon	Hospital	Kraljevo

Annex 4: Sub-set of National Quality Indicators to be included in Accreditation process

Quality indicators for PHCI (Dom Zdravlja) (2010)

- P1_OM:** No of referrals to specialists as % of total number of exams - General Medicine
- P2_OM:** No of preventative exams as % of total number of exams - General Medicine
- P3_OM:** % users with all four healthy behaviours noted in record - General Medicine (reworked data)
- P1_PSD:** No of referrals to specialists as % of total number of exams - Pre-school Paediatrics
- P2_PSD:** No of preventative exams as % of total number of exams - Pre-school Paediatrics
- P3_PSD:** % of cases with acute infection of the Upper Respiratory Tract who were prescribed antibiotics at their first visit- Pre-school Paediatrics
- P1_SD:** No of referrals to specialists as % of total number of exams - School-age Paediatrics
- P2_SD:** No of preventative exams as % of total number of exams - School-age Paediatrics
- P3_SD:** % of children aged 15 protected by complete immunisation in the previous year
- P1_Gyn:** No of referrals to specialists as % of total number of exams - Gynaecology
- P2_Gyn:** No of preventative exams as % of total number of exams - Gynaecology
- P3_Gyn:** % of users, aged between 25 and 69, who were included in the targeted examination for the early detection of cervical cancer in 2009

List of Clinical Indicators for Hospitals (2010)

- BO_P1_ALL:** Lethality rate (whole hospital)
Lethality rate (Internal Medicine)
Lethality rate (Surgery)
Lethality rate (Paediatrics)
Lethality rate (Gynaecology & Obstetrics)
Lethality rate (Intensive care)
Lethality rate (Coronary unit)
- BO_P2_ALL:** % deaths during first 48 hours after admission (whole hospital)
% deaths during first 48 hours after admission (Internal Medicine)
% deaths during first 48 hours after admission (Surgery)
% deaths during first 48 hours after admission (Paediatrics)
% deaths during first 48 hours after admission (Gynaecology & Obstetrics)
- BO_P3_ALL:** Average length of stay (whole hospital)
Average length of stay (Internal Medicine)
Average length of stay (Surgery)
Average length of stay (Paediatrics)
Average length of stay (Gynaecology & Obstetrics)
- BO_P4_ALL:** % patients monitored according to health care process

BO_P5_ALL: % patients readmitted to intensive care unit (ICU)

BO_P1_INT: Lethality rate from myocardial infarction

BO_P2_INT: % of readmissions to coronary unit of patients with acute myocardial infarction

BO_P3_INT: Lethality rate from cerebrovascular accident

BO_P4_INT: % of readmissions to intensive care unit of patients with cerebrovascular accident

BO_P1_SURG: Average number of days of pre-surgery treatment

BO_P2_SURG: Average number of patients per surgeon operated on, under local anaesthesia
Average number of patients per surgeon operated on, under regional anaesthesia
Average number of patients per surgeon operated on, under general anaesthesia
Average number of patients per surgeon operated on, under these three forms of anaesthesia

BO_P3_SURG: (Not included at present)

BO_P4_SURG: Lethality rate from appendectomy
Lethality rate from cholecystectomy

BO_P1_GYN: (Not included at present)

BO_P2_GYN: % of women who were injured during delivery

BO_P3_GYN: Average length of stay for regular childbirth

BO_P4_GYN: % of child births performed using epidural anaesthesia

BO_P5_GYN: % of deliveries done in the presence of woman's partner or family member

BO_P6_GYN: % of pregnant women or women giving birth who died during hospitalisation
% of live born infants who died before discharge from hospital
% of newborns injured during delivery

BO_P1_PR: No of complaints / appeals (written and oral) recorded at advocate of patients' rights

BO_P2_PR: Existence of forms for patient's acceptance of certain procedure / intervention (diagnostic and / or therapeutic) in the hospital - no chart presented; all hospitals report existence of such forms

Annex 5: Map of Serbia with Pilot sites for testing Accreditation Standards

1. Pharmacy „Subotica“

2. Regional General Hospital „Dr Đorđe Joanović“, Zrenjanin

3. Dom zdravlja „Dr Ristić“, Belgrade

4. Pharmacy „Farmanea“, Belgrade

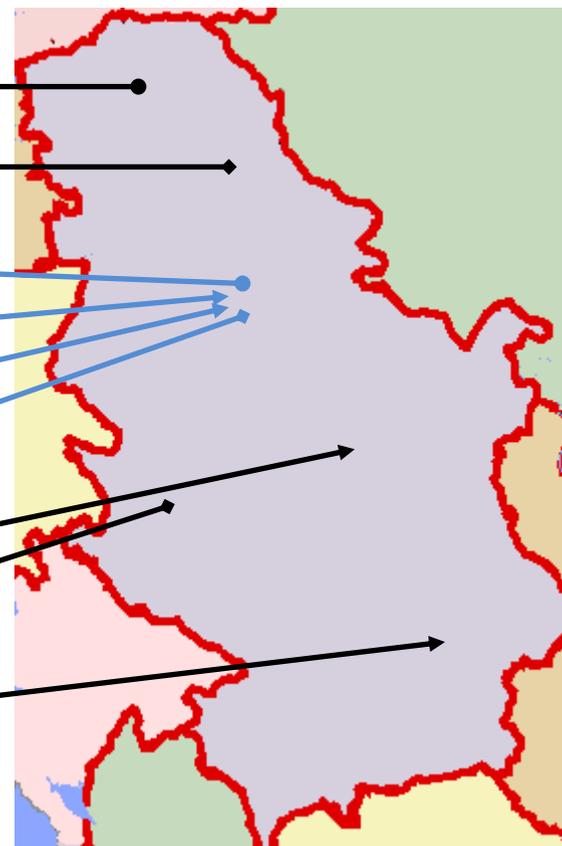
5. Laboratory „BioMedica“, Belgrade

6. General Hospital „BelMedic“, Belgrade

7. Dom zdravlja „Kragujevac“, Kragujevac

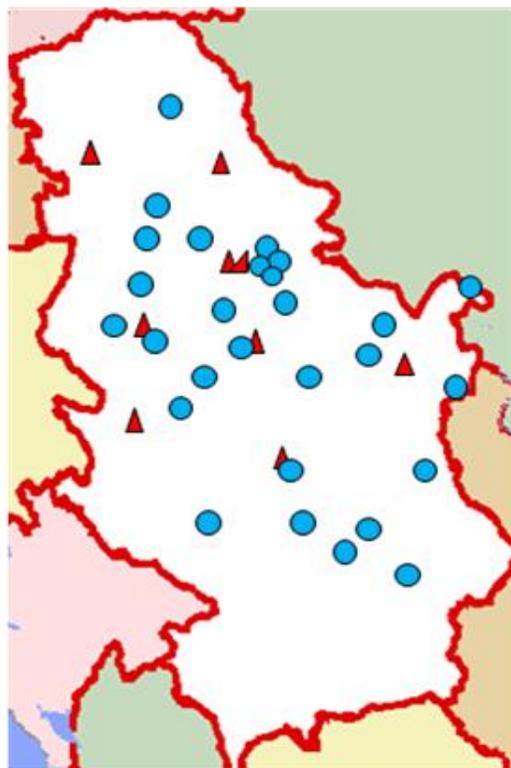
8. Regional General Hospital „Užice“, Užice

9. Dom zdravlja „Leskovac“, Leskovac



Annex 6: Map of Serbia with Pilot sites for testing Quality Indicators

No.	PHCI- DOM ZDRAVLJA
1	Lučani
2	Bela Palanka
3	Knić
4	Osečina
5	Indija
6	Voždovac
7	Knjaževac
8	Sjenica
9	Dimetrograd
10	Ruma
11	Vlasovince
12	Žagubica
13	Svitajnac
14	Topola
15	Kladovo
16	Šabac
17	Ada
18	Velika Plana
19	Novi Pazar
20	Lebane
21	Leskovac
22	Kragujevac
23	Valjevo
24	Kraljevo
25	Savski venac
26	Stari grad
27	Novi Sad
28	Dr Ristić



No.	HOSPITAL-BOLNICA
29	Zrenjanin
30	Užice
31	Valjevo
32	Kraljevo
33	Pirot
34	Vibas
35	Bel Medic
	CLINICAL HOSPITAL CENTRE-KBC
36	Dr Dragiša Mišović
	CLINICAL CENTRE-KC
37	Kragujevac