Health inspectorate as a tool for quality improvement in public health institutions of primary health care in Kosovo

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DISSERTATION

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This dissertation was made at the Ministry of Health, Republic of Kosovo, National Institute of Public Health, Republic of Kosovo and Department of Social Medicine and Organization of Health Care, Andrija Štampar School of Public Health, School of Medicine, University of Zagreb, Croatia.

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I dedicate this thesis to my son Bernard – my strength, motivation and happiness!

LIST OF ABBREVIATIONS

ASK	Agency of Statistics of Kosovo
BSHQ	Basic Standards of Healthcare Quality
FMA	Family Medicine Ambulantas
FMC	Family Medicine Centre
HIF	Health Insurance Fund
HUCSK	Hospital University Clinical Services of Kosovo
MFMC	Main Family Medicine Centre
MoH	Ministry of Health
NATO	North Atlantic Treaty Organization
QC	Quality Coordinators

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1.   INTRODUCTION AND BACKGROUND

1.1.   Quality in healthcare

Quality and continuous improvement have become integral to health services activities (1). Governments are interested in quality as healthcare is predominantly financed internally, healthcare expenditures are rising, and the overall population is ageing (2). Quality varies as a construct; some definitions are presented below.

The most cited **definition of quality of healthcare** comes from Donabedian (1980): "quality of care is the kind of care which is expected to maximise an inclusive measure of patient welfare after one has taken account of the balance of expected gains and losses that attend the process of care in all its parts" (3). According to this definition, quality of care has a final goal of maximising patient wellbeing and thus is related to all elements of the healthcare process. This concept is consistent with patient-centred approaches but also recognises that the care process contains gains and losses, which are to be expected (4).

In 1997, the Council of Europe defined the quality of care as 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" (5).

In 2001, The Institute of Medicine (IOM) defined quality of care as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." This definition appears to emphasise the importance of health outcomes rather than patient wellbeing. Nonetheless, the "desired" health outcomes mean that patient satisfaction and wellbeing are also included in health status or quality-of-life measures. This definition combines the importance of health services and individuals/population, focusing on health prevention and promotion. (4). The IOM's definition focuses on "health outcomes", which is more restrictive than the notion of "patient welfare" used by Donabedian. However, in the elaboration of the definition, the IOM specified that these "desired" health outcomes were expected to reflect patient satisfaction and wellbeing next to broad health status or quality-of-life measures (4).

The World Health Organization (2018) describes quality using three dimensions: effectiveness, safety, and patient-centeredness. The last two involve different attributes of

healthcare systems, such as access, timeliness, equity and efficiency, and are "necessary to realise the benefits of quality health care" (6).

Along with differences in perceptions and definitions of quality, other quality-related notions emerge, such as quality control, quality assurance, quality improvement and quality management. **Quality Control** means evaluating that the desired operations are conducted within the defined standards, usually through inspection and data collection (7). Quality control is considered a fundamental quality management structure and has been used since the 1920s (8). **Quality Assurance**, a notion raised in the 1950s, aims at employing quality control tools, verifying that performance stays at the defined standard level and reacts to faults in the process (7). In healthcare, the difference between the two concepts can be explained in the case of surgery: quality control collects data on wrong-site surgery, while quality assurance ensures that there is time between the two surgeries to verify the patient, procedure, and site of surgery (9). **Quality improvement** is defined as a process that "required the health workforce to be clear about the outcomes they are working towards; to know which changes would lead to improvements, and to evaluate their efforts. In addition, it requires them to translate evidence from their improvement efforts, and those of others, into practice" (10). **Quality Management** incorporates quality control and quality assurance and includes quality improvement. It refers to procedures and operations minimising damage while optimising healthcare and patient outcomes (11).

1.2. Theoretical framework in quality assessment and improvement

There is no common framework for assessing the quality of care or the regulatory role in quality improvement. In the literature review, the most common frameworks are the Donabedian framework for assessing the quality of care and five networks for external quality improvement: Taxonomy of Quality-enhancing Regulatory Interventions Model, Responsive Regulation Framework, The Life Cycle Model, System Based Regulation Framework, and The Effect Chain Model.

1.2.1. Donabedian framework for assessing the quality of care

A well-known conceptual model that provides a framework for assessing healthcare quality comes from Donabedian (1988), who believed that three basic types of standards and

indicators are needed: structural, process, and outcome (12). Donabedian believed structure affects the process, which in sequence affects outcome measures (Figure 1).

Figure 1. Donabedian's Structure-Process-Outcome framework for Quality Assessment
Source: Donabedian, 1988 (12)

Structural standards of healthcare can be described as the physical and human resources of healthcare organisations, including facilities, equipment and materials, the professionals and their knowledge. Process standards are defined as the actual process of providing healthcare, including prescription patterns, supply management, and other clinical and organisational processes. Finally, the outcome standards look into the final result of the healthcare process or the health state of people receiving healthcare, such as quality of life, mortality, and wellbeing (13).

Before quality improvement actions, there must be a quality assessment. In assessing quality, most initiatives foresee setting standards and evaluating if standards were met. Standards are "explicit statements of expected quality in the performance of a healthcare activity.", and can be explicit (written) or implicit (implied) (14). Explicit standards can be empirical – deriving from actual practice and used to compare care between similar healthcare settings, and normative – issued by a credible, legitimate body (15). In assessing if standards were met, indicators are used, and they can be defined as "quantitative measures that provide information about the effectiveness, safety and/or people-centeredness of care" (4).

The benefit of this framework is its flexibility and applicability in various situations in healthcare (16–19), such as: adjusting information exchanges, improving patient record keeping, and adjusting patient flow or clinical outcomes in a small practice or outpatient

centre. However, structure, process, and outcome are not always linear, resembling cause and effect; healthcare is much more complex and highly variable. Indeed, the framework is strongly focused on healthcare and does not consider the patient role in the system or any other external factors such as the economic, social and political environment (20).

Mountford and Shojania (2012) analysed which indicators from the Donabedian framework can be measured. Their results indicate that outcome indicators are more meaningful to caretakers and patients and are helpful when no evidence-based data exist. Still, they require longitudinal measurements and sophisticated techniques and are costly. Additionally, process indicators detect problems in the care process without waiting for a completed outcome; thus, they directly suggest improvement measures. However, because detailed clinical data are required to identify patients under scrutiny, and such measures are not very meaningful to patients, these data are not easily obtained through cooperation. Finally, structural indicators are easy to measure and evade the necessity of scrutinising multiple processes or outcomes in complex healthcare settings. By being general, essential, and not easily measurable through existing databases, (21) they require other approaches, such as on-site inspection.

1.2.2. Networks for external quality improvement

Walshe (2003) has described internal and external approaches to quality improvement in healthcare. Internal approaches are micro-level interventions applied inside a healthcare organisation, which are straightforward, highly targeted and customised for the organisational needs. Such interventions include quality teams, benchmarking, clinical governance, and process remodelling. However, the above often do not consider external social or economic environments and overall organisational context. Further, Walshe reports that external approaches are macro-level (governmental) interventions applied through several organisations, which provide strong incentives and sanctions to drive the organisational change toward governmentally defined goals (2003). Interestingly, these interventions generally do not consider organisational specifics and are based on the assumptions that directing institutions will instil change. Examples of such interventions are legislation and civil liability, publication of performance records and regulation (22).

The purpose of regulating healthcare quality, in general, is threefold: to improve performance and quality, to assure achievement of minimally acceptable standards and to

provide financial and public accountability. Regulation guides healthcare organisations in attaining determined standards and targets, with an expectation that their achievement will result in continuous quality improvement. The second purpose of regulating healthcare quality is the opposite of the first, as this one is not concerned with quality improvement but with quality assurance. Ensuring that acceptable standards are achieved improves poor-performing health care services, yet it does not promote further quality improvement beyond the set standards and targets. The third purpose entails the responsible use of funds to guarantee the public quality of healthcare (22).

It would be beneficial to clarify the terms **regulation, supervision and inspection,** as they are frequently used interchangeably to describe the quality evaluation of services. There are differences between the terms based on the magnitude of their activities (1). **Regulation** in healthcare regulation is described as "any set of influences or rules exterior to the practice or administration of medical care, that imposes rules of behaviour" (23). Regulation involves broad, top-level activities and mechanisms to oversee and guide healthcare, such as legislation, finances, and supervision (1). **Supervision** is a part of a regulation. Supervision in healthcare is defined as "several functions that range from developing the practitioner to protecting the public from poor practice" (24). Supervision can be normative, educational, and restorative. Normative supervision includes developing and preserving healthcare standards concerning security, ethics, quality, and public protection. Formative supervision involves the advancement of professional knowledge and skills. Restorative supervision means increasing the self-awareness and self-development of the supervised party (25). **Inspection** is a part of supervision. External healthcare inspection is "a system, process or arrangement in which some dimensions or characteristics of a healthcare organisation and its activities are assessed or analysed compared to a model of ideas, knowledge, or actions derived or developed outside that organisation" (26). External inspection is initiated and controlled by a body external to the one inspected (27). This research uses the terms regulation, supervision and inspection interchangeably.

Five networks for external quality improvement are The Taxonomy of Quality-Enhancing Regulatory Interventions Model, The Responsive Regulation Framework, The Life Cycle Model, The System-based Regulation Framework, and The Effect Chain model. All the presented frameworks can complement each other as they assess different regulatory-related features; they vary in their approach, generalisation, specificity, and theoretical foundation. Therefore, combining these complementary frameworks allows a broader

assessment of factors and measures to facilitate successful quality improvement utilising regulation.

- **Taxonomy of quality-enhancing regulatory interventions model**

Sutherland and Leatherman (2006) have conducted systematic research of empirical evidence about the impact of regulation on quality improvement in healthcare. They have produced a model highlighting three main regulatory streams when regulating healthcare: Institutional regulation, Professional regulation, and Market regulation, as described below (Figure 2).
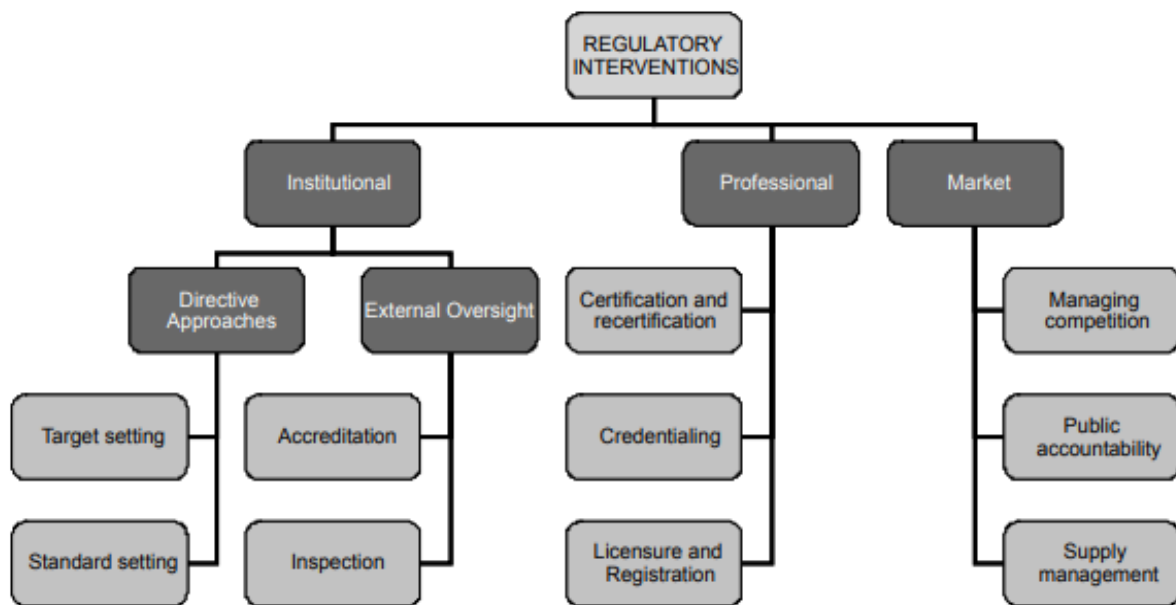
Figure 2. Taxonomy of quality-enhancing regulatory interventions model
Source: Sutherland & Leatherman, 2006 (28)

Institutional regulation can have a directive approach or rely on external oversight. The directive approach instructs about expected levels of performance in healthcare. This approach involves setting targets and setting standards. Setting targets drives healthcare organisations in the direction of the defined level of performance within a specific timeframe. On the contrary, the setting of standards defines a minimal quality level that has to be attained by healthcare organisations or professionals. The other type of institutional regulation, external oversight, is a type of institutional regulation that enforces healthcare quality through external supervision, usually achieved by accreditation or inspection of healthcare organisations. Both are done by employing visits to the healthcare organisation under scrutiny to evaluate compliance with the given standards. They differ in personnel profile, as healthcare inspections often involve inspectors who are health professionals, and in

measures – since the accreditation ends with a certificate/licence for the organisation, if standards are fulfilled (28).

Professional regulation involves guiding the professionals that provide healthcare by setting standards of knowledge and ability to perform their work. Quality assurance through professional regulation is achieved by licensure and registration, credentialing, and (re)certification. Credentialing and certification are less used by European regulating authorities and more in the United States. Certification provides the opportunity for a health professional to demonstrate skills beyond compulsory for regular licensing, while credentialing, usually organisation dependent, offers an opportunity for a health professional to be credited for their professional qualifications typically related to distinguished accomplishments. On the other side, licensure and registration are used in various healthcare systems and depend mainly on professional self-regulation. A professional organisation must license professionals to permit them to practice healthcare. In contrast, the breach of professional rules can result in different measures, including a temporary or permanent practice ban (28).

Market regulation strives to increase healthcare quality by managing competition, ensuring public accountability, and supply management. Through effective leadership, regulators encourage competition and reduce alliances and monopolies in the healthcare system. By doing this, a regulator will create a situation where individual healthcare organisations have equal competitive positions. Emphasising public accountability, the regulator should ensure that relevant information, such as inspection reports, accreditation results, or national ranking of healthcare organisations, is presented to the public, enabling people to make a well-informed choice. Competition for profit can become healthcare organisations' primary goal, associated with unnecessarily high healthcare costs and unnecessary treatments. For this reason, regulators must also verify that the provided healthcare is appropriate and within a rational price range. Finally, effective supply management induces healthcare regulators to closely monitor their responsibility to ensure equal access to healthcare for the entire population (28).

This model takes a macro-level perspective in organising regulatory efforts and helps draw insights into governmental approaches to regulating healthcare. Further, the model is easily transferable to various national regulatory settings, such as the research on the comparison of twelve European regulators (29). Critics might argue that the model does not consider healthcare organisation self-regulation, as supervision can be intra-institutional and

effectively completed with institutional controls, such as process management or internal quality bodies (30).

- **Responsive regulation framework**

This framework, developed by Ayres and Braithwaite (1992), designates that the style and harshness of regulatory response will rely on healthcare organisations' motivations, actions, and behaviour. It is "the most sustained and influential account of how and why to combine deterrent and cooperative regulatory enforcement strategies" (31). Responsive regulation aims to sustain healthcare organisations to improve their quality by balancing penalty and persuasion, depending on the organisational circumstances and motivations, rewarding compliance and sanctioning non-compliance (32–34). Responsive regulation is sustained by the notions of an "enforcement pyramid" (Figure 3).
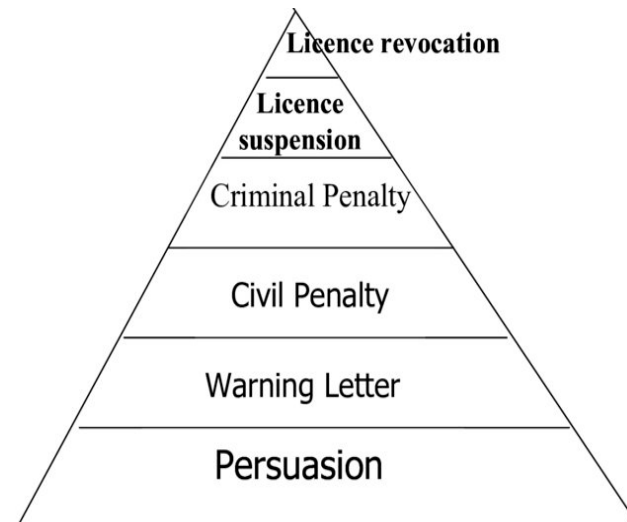
Figure 3. The enforcement pyramid
Source: Ayres & Braithwaite, 1992

The pyramid helps clarify the response level of the regulator based on the organisational behaviour towards regulation. The regulator uses persuasion at the bottom of the pyramid to encourage healthcare organisations to self-regulate. If the organisation self-regulates, the regulator responds with further communication, guidance and support (35). If the healthcare organisation does not self-regulate voluntarily, the regulator responds with a warning letter to impose regulation. If the healthcare organisation still does not regulate, the measures become severer, from a civil penalty to licence suspension and withdrawal. However, for the pyramid to be functional, a regulator ought to have the capacity, willingness and justification for moving upward toward firmer sanctions. Healthcare organisations must

also be convinced of the inevitable nature of sanctions, as administrative warnings show results if everybody recognises that non-compliance will have consequences (35). Such belief will result in healthcare organisations being more accepting of regulation, experiencing regulation more positively, and being more compliant with the imposed standards (36).

Further, responsive regulation does not foresee a relationship between the regulator and the regulated organisation but proposes "tripartism," the third party being other stakeholders. They can help ensure compliance and support quality improvement by acting as informants and pressuring healthcare organisations and the regulator. Stakeholders are critical in protecting against "regulatory capture," a situation where the regulator agrees too much with the viewpoint of the healthcare organisation instead of being concerned with protecting the public interest (33,36,37).

Finally, the concept of responsive regulation faces the challenge of having a highly skilful regulatory staff. The challenge involves consistency among staff about regulatory style and measures applied in a particular situation. Also, good communication skills were essential to thoroughly inform the healthcare organisation of the regulator's requirement while reestablishing trust upon imposing an enforcement action (38,39).

This framework recognises motivation as a factor for compliance with the regulation. It provides a theoretically sound and valuable means for choosing between regulation enforcement styles (40) while providing health organisations guidance in understanding progressive measures against non-compliance. The criticism of this framework is that the pyramidal approach is not always appropriate, as in high-risk cases, when immediate escalation to the higher level of the pyramid might be necessary (41). Another criticism is that the regulator should consider the organisation's characteristics when deciding on responsive measures instead of always starting from the bottom of the pyramid (42). Further, the pyramid may be impractical due to an often limited staff of regulatory entities, as they cannot afford to follow up with the healthcare organisation (43).

- **The Life Cycle Model**

The Life Cycle Model is another conceptual regulatory framework created by Devkaran & Farrell (2014). Four phases define the life cycle of quality in a healthcare organisation: a) initiation phase - a slight improvement of quality standards after acquaintance with the standards; b) pre-survey phase - a significant quality improvement reaching peak level due to increased efforts of the organisation for the reason of the proximity of the regulatory visit; c)

post-regulation slump phase - characterised with a drop in compliance level, and d) the stagnation phase – where compliance plateau is characterised by variability, but a total level of compliance to quality standards is significantly higher than before the first visit of the regulator (44,45).

Devkaran & Farell state that the framework describes the dynamics and complexity of regulation as quality intervention and denotes that only with continuous visits by the regulator within a more extended period continuous quality improvement can be assured in healthcare organisations. Notably, the model has limited generalisability to primary/secondary care healthcare facilities; therefore, its applicability in other settings is limited. Consequentially, the model does not consider other improvement initiatives that might have been taken by the healthcare organisation, as repetitive follow-up visits are conducted within longer periods (45).

- **System-based regulation framework**

Systems-based regulation is an approach in which healthcare organisations build upon the existing internal management system, assuming the system is already designed, to ensure regulatory compliance and quality improvement (46). De Bree & Stoopendaal (2018) emphasise that this regulatory approach requires that healthcare organisations self-regulate through internal supervisory systems. The approach can be referred to as "process-oriented regulation," taking a further step from a rigid, stringent, or reactive approach to regulation. It promotes a more proactive and preventive method of the regulators, in which the regulators support the management of the healthcare organisation to self-improve and maintain quality standards (46).

This approach is novel in its attempts to address the risk of "decoupling" and promotes "recoupling". Decoupling refers to the gap between the normative, formal requirements and the situation in practice in healthcare organisations where the formal requirements are introduced but not fully implemented (47,48). Decoupling is a gap between work imagined and work done (49). Decoupling can be intentional, which refers to deliberate avoidance of implementing the formal requirements while enjoying the benefits of symbolic policy adaption (50) with the knowledge that such action may backfire severely on the organisation (51). Decoupling may also result from a lack of consensus within an organisation (52).

According to this framework (Figure 4), decoupling is conceptualised in three ways: a) Goals-system decoupling, in which there is a gap between a healthcare organisation's goals and management systems (which also include structures, guidelines, and instructions); b) System-practice decoupling, in which there is a gap between management systems and daily practice healthcare organisations; and c) Practice-outcome decoupling, in which there is a gap between the daily practice in healthcare organisations and positive outcomes for patients or organisation (46).
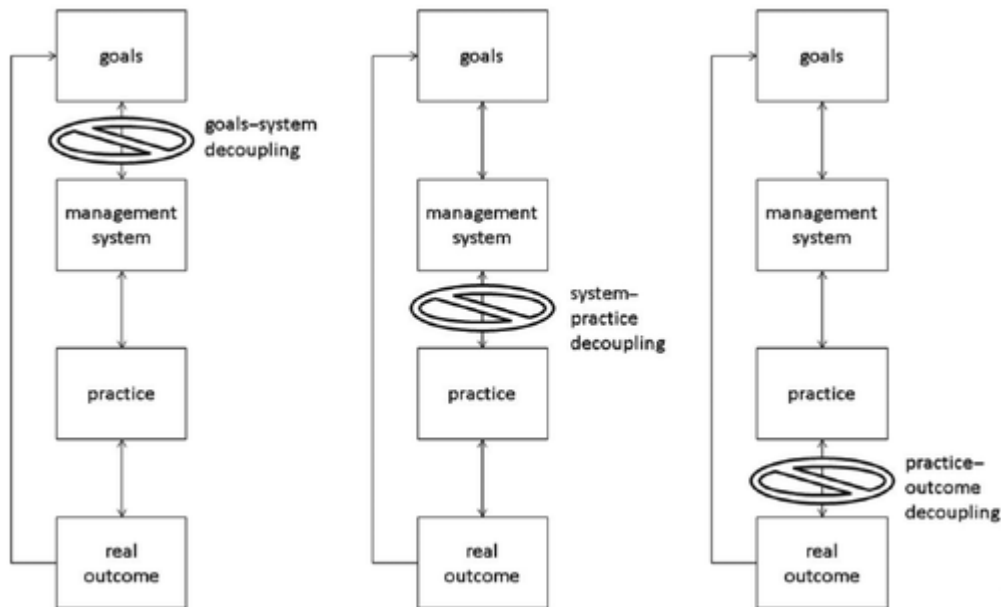
Figure 4. The path from goals to actual outcomes and the potential points of decoupling
Source: de Bree & Stoopendaal, 2018 (46)

Conversely, recoupling refers to the reverse process, finding synergy between the goals of the healthcare organisation and the expectations of the regulator (46). Recoupling depends on internal factors, such as an organisational statement or quality strategy, and external factors, such as market pressure and patient expectation (48). Regulators may initiate recoupling through observations and discussions, which may help identify possible management system gaps and foster quality improvement actions (53).

This model focuses on the management system of a healthcare organisation, as the performance of management duties towards quality measurement is expected to contribute to quality improvement. Also, the model builds on Bromley and Powell (2012), attending to the practice-outcome gap (54). However, this model is outside the regular duties' direction and would require a legislative modification for the regulator and the healthcare organisations to agree to participate in this type of supervision (46).

- **The Effect Chain Model**

The Effect Chain Model is also known as the impact of regulation on the healthcare organisation model. Healthcare regulators do not provide care themselves; therefore, they cannot directly control the outcome of their intervention. Instead, regulators try to alternate structures and processes in a healthcare organisation, intending to result in better patient outcomes. At the same time, impact studies are also focused on the internal operation of the regulator, striving to make a regulatory organisation more efficient and effective. The Dutch Health Inspectorate has come up with a chain effect model of the impact of regulation (55). According to the model, the output of the Inspectorate has an immediate and intermediate impact on the health organisation, which then, in chain effect, impacts patient outcome (Figure 5).
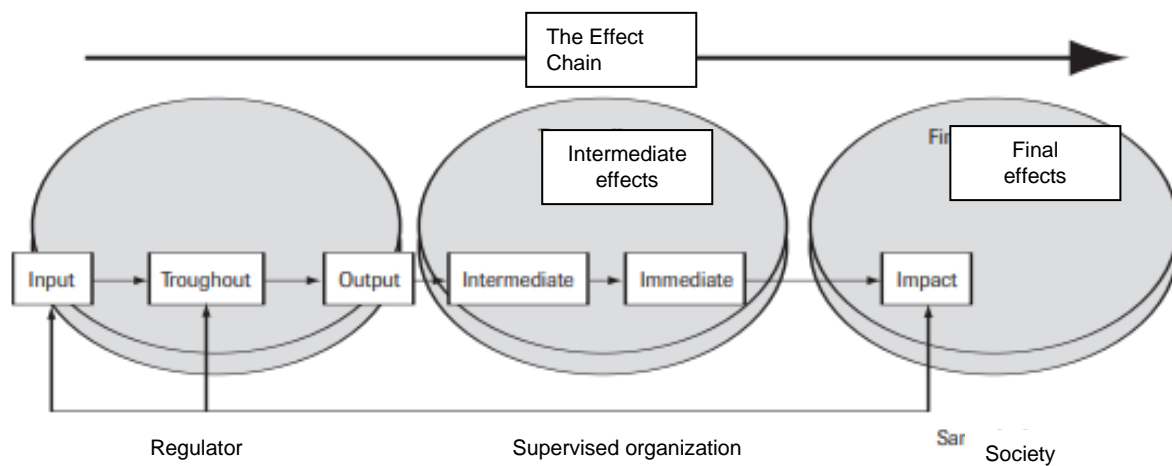
Figure 5. The effect chain model
Source: Werkgroep Effectmeting IG-Beraad, 2005 (55)

While this model provides a visual understanding of the intended impact of the regulator, it does not describe the impact that patient outcomes and organisational processes and structures have on the inputs of the regulator. This model was improved by Sparreboom (2009). The journey of the output of the regulator, altering processes and structures in the healthcare system, and resulting in specific outcomes or impacts in society, are displayed in the effect chain figure with dashed arrows (Figure 6).
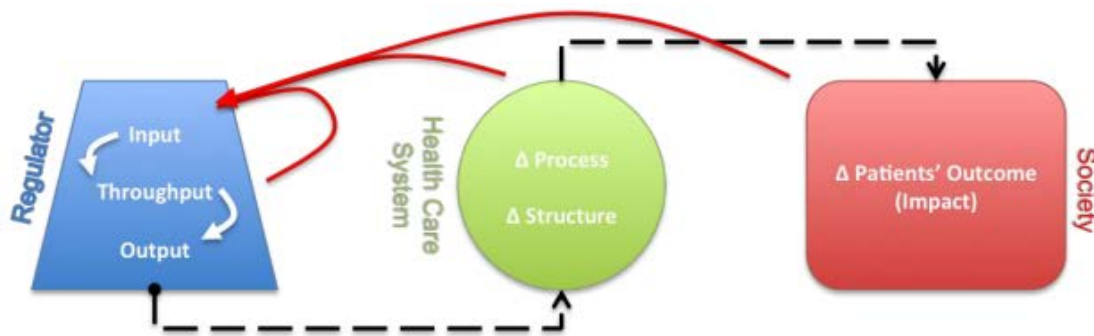
Figure 6. The impact of regulators on the healthcare organisation model

Source: Sparreboom, 2009 (29)

The added red arrows to the model, from regulators output, healthcare organisation and patients' outcome in the opposite direction of regulators influence, and directed towards regulator input, depict how regulators can measure their impact (29). Regulatory effectiveness can be measured in terms of changes in processes and structures that are known to be favourable outcomes in general (13). Additionally, it must be noted that the further the effect measurement moves from the output of the regulator, the more complex the proof of causality between monitored results and the output is (55).

1.3.   Health care system in the Republic of Kosova

To prevent confusion for international readers, the term "Kosova" instead of "Kosovo" is used throughout the text. Kosova is an Albanian language term for the country, and Kosova is populated mainly by Albanians. The internationally used term "Kosovo" is in Serbian (56). Contradictory, even in English, citizens of Kosova are called "Kosovars" (57,58).

Kosova was a part of former Yugoslavia after the Second World War. Dissolution of the former Yugoslavia and Serbian ethnic segregation over the Kosovar-Albanian population caused 100,000 Kosovar-Albanians to lose their employment by 1992 (59). Restricted access to public healthcare organisations and the non-existence of private healthcare organisations from 1990-1999 resulted in the informal organisation of the "parallel system" - voluntary health services of outpatient care all over the country through the humanitarian association "Mother Teresa" (60). After the war in 1999 that established Kosova, the public network of health services was destroyed and faced numerous problems. Kosovar-Albanian health personnel had not worked in a hospital setting for ten years. Young physicians were trained in

a parallel education system involving small clinics with no connection to hospital environments (61). There were shortages of electricity, water supply, medicines, and physicians. This situation produced unreliable health data which could not support evidence-based policies (62).

United Nations Interim Administration administered Kosova from after the war until its independence. International officials were in charge of The Department of Health (predecessor of the MoH) until the constitution of Provisional Self-Governing Institutions and the first local Minister of Health appointment in 2002 (60). Kosova proclaimed independence in 2008 but still is not a member of the European Union or the United Nations.

The Republic of Kosova has a territory of 10,905 km2 and a population of 1,782,115. More than 50% of the population is less than 28.2 years old, while the average population age is 30.2 years. The average longevity is 74.1 years for males and 79.4 years for females. 91% of the population are Kosovar-Albanians, 3.5% are Kosovar-Serbs, and the rest are other minorities (Turks, Bosnian, Montenegrin, Roma, Ashkali and Egyptian). 61.7% of the population lives in rural areas. Kosova is among the poorest countries in Europe, considered an upper-middle-income country (63). Brutto Gross Product is 3,746 €per citizen, while only 40.5% of the population is economically active (64). In 2017, 18.0% of the adult population lived below the poverty line of 1.85 €/day, while 5.1% per cent lived below the extreme poverty line of 1.31€/day (65).

Health services in Kosova are organised in three levels (primary, secondary and tertiary) in public and private healthcare organisations. Public primary healthcare services consist of 449 facilities governed at the local level, organised in 28 out of 38 administrative municipalities, and guided by the family medicine concept. Each administrative municipality has one Main Family Medicine Centre (MFMC) in the municipal city, several Family Medicine Centres (FMC, within a big city or in different smaller cities) and Family Medicine Ambulances (FMA, in rural areas), aiming to treat 80% of health conditions (Ministry of Health Kosova, 2016b). Public Secondary and Tertiary services form the Hospital University Clinical Services of Kosova (HUCSK). HUCSK consists of six general hospitals, six community mental health centres, National Centre of Telemedicine, National Centre of Sports Medicine, National Centre of Occupational Health, Integration and Rehabilitation Centre for Chronic Psychiatric Patients, Dentistry Hospital Clinical Centre, and Clinical University Centre with 37 clinics and administrative/technical services (66). The private sector had 1,685 licensed organisations in 2020, of which 28 were hospitals (67). Medical

facilities in the remaining ten municipalities with the Kosovar-Serbs minority do not generally participate in the Kosovar Health System (68) and have created a so-called parallel healthcare system governed and financed mainly by Serbia.

Kosova averages 1.2 doctors per 1,000 patients, far below the EU level of 3.6 (69). In public institutions of primary healthcare, in 2020, there were 1,133 doctors, 313 dentists, 18 pharmacists, 3,238 nurses, 40 health associates and 836 non-health associates (70). Health financing is mainly done by income tax, taxation, and co-financing, while out-of-pocket payments include 40% of expenditures for healthcare (67,69). Kosova has not been able to provide public health insurance for its citizens for some 21 years after the war, even though the Health Insurance Fund (HiF) was established in 2017 (71). The budget for healthcare in 2020 allocated to municipal Directorates for health and social welfare was €74,709,806, while the budget allocated for the central level of healthcare (MoH, HiF and HUCSK) was €209,142,564. Despite low financing, the low number of doctors and lack of health insurance, research confirms patients' satisfaction with healthcare services to be between 65 and 81%, slightly higher for the private sector than the public sector but generally equal among levels of healthcare. Patients mostly complain about poor behaviour by health personnel, the necessity to pay for medical materials and medicines from the essential list, and inadequate infrastructure and hygiene of the facilities. While there is a broad perception of corruption in the health sector, only 3.9% of patients declared that health personnel placed financial conditions on them to provide health services (72).

1.3.1. Quality of healthcare services in the Republic of Kosova

The healthcare quality in Kosova had its roots in the 1970s when normative healthcare standards were established. However, the healthcare quality declined in the 1990s due to the political situation in the country, culminating with war, The North Atlantic Treaty Organization (NATO) strikes and the subsequent withdrawal of Serbian forces and governing from Kosova in 1999. Healthcare quality in Kosova faced various issues after the war. Such issues included damaged infrastructure, extremely scarce resources, unclear competencies in public healthcare, and an unregulated private healthcare market (73,74). As a result, healthcare quality in Kosova was lower than in European Union countries and the region. The government in Kosova has committed to improving the quality and safety of health services, balancing the scarce budget, limited opportunities and best practices (75).

Among the first documents issued with relation to quality in general as well as in primary healthcare was the Administrative Instruction 15-2000 on the establishment of family medicine centres - regulating functioning, staffing, commodities, equipment, managerial and administrative tasks (76); and Administrative Instruction 18-2000 on Registration and Licencing of Health professionals – which establishes a Body responsible for registration and licencing of health professionals, for the first time in Kosova (77).

Despite difficulties in revitalising the healthcare system destroyed for more than a decade, further developments towards the quality of healthcare occurred between 2004-2007, such as the promulgation of The Administrative Instruction on standards for licensing and accreditation of health institutions of primary health care (78), The Administrative Instruction 09/2005 on quality and licencing standards of health institutions and their implementation (79). The Instruction specified three types of quality standards – basic, core developmental, and non-core developmental standards. Basic quality standards are mandatory and subject to monitoring by the Health Inspectorate in the MoH and the Division of quality services in cooperation with other relevant departments. The developmental standards are not monitored by the MoH but are used by the institutions for their development. The Instruction further highlights internal quality mechanisms within healthcare organisations, the Quality Committee and Quality Coordinators. The Quality Committee is responsible for developing the quality mechanisms and implementing the quality standards. On the other side, the Quality Coordinators are responsible for coordinating and assisting the implementation of the standards within the health organisation. For these purposes, Quality Coordinators will be subjected to continuous training on techniques of quality management organised by MoH or at the municipal level. The duties and the selection of Quality Coordinators and members of Quality Committees were listed in the Information Circular 1/2005 (80). According to the Circular, the newly established regular posts of Quality Coordinators have functional authority over all aspects of the healthcare organisation related to quality improvement and quality control, advising and supporting all personnel on necessary actions to improve the overall quality of services provided by the organisation. Quality Coordinators are selected via internal advertisement. Those with the right to apply are public health specialists, other specialists (preferred), nurses, other healthcare professionals, economists or lawyers. The Quality Coordinator shall work four hours daily, or if the institution can afford it, eight hours. The Quality Coordinator is a mandatory member of a Quality Committee established within the institution, which needs to meet every two months and review important cases for quality.

Lastly, the Circular states that MoH will: create strategies, programs, and action plans to ensure and improve healthcare quality; they will coordinate activities with Quality Coordinators, prepare a training plan, and provide training for the Quality Coordinators, reviewing their work reports.

The initiatives declined until 2010, when MoH's Division of Quality and Safety of Healthcare services and the Quality Coordinators network were revitalised (75). Among them, the Administrative Instruction on Clinical Protocols and Guidelines was promulgated (81) to standardise healthcare activities across the country and formalise the 14 clinical guidelines used till then in primary healthcare. The commitment to quality of healthcare was continuously reiterated in the Health Sector Strategy 2010-2014 (82), The Strategy of improving quality and safety of health services 2012-2016 (75), The Health Law (83), The International Accreditation of Specialist Postgraduate Education in Family Medicine (84) and The Health Sector Strategy 2017-2021 which specifically highlight the role of Quality Coordinators in primary healthcare in implementation of healthcare standards (67).

However, there was inconsistency in the efforts, and another decline in activities followed, mainly because of the shallow capacity of the Division of Quality in the MoH, having only one employee for years and minimal communication with healthcare organisations (85).

1.3.2. The Health Inspectorate of the Republic of Kosova

Healthcare supervision in Kosova is undertaken based on authority provided by the government, with a mission to safeguard and support the public interest. Healthcare supervision is conducted by the Health Inspectorate of Kosova, an administrative body of the Ministry of Health (MoH) with the duty to supervise, through external inspection, if health institutions and health personnel obey legal provisions, ethical norms and professional standards of health care. The Inspectorate was established in 2006 with the promulgation of Law No 02/L-038 on Health Inspectorate (86) to improve the quality of services provided in health institutions. The Inspectorate enforces and checks compliance with 19 laws, more than 110 administrative instructions, regulations, strategies, and other directives in the health area related to the Inspectorate's scope of competencies. Initially, the Inspectorate consisted of Chief Inspector and five inspectors; in 2019, it had nine inspectors, one administrative staff and the Chief Inspector. The Chief Inspector responds directly to the Minister of Health and

advises them on the course of action related to the issues within the competencies of the Inspectorate. All Inspectors and Chief Inspectors must be licensed doctors, dentists or pharmacists. However, high power and responsibility, unclear legal environments, low salary, lack of professional training and risk of losing health professional licences are common reasons for personnel fluctuation over the years, causing work inconsistencies and partial loss of organisational memory. In addition, the small number of personnel (5 to 9 inspectors) in charge of inspecting more than 2000 health organisations geographically distributed throughout the country's territory, of different sizes and profiles, causes one healthcare organisation to be inspected once in 3,5 years (87).

The Inspectorate functions only at the central level. The main task of the Inspectorate in its first years was to implement the legal requirement of licensing for private health practices (88). Subsequent attempts were made to analyse the Health Inspectorate's work efficacy and service quality. Efforts included acquiring the Technical Assistance and Information Exchange instrument, managed by the Directorate-General Enlargement of the European Commission and organising the 27th European Partnership of Supervisory Organisations in Healthcare and Social Care conference in Prishtina. Further outreach included conducting visits and initiating formal and informal collaboration with other European inspectorates and inspectorates of the region, attending relevant training, and conducting periodic analyses of work achievements and methods (89,90).

The Health Inspectorate of Kosova supervises an extensive range of public and private healthcare services, including ambulatory care, hospital care, mental health care, and public health care. The Inspectorate commonly applies regular inspection, thematic inspection, response-to-complaints inspection and re-inspection. The regular inspection entails assessing the implementation of basic standards of healthcare. Thematic inspections are focused on a specific topic in healthcare, based on strategic documents, previous yearly reports or are put forward by a minister or parliament. The response-to-complaints inspection usually consists of conducting inspections based on a citizen complaint. Finally, re-inspection is a follow-up inspection; it is conducted much sooner for high-risk cases, in which healthcare quality and safety are compromised, than for lower-risk cases. Other than inspections, the Inspectorate employs document review as an additional method to the inspection.

To standardise and ensure equal evaluation during the supervision, the Inspectorate has created a standard checklist for regular inspections based on basic quality of healthcare

standards introduced in Kosova in 2005. Also, for each group of thematic inspections, a specific inspection form is created based on relevant legislation before thematic inspections. Further, to obtain relevant information and enable comparison of complaints, the Inspectorate has developed specific complaints forms for the complainants in healthcare. Finally, re-inspections are done based on the previous inspection report concentrating only on negative findings from the report, with a note that if a new problem is found, a new inspection case is initiated.

During all on-site inspections, a verbal note is issued at the site containing significant findings, measures and the place for comments by the inspected organisation. After the on-site inspection, the Inspectorate publishes a written report for the inspected organisation, taking full caution in maintaining the confidentiality of the data, such as patient information. The Health Inspectorate has a right to recommend, request corrective measures, initiate administrative measures (such as issuing an order, administrative fines, advice to the Minister or other relevant Bodies to take action), and file criminal charges.

The inspected organisation has a right to complain to the Chief Health Inspector against the inspection report and measures cited. The Chief Health Inspector will: a) verify the objectivity of the Inspector towards the inspected party and b) notice eventual irregularities in procedure and measures applied. If the inspection report fails to satisfy the previous two requirements, the Chief Inspector has the right to withdraw the inspection report.

The work of the Health Inspectorate highly involves reviewing media reports to find new cases and collaborating with other inspectorates or entities. The Inspectorate regularly works with the media in line with the right to public information and transparency. It informs the public of its activities, especially in cases that compromise the safety and quality of healthcare.

1.4.   Problem of the research

This research is based on problems in quality assurance and improvement in primary health care in developing countries, particularly on quality improvement challenges in the Republic of Kosova.

Although the issue of quality in healthcare is being recognised as very important, quality assessment efforts in developing countries have been relatively scarce. Such

assessments focus on measuring mortality and morbidity changes or coverage levels but lack emphasis on the healthcare delivery process or service quality. In addition, applying findings in healthcare delivery procedures to improve quality systems are also scarce (91). In developed countries, interest in quality assurance is focused on clinical medicine (92) and hospital care; based on healthcare standards developed by accreditation agencies, but little research permeates to the primary healthcare level, especially in developing countries (92). The interest in quality assurance in primary healthcare in developed countries started in the 1980s and followed a few years later in developing countries (91).

In attempts to improve healthcare quality, there is an international tendency to use more governmental regulation in healthcare (93). This tactic has raised discussions, and critiques, such as, a) inspections (as part of the regulation) cannot directly improve quality since inspections are external activities while quality improvement is an organisational issue; b) inspection highlights the problem in the organisation but does not tell how to solve it (94); c) the modern requirements for transparency of inspection, despite being helpful for the evaluated institutions' managers, actually weakens the control (95); or, d) setting targets while inspecting can result in poor performance in areas not covered by inspection (96). Overall, scientific research on the impacts of inspection is reasonably novel, mainly covering developed countries and focusing on supervisory style (40), patient perspective on the role of the regulation (37,97), and a broader subject of the regulation (98). These studies lack focus on the structure of the Inspectorate as a part of the regulation, on planning and targeting inspections or specific instruments used during inspections, e.g., checklists (98).

As the healthcare system is subject to several regulations, it is challenging to attribute improvement changes to a specific regulation practice. Subsequently, regulators face a challenge when evaluating the impact of regulation, as such studies may result in being rather associative instead of causal. As a result, attributing quality improvements to a specific inspectorate is challenging but not impossible. One possibility is to follow up on changes over time and compare sufficiently similar organisations. Therefore, evaluation of the effectiveness of the inspectorates can only be tracked over a reasonably long timeframe, ensuring the accurate measurement process and considering the possible impact of the external factors on the process. Measurement is even more difficult, keeping in mind that inspectorates do not have clear indicators and targets in many countries. Having clear procedures and instruments is necessary to limit inspectors' discretion or variability of opinions. Therefore, it is critical to shift from a position where inspectorates' activities are

accepted as successful to one in which they have to prove their positive impact on the specified aim (98).

Little is also known about the experience with instruments and their effectiveness in quality improvement. Also, research on the success of inspection activities in improving healthcare quality is scarce. Furthermore, knowledge about the role of supervision in quality improvement in countries in general, including Kosova, is scarce. It is vital to learn more about the role of supervision in primary healthcare settings, which provides an opportunity for further development and professionalisation of supervision by gaining more insight into the supervision instruments.

The Kosova model of quality assurance in primary health services is described in the introductory part of this thesis. The model is based on Quality Coordinators in each publicly funded healthcare organisation. They serve as an internal quality mechanism, coordinating and assisting the implementation of quality standards. Besides this internal quality mechanism, the Health Inspectorate of the Ministry of Health performs external monitoring using a method of inspection. The problem is that, until now, there is no evidence of the strengths and weaknesses of this quality assurance model applied in practice in the developing post-war country of Kosova. For example, there is no evidence on what are Quality Coordinators' demographic characteristics, how much they know about inspection standards on which the Health Inspectorate evaluates their organisations, and what their experience is in practice. Also, there is a lack of evidence-based evaluation of the described model, particularly the answer to the question of whether the Health Inspectorate could be an efficient tool in improving the quality of healthcare services in outpatient care. Answers to those questions should expand the relatively limited body of knowledge on supervisory activities, establish evidence for informed decision-making for health policy in Kosova, and serve as a benchmark for other countries in development.

In summary, the problems that initiated this research are as follows: In many countries, there are various governmental actions for quality improvement, focused on the quality of a setting, standards of care, health personnel qualifications or patient safety and satisfaction. However, the studies and proof of the effectiveness of any supervision in improving the quality of healthcare are scarce (29),(28,99–101). It is crucial to find out if external supervision is the right and successful approach. Alternatively, on the opposite, there is a need to make necessary changes and improve internal work processes to justify the purpose of the existence of the Health Inspectorate of Kosova. The intent, therefore, is to

keep the process simple and avoid the suggestion that "one-size-fits-all" and that there are "magic bullets" for quality (92,102). It is of essential importance to build and sustain the ability of primary healthcare organizations to continuously and effectively engage in quality improvement (103–105).

2.   HYPOTHESIS

Health Inspectorate is an efficient regulatory tool for quality improvement in public institutions of primary health care in Kosovo.

3. AIM, PURPOSE AND SPECIFIC OBJECTIVES

This research aimed to determine if health inspectorate is a practical tool to evaluate and improve adherence to the basic standards of healthcare quality at the meso-level of governance (institutional level) of the public organisations of primary health care.

The purpose of this research is to support quality improvement efforts in public institutions of primary health care in Kosovo.

1. To achieve the main aim of the doctoral thesis, three **specific objectives** were defined: To evaluate the compliance level of public institutions of primary health care to the legally set basic standards of healthcare quality on initial, follow-up and final inspections.
2. To determine the level of improved compliance of public institutions of primary health care to the legally set basic standards of healthcare quality after final inspections.
3. To identify factors influencing personnel in charge of quality in public institutions of primary healthcare to perform their duties.

4. MATERIALS AND METHODOLOGY

4.1. Study design

In combined quantitative-qualitative research, the case of the Republic of Kosova is used to describe the development of basic healthcare quality standards at the mid-level of government (institutional level) from the macro-level perspective (central level of government) in a developing country. Specifically, the focus lies on compliance with the basic standards of healthcare quality in public organisations of primary healthcare in Kosova and the role of the Health Inspectorate in improving compliance, trying to identify internal/external factors impacting the quality and where opportunities for improvement exist. This combined quantitative-qualitative research is the aptest design to answer these questions, as it combines raw field data with people's insights into the quality in the primary healthcare organisations in Kosova, as well as "to understand the world as others experience it" (106).

The approach to this mid-level perspective entails field data collection during initial and follow-up inspections, document analysis, pre-and post-training tests for the experimental group, and notes from focus group discussions with the experimental group. The organisations and participants were selected based on purposeful sampling, adding "identification and selection of information-rich cases related to the phenomenon of interest" (107). Thus, the participants are Quality Coordinators from the 14 MFMC, enabling an insider perspective on difficulties in working with the quality and providing relevant information for decision-making in healthcare.

A thorough explanation of the study design is described in the following text, while the readers can refer to Figure 7 to understand the process flow easier. In the figure, steps 1-6 guide through the quantitative part of the research, steps 7-9 refer to the qualitative part of the study, while step 10 refers back to the quantitative part of the research.

The quantitative part of the research

Step 1
- Select healthcare organisations for the research   (in 2016)
- Obtain a list of Quality Coordinators for the research

Step 2
- Develop standard check-list and demographic and work related questionnaire
- Prepare the Health Inspectors

Step 3
- Conduct initial inspections in 14 MFMC
- Demographic/work-related questionnaire for Quality Coordinators in 14 MFMC
- Send the report to the organisations, with recommendations for improvement

Step 4
- Review the check list   (in 2018)
- Review the task with the Health Inspectors

Step 5
- Conduct follow-up inspections in the same 14 MFMC
- Demographic/work related questionnaire redistributed
- Send the reports to the organisations, with recommendations for improvement

Step 6
- Select Quality Coordinators from the 7 out of 14 MFMC, for training
- Plan the training, participants, and send invitation for the training

The qualitative part of the research

Step 7
- Pre-training test on knowledge of 32 standards used by Health Inspectorate
- 1 day training with 7 Quality Coordinators from the MFMC

Step 8
- 1/2 day follow-up training with 7 Quality Coordinators from the MFMC
- Post training test   (in 2019)

Step 9
- Semi-structured focus group discussion with the 7 Quality Coordinators

The quantitative part of the research

Step 10
- Conduct final inspections in the 14 MFMC
- Send the report to the respective institutions

Figure 7. The sketch of the chronological steps of the study design

The selection of healthcare organisations went as follows: 1) Out of 38 administrative municipalities, ten were removed from the research to avoid political and professional complications of healthcare organisations placed in Kosovar-Serbian minority municipalities working in a parallel health system, possibly with a dual set of quality standards, 2) From the 28 remaining municipalities, 14 were removed from the research as they have maternities, while the focus of this research is outpatient care. Accordingly, the author selected the remaining 14 municipalities for the study. 3) Since MFMC has the highest influx of patients and the highest number of personnel within those municipalities, selecting an MFMC from each of the 14 municipalities was a reasonable course of action.4) The list of Quality Coordinators of the 14 selected MFMC was obtained to include them in the research, as they are existing employees of the MFMC responsible for quality improvement in the given institution. More information about the Quality Coordinators can be found under Introduction, section 1.3.1. All the above described in this paragraph are referred to as "step 1" in the research design.

For Step 2 of the research, two health inspectors were selected to conduct all of the inspections jointly and be responsible for report writing for half of them. The inspectors were existing, experienced employees of the Health Inspectorate. They were selected to conduct these inspections based on their medical speciality (family medicine and dentistry), experience in working in primary healthcare, and experience in inspecting primary health care. In addition to these inspections, the two inspectors would perform other regular duties, such as inspections in secondary healthcare or private healthcare. On the other side, the researcher drafted an inspection checklist based on legislation and written standards of the Ministry of Health of Kosova – all used during inspections but not in a formal document. The list was tested in a small sample of four other public institutions of primary healthcare not included in the research. Finally, the researcher prepared a demographic and work-related questionnaire based on information tailored for the study: gender, year of birth, education, years of experience in MFMC, years of experience as Quality Coordinator, self-declared knowledge of their job description, regular performance of their duties and training opportunities in the past. The inspectors were introduced to the checklist and the questionnaire; they reviewed them, commented on them or asked for clarifications. The final checklist (Appendix 1) and questionnaire (Appendix 2) were prepared for inspections.

For Step 3 of the research, the selected health inspectors conducted unannounced initial inspections of 14 MFMC based on a standard checklist within three months in 2016.

During the initial inspection, the questionnaire on selected demographic and work-related data for the Quality Coordinators was distributed. After an inspection, an official written report is sent back to each of the inspected institutions, stating the findings based on the checklist, the needs for corrections (if any) and suggested significant time for improvement, if feasible.

In step 4 of the research, the existing checklist and demographic and work-related questionnaire were reviewed. Additional items were added to the checklist due to novel legal requirements, but they were not included in the research. Further, the knowledge test was created with open-ended questions. The test contained the same indicators that were in the standard checklist, and the purpose of the test was to find out the level of knowledge of the Quality Coordinators on the basic standards of healthcare and Health Inspectorate requirements from a health organisation during a regular planned inspection

For step 5 of the research, due to the high number of healthcare organisations being supervised by the Health Inspectorate and a small number of healthcare inspectors (see chapter 1.3.4.), follow-up inspections were conducted in June-August 2018. Unannounced follow-up visits of the same organisations were performed to verify if previously found irregularities were corrected. The same standard checklist and demographic and work-related questionnaire were applied in both visits to establish staff changes. After the inspection, an official written report was sent back to each of the inspected institutions, stating the findings based on the checklist and the previous inspection report and further needs for corrections, if any.

Regarding Step 6 of the research, seven of fourteen MFMC were initially selected to partake in training by the Health Inspectorate. The MFMC were ranked by compliance with the basic standards of healthcare quality, and then the author chose the three lowest ranking MFMC for the experimental group. The final four MFMC for the experimental group were selected by comparing the organisations with population and health personnel sizes and choosing the lower performing institution among them. The Quality Coordinators from set seven MFMC were invited as an experimental group for the training. After this, technical preparations were conducted to organise and facilitate the training. Step 6 concludes the quantitative part of the research, although another portion of quantitative data appears in Step 10.

Step 7 of the research was the training provided by the Health Inspectorate, a full-day training in December 2018 and a half-day follow-up in March 2019. Participants were 7

Quality Coordinators from the experimental group, the Chief of Primary Health Care Division and Chief of Quality Division in the MoH, the Chief Inspector Health and two Health Inspectors that conducted the follow-up inspections. The training consisted of an introduction to quality documents in Kosova, new plans in the MoH regarding Quality Coordinators, the reason why they were selected for training, and a detailed introduction of each of the 32 BHQS from the Inspectorates checklist, how they are evaluated, and how they can be improved. The participants also shared their practices in dealing which a specific indicator and what worked for them or not. At the end of the training, the Health Inspectorate provided their checklist to the participants to assist them in performing work in their institutions.

In Step 8 of the research, another half day of follow-up training was conducted with the same participants on the same subjects in March 2019. The training merely focused on clarification of unclarities, suggestions for solutions, and experience sharing between all participants. The post-training knowledge test was administered to the Quality Coordinators during the training.

Step 9 was conducted at the end of the follow-up training by holding a semi-structured focus group discussion based on five more significant subjects: motivation to serve as Quality Coordinator, their previous experiences in this position, factors that impact healthcare quality in their opinion, suggestions for improvement, and their impression of the training. The list of questions can be found attached to this thesis as Annex 3. With step 9, the qualitative part of the research is concluded.

Step 10 entailed repeated final inspections of the 14 MFMC in April 2019 to evaluate the changes in adherence to basic standards of healthcare quality, with the same methodology as in the previous two inspections, explained in steps 3 and 5 of the research.

4.2.   Organizations, respondents and ethical approval

The subjects for the quantitative part of the study are Main Family Medicine Centres (MFMC) - public organizations of primary healthcare at the municipal level, governed independently by the Ministry of Health. MFMC is managed by the Director and has one Quality Coordinator. MFMC provides family medicine concept of care and oversees the smaller organizations, Family Medicine Centres and Family Medicine Ambulantas, distributed throughout the administrative territory of a municipality, depending on geography

and population. MFMC have differences in the population they serve, staff size, services provided, and budget, which will be considered during the research. The 14 MFMC that were eligible for the analysis are MFMC Pejë, Prishtinë, Prizren, Gjakovë, Gjilan, Mitrovicë, Ferizaj, Han Elezi, Shtime, Fushë Kosovë, Junik, Vushtrri, Obiliq, Mamushë (Figure 8).

[01] Deçan
[02] Gjakovë
[03] Gllogoc
[04] Gjilan
[05] Dragash
[06] Istog
[07] Kaçanik
[08] Klinë
[09] Fushë Kosovë
[10] Kamenicë
[11] Mitrovicë
[12] Leposaviq
[13] Lipjan
[14] Novobërdë
[15] Obiliç
[16] Rahovec
[17] Pejë
[18] Podujevë
[19] Prizren
[20] Prishtina
[21] Skënderaj
[22] Shtime
[23] Shtërpcë
[24] Suharekë
[25] Ferizaj
[26] Viti
[27] Vushtrri
[28] Zubin Potok
[29] Zveçan
[30] Malishevë
[31] Hani i elezit
[32] Mamush
[33] Junik
[34] Kllokot
[35] Graçanicë
[36] Ranillug
[37] Partesh
[38] Mitrovica e Veriut

Figure 8. Map of Kosova municipalities

Note: Municipalities are listed on the left side of the figure. Kosovar-Serbian minority municipalities are in boxes, and Municipalities having MFMC with maternities are underlined in green. The remaining municipalities, presented in green dots on the map, are the MFMC under research.

For the qualitative share of the research, the subjects are 14 MFMC Quality Coordinators, whose age, education and length of service in this position were collected during the first and second inspection. The Quality Coordinators are MFMC staff, appointed by and responsible to the Director, selected to perform an additional role of the Quality Coordinator in addition to their regular duties, for which they receive a small financial incentive – half a point in the salary scale. Initial Quality Coordinators had received some

training about their duties and responsibilities; however, due to personnel fluctuation, not all knowledge is updated. Although the duty aim is somewhat similar, Quality Coordinators (unlike Health Inspectors) cannot discipline and request improvements if the healthcare quality is not achieved; they can only inform the Director and propose positive correctional measures.

Private healthcare organisations were excluded from the study as they could not access the public health information system (108). Furthermore, healthcare organisations functioning in areas populated by Kosovar-Serbs were excluded, as they are not integrated into the Kosovar Health system (68). Finally, secondary and tertiary healthcare (public) organisations were not included as they have inpatient services too, which was out of the scope of this research.

Focus group participants were selected based on their position as Quality Coordinators of the MFMC. The interviews with Quality Coordinators aimed to get insight into their motivation to serve, development of healthcare quality initiatives, successes or improvement needs, and factors that impacted healthcare quality.

Written Approval from the Ethical Board in the Ministry of Health of Kosova before initiating any activities related to this research was acquired. In addition, participants of the experimental groups signed informed consent to participate in the study.

4.3. Data collection methods

Data for the quantitative part of the research were collected from unannounced inspections in the selected MFMC, evaluating compliance with the legally set basic standards of healthcare quality (BSHQ). For this purpose, a previously developed and already in-use standard checklist was applied. The checklist consists of 32 indicators based on mandatory legal provisions for the functioning of health organisations defined by the legislation in the Republic of Kosova - including but not limited to the Health Law, the Law on rights and duties of citizens in health care, Tobacco Law, the Law on medical equipment and products, Administrative Instruction for health information system database, Administrative Instruction on medical documentation, and Administrative Instruction on the pharmaceutical recipe.

The checklist covers patient information (name of institution, working hours, service list and price, name of office, doctors name, smoking prohibition sign, complaints free-phone line), medical documents (patient registry, unique medical documentation, patient history),

medicines (supply, expiration, anti-shock therapy, guidance on anti-shock therapy), hygiene (general, soap, drying hands, water, toilets, bed cover), managing medical disposal (safety-box, disposal manner), work resources (medical devices/equipment in place, devices/equipment working, sufficient staff providing service), professional identification (uniform, id card) and other legal requirements (general infrastructure condition, access for disabled, presence of staff, signature lists, prohibitions on promoting milk-formula and branded medicines). The checklist marks the results with "Yes", meaning that the legal requirement is fulfilled, or "No", meaning that the requirement is not fulfilled, which will then need an explanation for the adverse finding. The inspected organizations are officially informed of the results and are requested to initiate improvement measures within a given period. Follow-up unannounced inspections are conducted to verify if requested improvement measures are in place. The data from both inspections were analysed for compliance with the BHQS and rate of improvement by demographic and work-related characteristics (municipality; gender, age, education and length in the position of MFMC Quality Coordinators) and by clustered groups of repeated irregularities.

For the qualitative part of the research, interviews were conducted with the Quality Coordinators in the respondent's native language to determine motivation factors for this role, previous on-job experiences, factors influencing quality of healthcare, proposals for improvement of the system and their experience with the training. Non-self-disclosure of identity and privacy stipulations were maintained by not recording interviews, although verbatim notes were taken. Each participant granted consent, confirming their willingness to participate in the study. Each interview involved previously prepared open-ended questions to allow discussion with the respondents and obtain their perception of the research questions.

Research data were attained through document analysis of checklists, inspection reports, field notes, legislation, strategies, reports, information from the Agency of Statistics in Kosova, and other documents found online from open sources.

4.4. Data analysis

Inspection data from the checklists and reports for the quantitative part of the study were registered to the IBM SPSS 27. Fulfilled standards are marked with a score of "1", while unfulfilled (partially or entirely) was marked as "0". Results were represented graphically utilising summary, percentages, standard deviation, comparison of means and

coefficient of variation; the significance level in descriptive statistical tests was set at 0,05. In addition, relevant data were collected and processed from the Agency of Statistics of Kosova (ASK) web page to present demographic and health services indicators, compare MFMC and select which will be trained.

For the qualitative portion of the study, the verbatim notes of the discussions were analysed to extract noteworthy statements/phrases and formulate meaning. A coding system was used to cluster similar meanings into larger theme categories, assisting in answering the discussion's semi-structured questions (109). When appropriate, a search for emergent codes was made to identify themes that derive from the experiences of the research participants. Finally, the results were translated into English.

4.5. Validity and reliability

Internal validity of this research was ensured by: a) consulting other experienced local and international researchers to address researchers' bias; b) steering precise and verifiable record keeping; and c) triangulating data from different available sources (e.g. documents, interviews, expert opinions). The external validity of this study was ensured by discussing the findings with sample participants to ensure that all understood and accepted the results.

In scientific research, reliability refers to the precise replicability of the procedures and the outcomes (110). All the documents, forms, reports and field notes are preserved to ensure reliability. The preserved documents and the presentation of results are structured keeping in mind confidentiality requirements, so the link to the identity of the respondents cannot be established. Risk to the validity and reliability of the research involves accurate translation and interpretation from Albanian into English, preserving the meaning of information gained from the interviews. For this reason, during the interviews, the native language of the respondents was spoken. The interview notes were double-checked while translating, and a professional interpreter experience was sought, as van Nes et al. (2010) suggested. In addition, sample member checks were made to verify if the respondents could recognise themselves in the analysis.

5. RESULTS

Results are presented according to the timeline of activities, in line with research objectives. First, the primary data of health organizations under research are presented, then the checklist, and then the research results in the order of phases of research: the results of the initial inspections, the profile of the Quality Coordinators, the results of the follow-up inspections, the results of interview with the Quality Coordinators, to conclude the chapter with the results of the final inspections.

5.1. Health indicators of the municipalities under research

Kosovo has 38 municipalities, each with one MFMC – a public primary healthcare organization having one Quality Coordinator (QC). Each MFMC serves a different population and has different health indicators, staff, services and budget, which must be considered in research. Therefore, it is essential to present and analyse the primary data of 14 MFMC included in this research. The chapter Materials and Methodology describes why the other 24 municipalities in Kosovo were excluded from this research.

Natality in Kosova measured in 2016 was 13.1‰; mortality was 5.2‰, natural increase was 7.9‰, infant mortality was 8.5‰, and the vital index was 265. The municipalities under the research displayed similar total average values, except for a natural increase of 8.5‰, which is slightly higher than the national average of 7.9‰, and infant mortality of 11.0 ‰ being well above the national average of 8.5‰. Among the municipalities, the lowest natality was in Junik (5.6‰), while the highest was in Obiliq (17.5‰). Mortality was lowest in Junk (3.4‰) and highest in Gjilan (6.3‰). Infant mortality was the lowest in Vushtrri (3.0‰) and the highest in Junik (27.8‰) (Table 1).

Mamusha has the highest number of youngest children, 0-15 years old (33.2% of their population) within the researched municipalities, a value higher than the national average of 28.0%. Prishtina has the lowest number of children 0-15 years old (25.8% of the population), which is also below the national average. The highest number of elderly above 65 years of age within the researched municipalities is in Peja (7.8% of their population), higher than the national average of 6.7%; while the lowest number of elderly is in Mamushë (4.4% of their population) (Figure 9).

Table 1. Health Indicators of municipalities under research, 2016

Municipality	Natality ‰	Mortality ‰	Natural increase ‰	Infant mortality ‰	Vital index
Ferizaj	15.0	5.6	9.4	7.8	268.5
Fushë Kosovë	17.3	5.3	12.0	6.1	325.5
Gjakovë	11.7	6.1	5.6	12.6	191.4
Gjilan	13.6	6.3	7.3	12.6	214.7
Hani i Elezit	12.3	4.3	8.0	8.2	283.7
Junik	5.6	3.4	2.2	27.8	163.6
Mamushë	13.1	4.6	8.5	26.0	285.2
Mitrovicë	15.8	5.7	10.1	7.3	276.5
Obiliq	17.5	4.9	12.6	8.8	357.9
Pejë	11.9	5.4	6.5	6.8	222.3
Prishtinë	15.7	4.6	11.1	12.6	339.6
Prizren	11.9	5.0	6.9	6.2	238.8
Shtime	13.9	4.6	9.4	7.8	305.6
Vushtrri	15.2	6.1	9.1	3.0	249.5
Avg	13.6	5.1	8.5	11.0	265.9
SD	3.0	0.8	2.7	7.3	56.4
Kosova	13.1	5.2	7.9	8.5	265.0

Source: Health Analysis 2017, NIPHK (111)
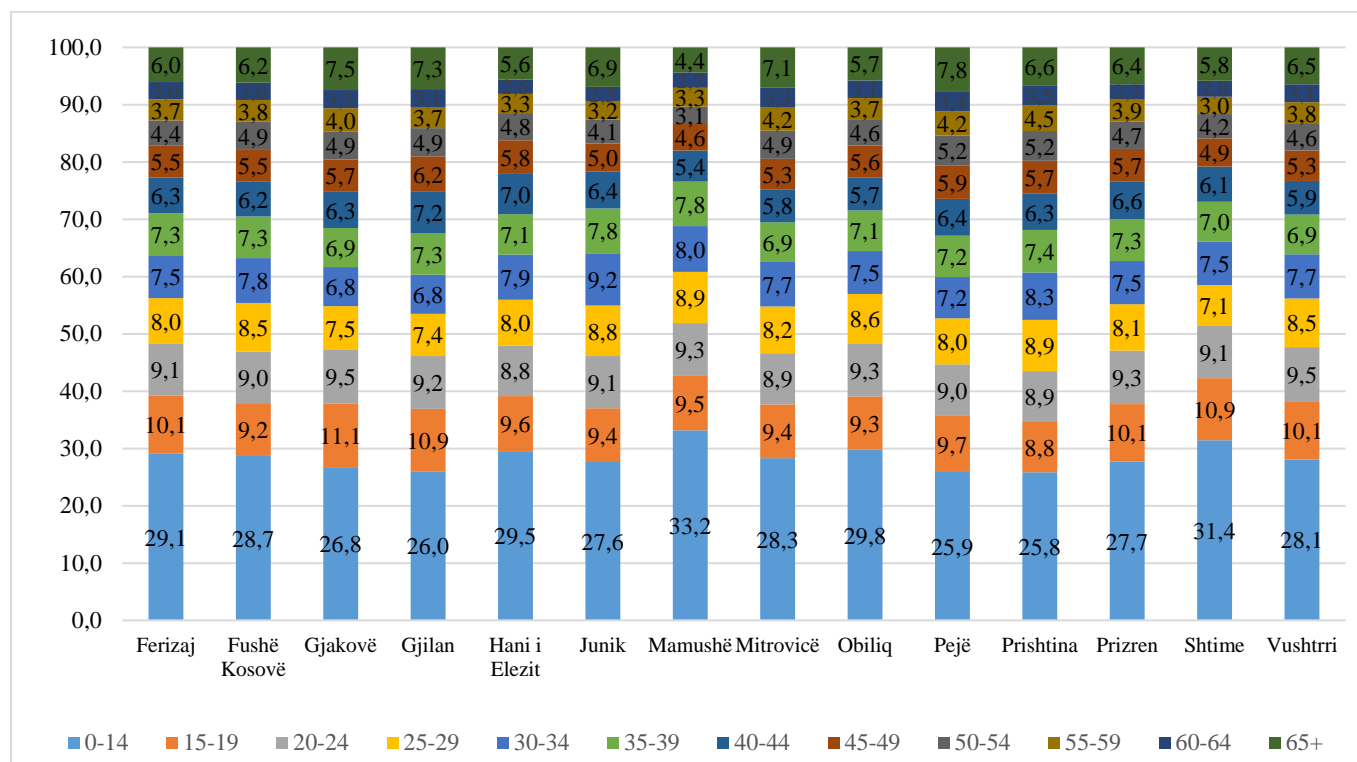
Figure 9. Age distribution of population in municipalities under research, 2016

Prepared from: ASK, 2016 (112)

The health workforce within the 14 MFMC together serve 915,196 inhabitants, which represent 52.6% of the population of Kosova based on the 2011 population census. The total health workforce serving in the 14 MFMC represents 64.8 % of the primary care doctors in Kosova, 80% of the dentists in primary care in Kosova and 61.1% of nurses in primary care in Kosova. Remarkably, there are but two pharmacists, one each in Gjilan and Vushtrri MFMC (Table 2).

Table 2. Population and work resources in MFMC, 2016

MFMC	Population	Doctors	Dentists	Nurses	Pharma-cysts	Collabo-rators	Total
Ferizaj	10,861	57	18	185	-	50	310
Fushë Kosovë	34,827	23	5	47	-	28	103
Gjakovë	94,556	73	52	207	-	21	353
Gjilan	90,178	55	16	162	1	49	283
Hani i Elezit	9,403	7	1	21	-	3	32
Junik	6,084	4	2	14	-	3	23
Mamushë	5,507	4	1	10	-	2	17
Mitrovicë	71,909	39	15	160	-	71	285
Obiliq	21,549	21	4	54	-	-	79
Pejë	96,450	72	25	200	-	52	349
Prishtinë	198,897	196	45	430	-	81	752
Prizren	177,781	92	39	270	-	73	474
Shtime	27,324	17	2	50	-	12	73
Vushtrri	69,870	32	7	134	1	29	203
Total, 14 MFMC	915,196	692	232	1,944	2	474	3,336
%	52.6	64.8	80.0	61.1	100.0	51.1	61.0
Total in PC	1,739,825	1,068	290	3,180	2	927	5,467

Source: https://askdata.rks-gov.net/ retrieved 12.02.2022, "-" no data, PC- primary care (112)

In the 14 MFMCs under study, one doctor, on average, serves 1000 inhabitants (SD=1.2), 0.3 nurses/1,000 inhabitants (SD=0.4) and 3.1 dentists per 1,000 inhabitants (SD=4.0). On average, there are three nurses per 1 doctor. The majority of MFMC display similar characteristics, except for Ferizaj MFMC, whose values are much higher for doctors and dentists per 1000 population (5.3 respectively 17.0), slightly higher for nurses per 1,000 population (1.7) and within the average nurse/doctor ratio (3.2) (Table 3).

Table 3. Health force indicators, 2016

MFMC	Doctor/ 1,000	Nurse/ 1,000	Dentist/ 1,000	Nurse/ Doctor
Ferizaj	5.2	1.7	17.0	3.2
Fushë Kosovë	0.7	0.1	1.3	2.0
Gjakovë	0.8	0.5	2.2	2.8
Gjilan	0.6	0.2	1.8	2.9
Hani i Elezit	0.7	0.1	2.2	3.0
Junik	0.7	0.3	2.3	3.5
Mamushë	0.7	0.2	1.8	2.5
Mitrovicë	0.5	0.2	2.2	4.1
Obiliq	1.0	0.2	2.5	2.6
Pejë	0.7	0.3	2.1	2.8
Prishtinë	1.0	0.2	2.2	2.2
Prizren	0.5	0.2	1.5	2.9
Shtime	0.6	0.1	1.8	2.9
Vushtrri	0.5	0.1	1.9	4.2
Avg	1.0	0.3	3.1	3.0
SD	1.2	0.4	4.0	0.6
Total in PC	0.6	0.2	1.8	3.0

Note: PC-primary care, Prepared from ASK, 2016 (112)

The 14 MFMCs under study, during 2016, provided 1,861,201 family medicine services or 50.5% of all family medicine services in Kosova; they initiated 4,141,613 interventions or 66.1% of the overall number of interventions in primary care in Kosova; and, undertook 290,967 dental services or 67.2% of overall dental services provided in primary care. Other specialist services (paediatrics, occupational medicine and gynaecology) provided only 3.5% of overall specialist services in primary healthcare in 2016 (Table 4).

Table 4. Visits in Family Medicine, 2016

MFMC	Family medicine	Pediatrics	Occupational Medicine	Gyneacology	Interventions	Laboratory	Radiology	Dental services
Ferizaj	25,428	-	-	-	390,379	-	5,143	40,028
Fushë Kosovë	68,609	14,307	-	3,751	137,218	10,787	-	9,472
Gjakovë	128,563	8,398	-	-	257,126	10,023	-	28,293
Gjilan	181,537	6,926	-	-	332,606	26,297	-	26,722
Hani i Elezit	28,013	2,604	-	-	56,026	2,495	609	-
Junik	1,413	-	-	-	1,494	1,208	-	2,137
Mamushë	3,535	-	-	-	7,070	472	-	274
Mitrovicë	166,875	-	-	-	801,513	27,526	-	27,659
Obiliq	10,875	3,230	-	410	7,494	1,484	598	1,275
Pejë	134,261	49,031	3,908	2,689	268,522	13,854	2,203	29,698
Prishtinë	604,397	135,167	-	27,304	1,208,794	80,984	-	83,218
Prizren	324,578	8,118	-	3,611	171,884	41,603	5,804	30,135
Shtime	47,598	-	-	-	230,449	-	1,828	2,444
Vushtrri	135,519	-	-	-	271,038	15,983	6,018	9,612
Total, 14 MFMC	1,861,201	227,781	3,908	37,765	4,141,613	232,716	22,203	290,967
%	50.5	3.5			66.1	35.9	40.5	67.2
Total in PC	3,688,571	7,673,601			6,265,155	647,811	54,888	433,211

Source: https://askdata.rks-gov.net/ retrieved 12.02.2022, "-" no data, PC- primary care (112)

The workload of doctors in overall primary healthcare in Kosova is 9.5 patients per day. Within the 14 MFMCs under research, the workload was the highest for the doctors in MFMC Han i Elezit, Mitrovicë, and Vushtrri, with averages of 12.0, 11.7, and 11.6 patients per day, respectively, while the lowest average for doctors was found in Junik, Ferizaj, and Obiliq with 1.0, 1.2 and 1.9 patients per day, respectively. The workload for dentists in primary healthcare in Kosova is 4.1 patients per day. Within the 14 MFMCs under research, the workload was the highest for the dentists in MFMC Ferizaj (6.1 patients per day) and Fushë Kosovë (5.2 patients per day), while the lowest for the dentists in MFMC Mamushë (0.8 patients per day) and Obiliq (0.9 patients per day) (Table 5).

Table 5. The workload of doctors and dentists in primary health care, 2016

MFMC	Doctors	Dentists
Ferizaj	1.2	6.1
Fushë Kosovë	10.3	5.2
Gjakovë	5.1	1.5
Gjilan	9.4	4.6
Hani i Elezit	12.0	-
Junik	1.0	2.9
Mamushë	2.4	0.8
Mitrovicë	11.7	5.1
Obiliq	1.9	0.9
Pejë	7.2	3.3
Prishtinë	10.7	5.1
Prizren	10.0	2.1
Shtime	7.7	3.3
Vushtrri	11.6	3.8
Total in PC	9.5	4.1

Prepared from ASK, 2016 (112)
PC– primary care, "-" - no data

The morbidity from cancer, communicable diseases, and tuberculosis have been calculated for the municipalities under research from the available data. The morbidity rate for cancer in Kosova in 2016 was 1.4/1,000 population. Within the 14 MFMC under the research, the highest cancer morbidity was in Ferizaj, 11.8/1,000, while the lowest was in Shtime, 0.5/1,000. The morbidity rate for communicable diseases in Kosova in 2016 was 105.5/1,000 population. Within the 14 MFMC under research, the highest communicable disease morbidity was in Ferizaj, 893.2/1,000 population, while the lowest was in Han i Elezit, 0.2/1,000 population. The morbidity rate for tuberculosis in Kosova in 2016 was 0.4/1,000 population. Within the 14 MFMC under the research, the highest tuberculosis morbidity was in Ferizaj, 6.9/1,000 population, while the lowest was in Gjakovë, 0.1/1,000 population (Table 6).

Table 6. Morbidity rates per 1,000 population, 2016

Municipality	Cancer	Communicable diseases	*TBC
Ferizaj	11.8	893.2	6.9
Fushë Kosovë	1.4	107.5	0.8
Gjakovë	1.4	68.7	0.1
Gjilan	1.1	80.2	0.2
Hani i Elezit	1.1	0.2	-
Junik	1.2	216.0	0.2
Mamushë	-	38.9	-
Mitrovicë	1.5	120.9	0.4
Obiliq	0.9	153.5	0.4
Pejë	1.5	86.8	0.5
Prishtinë	1.8	220.9	0.5
Prizren	0.8	80.1	0.2
Shtime	0.5	56.9	0.7
Vushtrri	1.2	45.2	0.6
Kosova	1.4	105.5	0.4

Source: ASK, Health Statistics 2016-2017, *TBC is for 2017, "-" no data (113,114)

5.2. Development of standardized Health Inspectorate's checklist

Following the described research stages, one of the results of this research was the development of a checklist for standardized assessment of the BSHQ. The standard checklist for general health inspections consists of 32 indicators based on mandatory legal provisions for the functioning of health institutions defined by the legislation in force in the Republic of Kosova - including but not limited to the Health Law, the Law on Rights and Duties of Citizens in Health Care, Tobacco Law, the Law on Medical Equipment and Products, Administrative Instruction (AI) for Health Information System Database, AI on Medical Documentation, AI on the Pharmaceutical Recipe.

The checklist covers eight areas dealing with structural indicators: (1) *patient information* (Name of institution – placed at the entrance, Working hours - displayed, Service list and prices - displayed, Name of office – for each office displayed, Doctors name – written outside office, Smoking prohibition sign - displayed, Patient complaints phone line - displayed), (2) *medical documents* (Patient registry – new format and correctly completed, Unique medical documentation – available, in use and correctly completed, Patient history – in use and correctly completed), (3) *medicines* (sufficient Supply from the essential list, valid

Expiration date of medicines, Anti-shock therapy complete and in place, Guidance on anti-shock therapy is displayed next to it), (4) *hygiene* (Overall hygiene of the institution, Soaps available in every sink, available means to Dry hands such as paper towels, air dryer etc., running Water and warm water, functional Toilets, clean Bed cover), (5) *managing medical disposal* (the existence and usage of Safety-boxes, regulated Disposal manner of medical waste outside the organization), (6) *work resources* (necessary Medical devices/equipment in place, Medical devices working, Sufficient staff to provide service), (7) *professional identification* (health professionals wear Uniform and Identity card) and (8) *other legal requirements* (General infrastructure condition, Access for disabled, Presence of staff, Signature lists of daily presence, Prohibitions on promoting milk-formula and branded medicines). The checklist displays results with "Yes", meaning that the legal requirement is completely fulfilled, or "No", meaning that the requirement is not fulfilled, whether partially or entirely, which will need an explanation for the adverse finding, usually highlighted in the inspection report. The checklist can be found in Appendix 1.

5.3. Initial Inspections

At initial inspections in the 14 selected MFMCs, the average adherence to the basic standards of healthcare quality (BSHQ) was 79.7% (SD=12.1), ranging from a minimum of 53.1% for MFMC Mamushë to a maximum of 96.9% for MFMC Prishtinë (Figure 10).
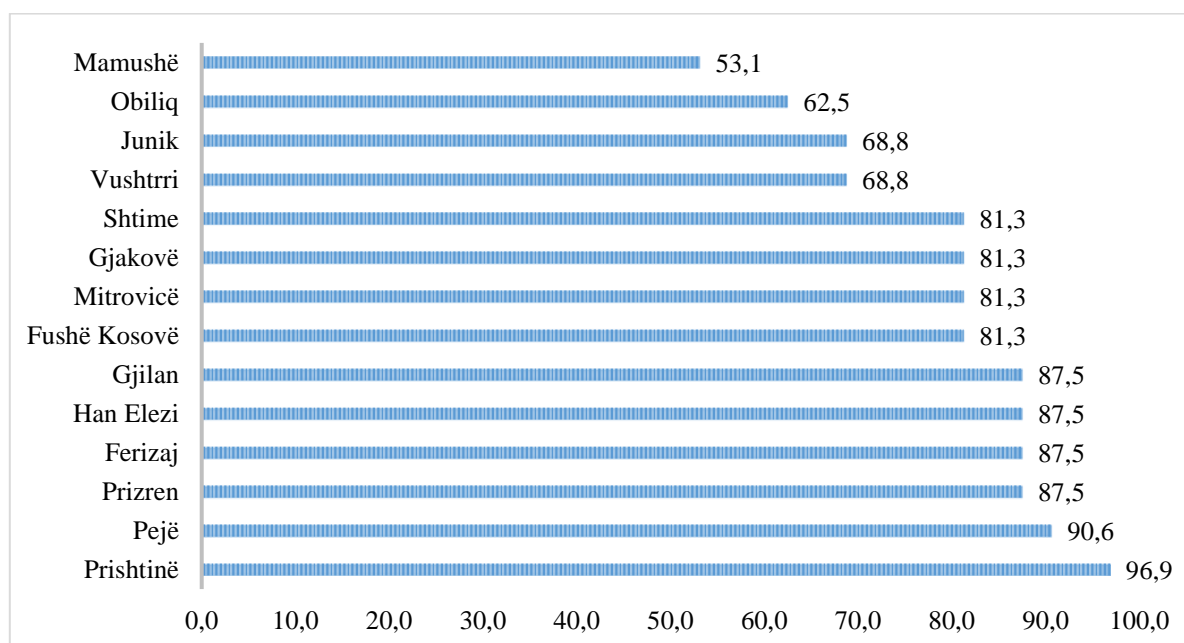
Figure 10. Fulfilment of BSHQ by MFMC in Kosova, 2016 (%)

By clustered groups of quality standards, presented in Table 7, the groups that had the highest mean of the fulfilment of the BSHQ were the Medical Waste (Mean=12.5, SD=0.7) followed by Medicines (Mean=12.3, SD=3.5), while the lowest mean was found for the clustered groups of Work Resources (Mean=8.3, SD=3.9) and Health Documents (Mean=9.0, SD=1.7). The differences between the means of the eight independent standards groups are not statistically significant (F-Stat=1.14, P-value =0.37). There is a more extensive distribution in Medicine, Work resources and Hygiene clustered groups compared to others (Figure 11).

Table 7. Fulfilment of clustered groups of BSHQ by 14 MFMC, 2016

Standard category	Standard N	Mean	Std. Dev.	Std. Error
Patient information	7	12.0	1.4	0.5
Health documents	3	9.0	1.7	1.0
Medicines	4	12.3	3.5	1.8
Hygiene	6	11.0	3.2	1.3
Medical waste	2	12.5	0.7	0.5
Work resources	3	8.3	3.8	2.2
Professional ID	2	11.5	2.1	1.5
Other	5	11.6	2.1	0.9

ANOVA Summary					
Source	Degrees of Freedom DF	Sum of Squares SS	Mean Square MS	F-Stat	P-Value
Between Groups	7	52.6026	7.5147	1.1443	0.3698
Within Groups	24	157.6153	6.5673		
Total:	31	210.2179			

Figure 11. One-way ANOVA, Mean value ± Standard Deviation, standards groups

The mean value for the Patient information cluster among the 14 MFMC is 12, SD=1.4 (Table 8). The most achieved standard is placing the name of service/office, performed by all the MFMC, while the least achieved standard is placing the telephone line for patient complaints, 71.4% (Table 8).

Table 8. Fulfilment of patient information standards by the 14 MFMC, 2016

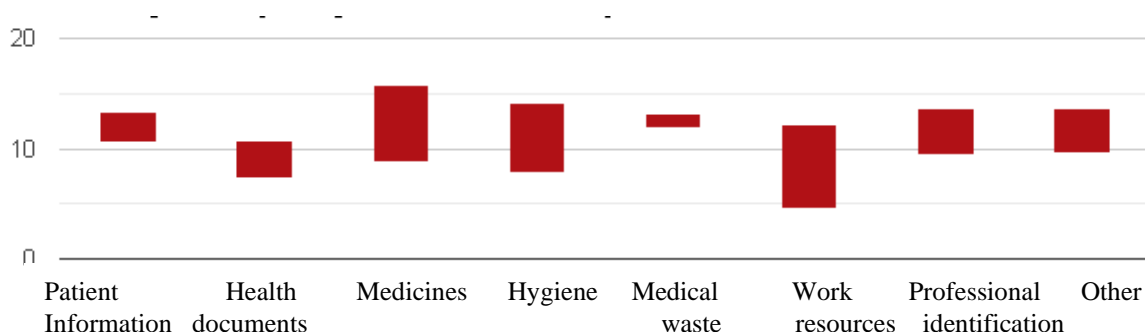| Patient Information	n	%
The name of the institution is displayed	13	92.9
Working ours are written	11	78.6
List of services with prices	13	92.9
Name of service/office	14	100.0
Name of doctor in office	11	78.6
Sign forbidden smoking	12	85.7
Telephone line for patient complaints	10	71.4

The mean value for the Health documents cluster is 9, SD=1.7 (Table 7). Within the group, the Patient registry was fulfilled by 11 MFMC or 78.6%, while Unique health documentation and Patient history were achieved in 8 MFMC or 57.1% of cases (Table 9).

The mean value for the Medicines cluster is 12.3, SD=3.5 (Table 7). Within the Medicines cluster, all standards were fulfilled except for Sufficient supply from the essential list, which was fulfilled in half of seven MFMC or 50% (Table 9).

Table 9. Fulfilment of Health documents and Medicines standards by 14 MFMC, 2016

Health documents	n	%
Patient registry	11	78.6
Unique health documentation	8	57.1
Patient history	8	57.1
Medicines	n	%
Supply from the essential list	7	50.0
Expiry date	14	100.0
Anti-shock therapy complete	14	100.0
Instructions for antishock therapy	14	100.0

The mean value for the Hygiene clustered group of standards is 11, SD=3.2 (Table 7). Within the Hygiene group of standards, soaps were in every sink (14 MFMC or 100%) while Things to dry hands were found only in 5 MFMC or 35.7% (Table 10).

The mean value for the Medical waste cluster is 12.5, SD=0.7 (Table 7). Within the Medical waste cluster, Safety boxes were present in 13 MFMC or 92.9%, while Regulated waste disposal occurred in 12 MFMC or 85.7% of cases. (Table 10).

Table 10. Fulfilment of Hygiene and Medical Waste standards by 14 MFMC, 2016

Hygiene	n	%
Of the overall institution	13	92.9
Soaps in every sink	14	100.0
To dry hands	5	35.7
Water (warm)	10	71.4
The functional toilet is clean; all supplies	12	85.7
Clean bedsheets	12	85.7
Medical waste	n	%
Safety boxes	13	92.9
Disposal manner	12	85.7

The mean value for the Work resources cluster is 8.3, SD=3.8 (Table 7). Within the Work resources cluster, Medical equipment functioned properly in 11 MFMCs or 78.6% of cases. The Necessary medical equipment standard was achieved in 10 MFMC, or 71.4% of cases, but Sufficient staff was found in only 4 MFMC or 28.6% of cases (Table 11).

The mean value for the Professional identification cluster is 11.5, SD=2.1 (Table 7). Within the Professional identification group, proper wearing of Uniform was found in 13 MFMC or 92.9% of cases, while Identity badges were found in 10 MFMC or 71.4% of cases (Table 11).

Table 11. Fulfilment of Work resources and Professional ID standards by 14 MFMC, 2016

Work resources	n	%
Necessary medical equipment	10	71.4
Medical equipment working	11	78.6
Sufficient staff	4	28.6
Professional Identification	n	%
Uniform	13	92.9
Identity badges	10	71.4

The mean value for the Other legal requirements cluster is 11.6, SD=2.1 (Table 7). Within the Other legal requirements group, Staff was present in their workplaces in all 14

MFMC or 100% of cases, while Access for the disabled was found the least, in 9 MFMC or 64.3% of cases (Table 12).

Table 12. Fulfilment of Other group of standards by 14 MFMC, 2016

Other	n	%
The overall infrastructure is good	10	71.4
Access for disabled - stairs, elevator, light	9	64.3
Staff in their working places	14	100.0
Signature list of staff present	12	85.7
No advertisement for milk formula and medicines	13	92.9

5.4. Profile of the Quality Coordinators

Of the 14 MFMCs inspected in 2016, one (MFMC Han i Elezit) did not have a Quality Coordinator or person in charge of quality. Of 13 Quality Coordinators, ten were appointed while three were acting as Quality Coordinators - in MFMC Fushë Kosovë, Mamushë, and Ferizaj, with a note that in Mamushë, there was no official letter of appointment for acting duty of Quality Coordinator. The Quality Coordinator of MFMC Junik declared not to perform the duty since, although appointed, the financial reward was not granted accordingly.

The majority of Quality Coordinators were males (11 or 84.6%). Most of the Quality Coordinators were in the age group 51-55 years. Only one Quality Coordinator (7.7%) did not have a university education (in Mamushë). In contrast, five, or 38.5% of them, had postgraduate education – in MFMC Fushë Kosovë, Mitrovicë, Pejë, Junik, and Gjilan, all of them were specialists in Family Medicine (Table 13).

Table 13. Demographic characteristics of the Quality Coordinators, 2016

		n	%
Gender	Female	2	15.4
	Male	11	84.6
Age group	41-45	1	7.7
	46-50	3	23.1
	51-55	6	46.2
	56-60	2	15.4
	61-65	1	7.7
Education	High school	1	7.7
	University	7	53.9
	Postgraduate	5	38.5

Most of the Quality Coordinators (6 or 46.2%) have served more than 16 years in their MFMC, while the lowest number of years the Quality Coordinator has served is between 6-10, in 3 cases or 23.1%. Despite the work experience in the MFMC, the experience in the Quality Coordinator job is, in most cases (8 or 61.5%), five years or less (Table 14).

Table 14. Work-related characteristics of the Quality Coordinators, 2016

	years	n	%
Previous employment in MFMC	6-10	3	23.1
	11-15	4	30.8
	16+	6	46.2
Work experience as a Quality Coordinator	≤5	8	61.5
	6-10	4	30.8
	10+	1	7.7

The Quality Coordinators were asked to identify the characteristics of a high-quality healthcare system, according to the IOM (2008). On average, 10.6 Quality Coordinators or 82.1% of them, could identify all six characteristics of a high-quality healthcare system. Two Quality Coordinators could identify only two characteristics each; both identified patient orientation; one identified timely service while the other identified efficiency. One Quality Coordinator could not identify any of the characteristics (Table 15).

Table 15. Identification of 6 characteristics of the high-quality healthcare system (IOM, 2008) by the Quality Coordinators, 2016

Characteristics	n	%
Safe	10	76.9
Effective	10	76.9
Patient Orientated	12	92.3
Timely	11	84.6
Efficient	11	84.6
Equal	10	76.9
Average	10.6	82.1
SD	0.89	

Twelve (92.3%) of the Quality Coordinators declared to know the duties prescribed in the official job description of the quality Coordinator and to report regularly to the MFMC

Director. Some 84.6% of the Coordinators declared to perform their duties regularly, while all declared that the MFMC Director consults them about quality issues. Only four Coordinators (30.8%) have had previous training sessions in quality; three, or 23.1%, participated in a quality session organised by the Health Inspectorate. Most (92.3%) are willing to participate in another training by the Health Inspectorate (Table 16).

Table 16. Self-declared job knowledge of Quality Coordinators, 2016

Job process	n	%
Knowledge of job description	12	92.3
Regular performance of duties	11	84.6
Regular reporting to the MFMC Director	12	92.3
Director consults on quality issues	13	100.0
Participation in a quality session by the Health Inspectorate in 2012	3	23.1
Willingness to participate in training led by the Health Inspectorate	12	92.3
Other previous quality training	4	30.8

5.5. Follow-up Inspections

Before conducting the follow-up inspections, the standard checklist was revised, and items were added due to additional legal requirements. Those items were not included in the research. Also, due to workload, one Inspector (Dentist) could not participate in the follow-up inspections and was substituted with another (Pharmacist), who had undergone necessary preparations for conducting the inspections.

After follow-up inspections, the overall average number of the basic standards of healthcare quality (BSHQ) adhered to was 26.9 standards or 84.2% (SD=3.1), ranging from a minimum of 20 standards or 62.5% for MFMC Mamushë to a maximum of 30 standards or 93.8% for MFMC Prizren and Fushë Kosovë (Figure 12). The overall average value was slightly higher than initial inspections, 25.5 standards or 79.7% (SD=3.9), with between-group differences not reaching statistical significance (two-tailed t-test, P-value=0.1716, 95% CI= -3.56 to 0.70). The minimum percentage recorded was also slightly higher in follow-up inspections (62.5% in 2018, in comparison to 52.1% in 2016 for MFMC Mamushë), but the maximum percentage in follow-up inspections was slightly lower (96.9% for MFMC Prishtinë in 2016 in comparison to 93.8% for MFMC Prizren and Fushë Kosovë in 2018).
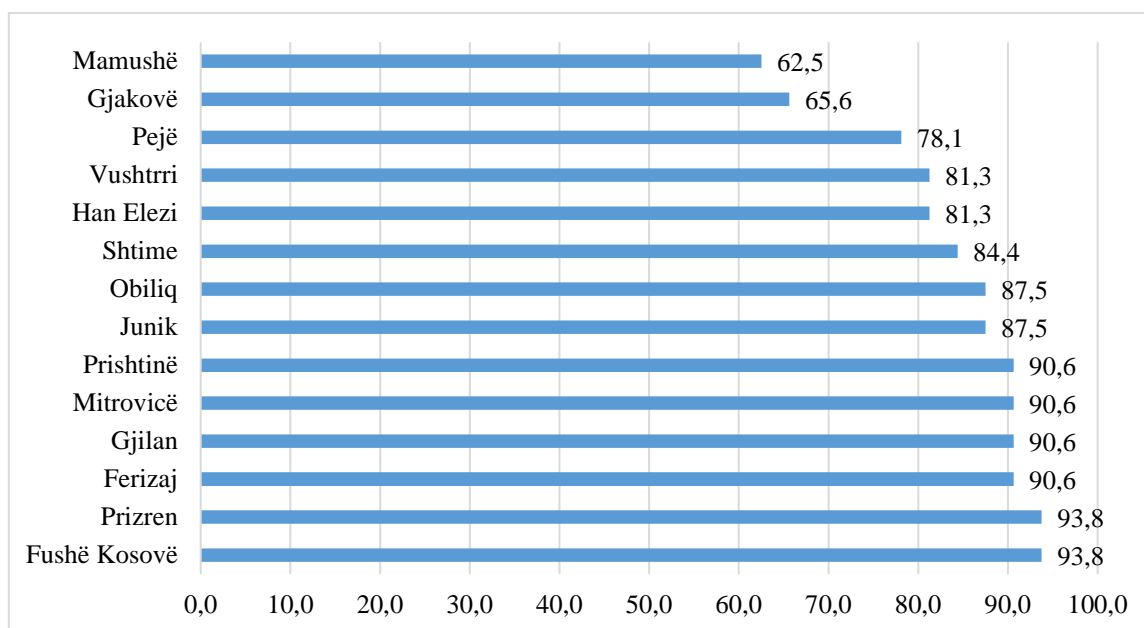
Figure 12. Fulfilment of BSHQ in follow-up inspections, 2018 (%)
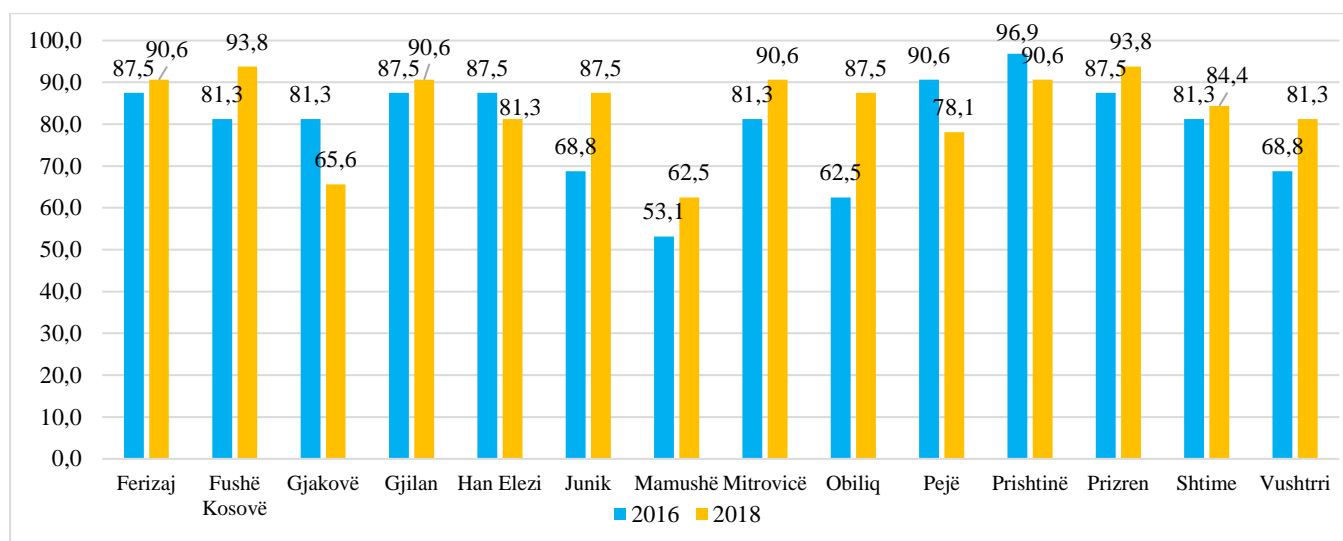
Figure 13. Comparison of the fulfilment of BSHQ by MFMC, 2016-2018 (%)

As noted in Figure 13, in comparison to the initial inspections, in follow-up inspections, 10 MFMC were found to have an improved percentage - Ferizaj, Fushë Kosovë, Gjilan, Junik, Mamushë, Mitrovicë, Obiliq, Prizren, Shtime and Vushtrri. Among them, the highest improved percentage of 25% was recorded for MFMC Obiliq (from 62.5% to 87.5%), followed by 18.8% for MFMC Junik (from 68.8% to 87.5%), while the lowest improvement of 3.1% was recorded for MFMC Ferizaj, Gjilan and Shtime. The remaining 4 MFMCs have shown a decline in adherence to BSHQ: Gjakovë, Han i Elezit, Pejë and Prishtinë. The

highest decline was recorded for MFMC Gjakovë (from 81.3% to 65.6%), while the lowest was recorded for both MFMC Han i Elezit (from 87.5% to 84.4%) and MFMC Prishtina (from 96.9 to 90.6%).

By clustered groups of quality standards, presented in Table 17, the groups that had the highest mean of the number of MFMC fulfilling that particular clustered group of the BSHQ were the Medical Waste (Mean=14.0, SD=0.0) followed by Patient information (Mean=12.7, SD=1.0), while the lowest average was found for the clustered groups of Hygiene (Mean=10.0, SD=3.6) and Work Resources (Mean=11.0, SD=4.4). The differences between the means of the eight independent standards groups are not statistically significant (F-Stat=0.6451, P-value =0.7146).

Table 17. Fulfilment of clustered groups of BSHQ by 14 MFMC, 2018

Standard category	N	Mean	Std. Dev.	Std. Error
Patient information	7	12.7	1.0	0.4
Health documents	3	12.3	2.1	0.9
Medicines	4	11.3	4.9	2.4
Hygiene	6	10.0	3.6	1.5
Medical waste	2	14.0	0.0	0.0
Work resources	3	11.0	4.4	2.5
Professional ID	2	12.0	2.8	2.0
Other	5	12.2	2.0	0.9

ANOVA Summary					
Source	Degrees of Freedom DF	Sum of Squares SS	Mean Square MS	F-Stat	P-Value
Between Groups	7	39.8236	5.6891	0.6451	0.7146
Within Groups	24	211.6463	8.8186		
Total:	31	251.4699			

As can be seen in Figure 14, in follow-up inspections compared to initial inspections, six clustered groups of standards have an increased mean score (Patient Information, Health documents Medical Waste, Work resources, Professional identification and Other legal requirements); among them, the highest increase (23.8%) was found for Health Documents, from 64.3% to 88.1%. The remaining two clustered groups of standards have shown a decline in their mean scores, for Hygiene -7.2% (from 78.6% to 71.4% of the MFMC) while for Medicines -7.1% (from 87.5 to 80.4%).
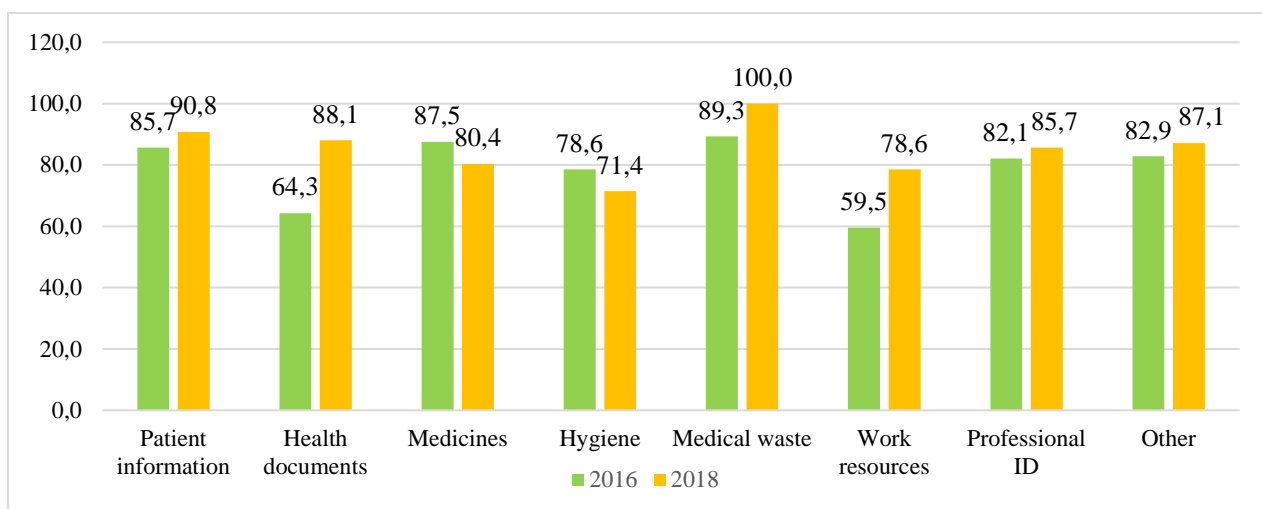
Figure 14. Comparison of mean values of the fulfilment of BSHQ by groups of standards (%)

Within the Patient Information standards group, the mean value for the Patient information standards cluster in follow-up inspection is 12.7, SD=1.0 (Table 17). The most fulfilled standard is placing the Name of the organization, achieved by 14 MFMC, while the least achieved standard was placing the Name of doctors in offices, 11 or 78.6% of the MFMC (Table 18). Four standards have displayed higher values than in the initial inspections - Name of institution, Working hours, Smoking prohibition sign and display of Telephone line for patient complaints. The highest increase of 21.5% was noted for placing the Telephone line for patient complaints, from 71.4% to 92.9%. The other two standards have remained at the same level - List of services with prices (92.9%) and Name of doctor in office (78.6%), while one standard has suffered a decline by 7.1% - Name of service/office, from 100% to 92.9% (Figure 15).

Table 18. Fulfilment of Patient Information standards by 14 MFMC, 2018

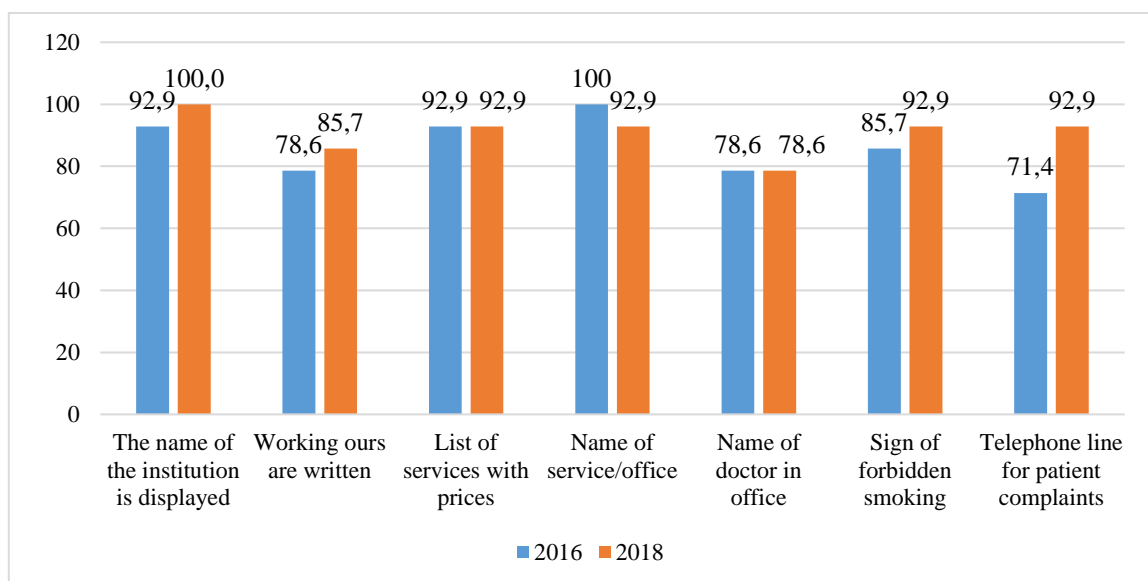| Patient Information	n	%
The name of the institution is displayed	14	100.0
Working ours are written	12	85.7
List of services with prices	13	92.9
Name of service/office	13	92.9
Name of doctor in office	11	78.6
Sign of forbidden smoking	13	92.9
Telephone line for patient complaints	13	92.9

Figure 15. Comparison of the fulfilment of Patient Information standards (%)

The mean value for the Health documents clustered group of standards in follow-up inspection is 12.3, SD=2.1 (Table 17). Patient history was the least fulfilled standard within the group in 10 MFMCs, or 71.4% of them, while completing Unique Patient Documentation was found in all 14 inspected MFMCs or 100.0% of cases (Table 19). Compared to the initial inspections, the values for all three standards recorded an increase, the highest for Unique Health documentation (from 57.1% to 100%) (Figure 16).

The mean value for the Medicines clustered group of standards in follow-up inspections is 11.3, SD=4.9 (Table 17). Within the Medicines clustered group of standards, Anti-shock therapy and Instructions for its use were the standards fulfilled by all 14 MFMCs, while the Supply of medicines from the essential list was fulfilled only in 4 MFMCs or 28.6% of them (Table 19). Compared to the initial inspections, two standards within this group have remained at the same score – the highest, Anti-shock therapy and Instructions for its use. Another two standards have declined: Expired medicines (by -7.1%, from 100% to 92.9% of the MFMC) and the Supply of medicines from the essential list (by -21.4%, from 50.0% to 28.6% of the MFMC) (Figure 17).

Table 19. Fulfilment of Health documents and Medicines standards by 14 MFMC, 2018

Health documents	n	%
Patient registry	13	92.9
Unique health documentation	14	100.0
Patient history	10	71.4
Medicines	n	%
Supply from the essential list	4	28.6
Expiry date	13	92.9
Anti-shock therapy complete	14	100.0
Instructions for antishock therapy	14	100.0

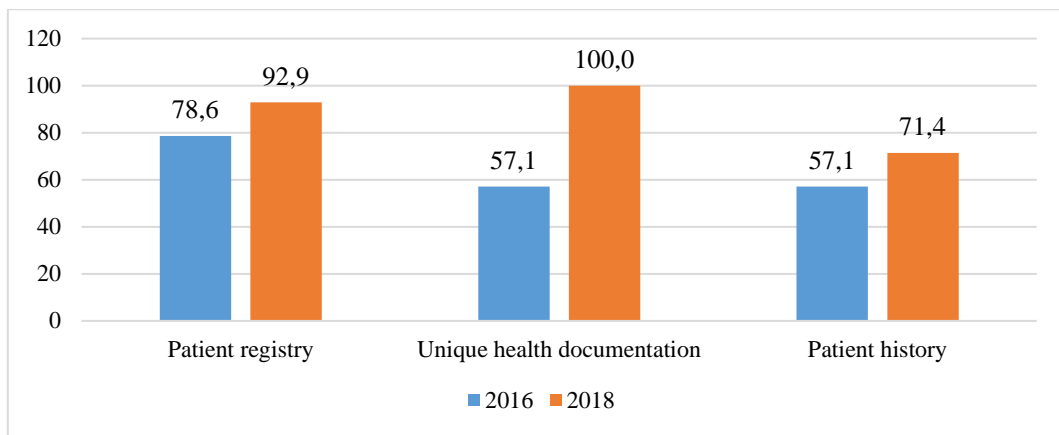Figure 16. Comparison of the fulfilment of Health documents standards (%)
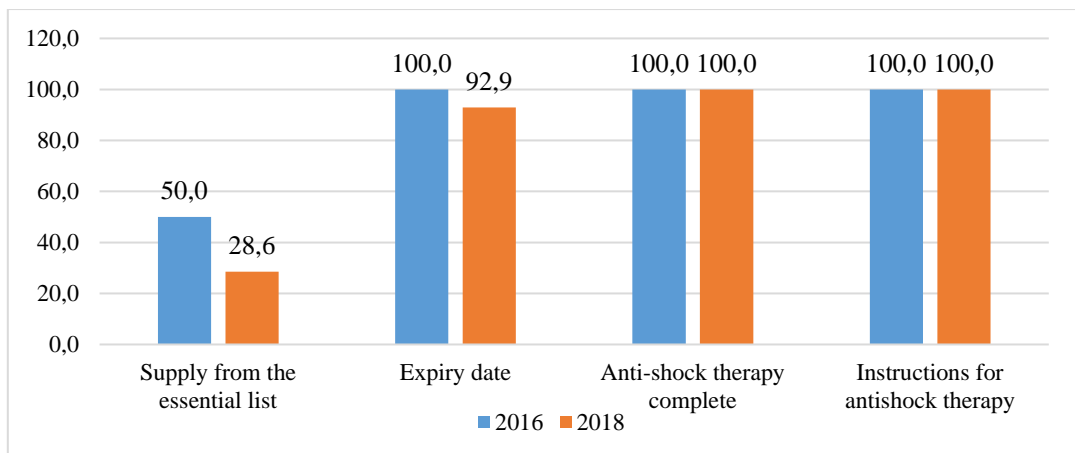

Figure 17. Comparison of the fulfilment of Medicines standards (%)

The mean value for the Hygiene clustered group of standards in follow-up inspections is 10.0, SD=3.6 (Table 17). Within the Hygiene group of standards, the highest score was for the overall hygiene of the institution, 13 MFMC or 92.9%, while the lowest score was for the

standard, Means to dry hands, with only 3 MFMC or 21.4% (Table 20) meeting this requirement. Compared to the initial inspections, three standards had a decline in their scores, Soap availability, Toilets and Means to dry hands; the most profound decline of -21.4% being for Soaps in every sink (from 100% to 78.6% of the MFMC). Clean bedsheets and Overall hygiene of the institution did not change their scores. The only standard that displayed a slight improvement was the standard of having (warm) Water, from 71.4% to 78.6% (Figure 18).

Table 20. Fulfilment of Hygiene and Medical Waste standards by 14 MFMC, 2018

Hygiene	n	%
Of the overall institution	13	92.9
Soaps in every sink	11	78.6
To dry hands	3	21.4
Water (warm)	11	78.6
The functional toilet is clean, and all supplies	10	71.4
Clean bedsheets	12	85.7
Medical waste	n	%
Safety boxes	14	100.0
Disposal manner	14	100.0

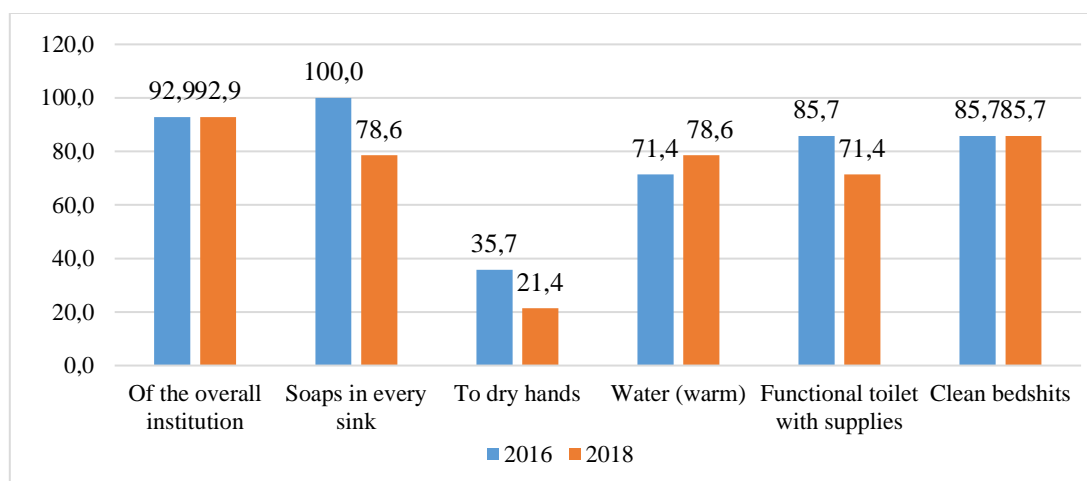Figure 18. Comparison of the fulfilment of the Hygiene standards (%)

The mean value for the Medical waste cluster in follow-up inspections is 14.0, SD=0.0 (Table 17). Within the Medical waste group of standards, both standards (Safety boxes and Regulated Disposal of waste) were found in all 14 MFMC or 100.0% of cases (Table 20). Compared to the initial inspections, both standards improved their score, with the

highest increase of 14.3% noted for the Regulated disposal of waste, from 85.7 to 100% (Figure19).
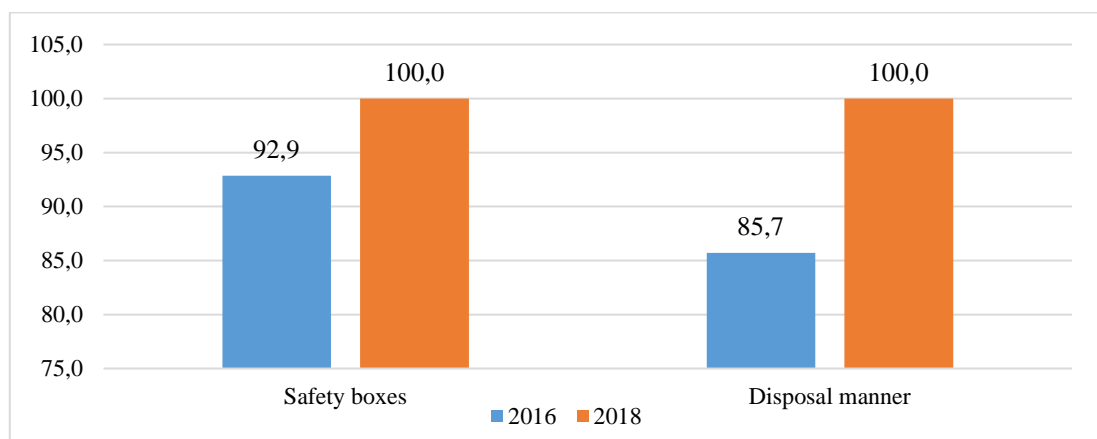
Figure 19. Comparison of the fulfilment of Medical Waste standards (%)

The mean value for the Work resources cluster in follow-up inspections is 11.0, SD=4.4 (Table 17). Within the Work resources cluster, the Necessary medical equipment was found in 14 MFMC or 100.0% of cases, Medical equipment was working in 13 MFMC or 92.9% of cases, but Sufficient staff was found only in 6 MFMC or 42.9% of cases (Table 21). Compared to the initial inspections, all three standards have improved their percentage score, the highest 28.6% increase for Medical equipment, from 71.4% to 100.0% of the MFMC (Figure 20).

The mean value for the Professional identification cluster in follow-up inspections is 12.0, SD=2.8 (Table 17). Within the Professional identification group, proper wearing of Uniform was found in 14 MFMC or 100.0% of cases, while Identity badges were found in 10 MFMC or 71.4% of cases (Table 21). The Identity Badges standard maintained the exact percentage value of the initial inspections, while the Uniform standard improved from 92.9% to 100% or +7.1% (Figure 21).

Table 21. Fulfilment of Work resources and Professional ID standards by 14 MFMC, 2018

Work resources	n	%
Necessary medical equipment	14	100.0
Medical equipment working	13	92.9
Sufficient staff	6	42.9
Professional Identification	n	%
Uniform	14	100.0
Identity badges	10	71.4
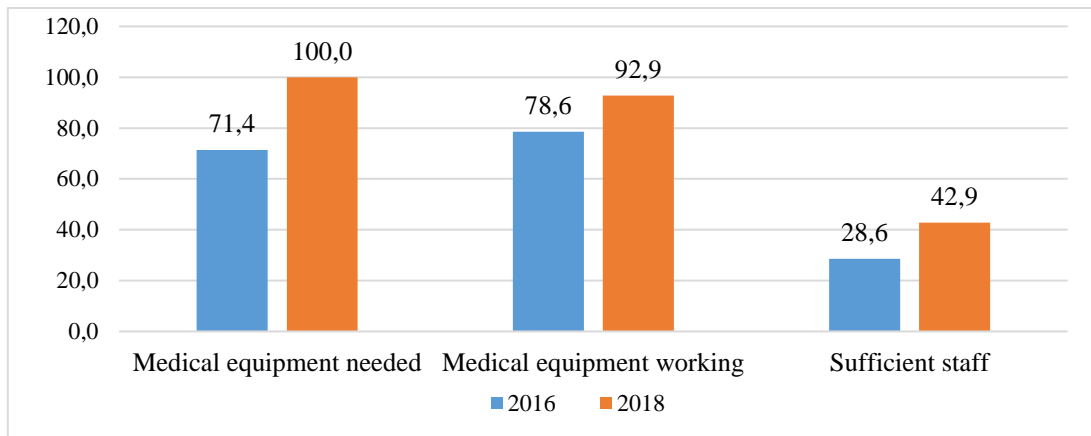
Figure 20. Comparison of the fulfilment of the Work resources standards (%)
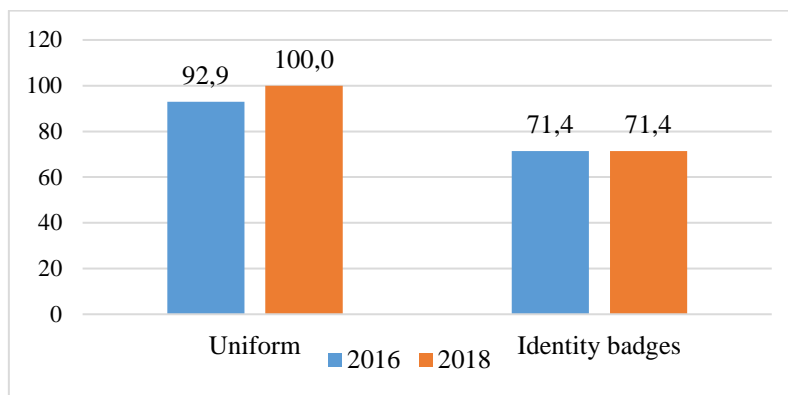
Figure 21. Comparison of the fulfilment of the Professional identification standards (%)

The mean value for the Other legal requirements cluster in follow-up inspections is 12.2, SD=2.0 (Table 17). Within the Other legal requirements group, the standards of No advertisement of milk formula and medicines and the Overall infrastructure were fulfilled in 14 MFMC or 100.0% of cases. Access for the disabled was found the least, in 9 MFMC or 64.3% of cases (Table 22). Compared to the initial inspections, Infrastructure improved by 28.6% (from 71.4% to 100.0%), while the adherence to the Advertisement bans improved by 7.1% (from 92.9 to 100.0%). Access for the disabled and the Signature list did not change their scores, while the standard of Presence of staff declined by -14.3%, from 100.0% to 85.7% (Figure 22).

Table 22. Fulfilment of Other legal requirements standards, 2018

Other legal requirements	n	%
The overall infrastructure is good	14	100.0
Access for disabled - stairs, elevator, light	9	64.3
Staff in their working places	12	85.7
Signature list of staff present	12	85.7
No advertisement for milk formula and medicines	14	100.0
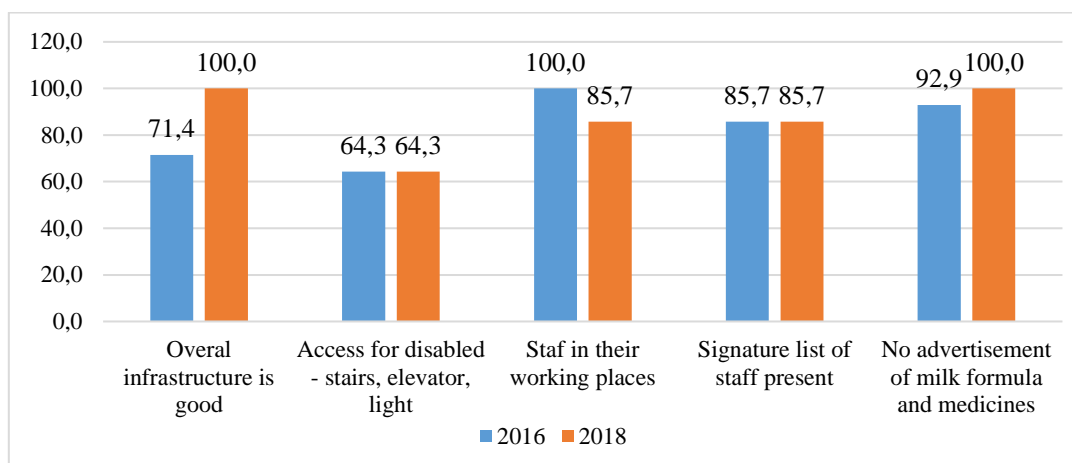
Figure 22. Comparison of the fulfilment of Other requirements standards, (%)

5.6.   Quality Coordinators' knowledge of BSHQ in follow-up inspections

Eleven MFMC had the same Quality Coordinators between 2016 and 2018. MFMC Shtime changed its Quality Coordinator. Han i Elezit, which did not have any, appointed one nurse as Quality Coordinator on an interim basis, while MFMC Junik had problems with the existing Quality Coordinator, who did not perform duties, resigned and restarted the same position. The Quality Coordinator from MFMC Gjilan did not participate in further activities; therefore, research continued with the remaining 13 Quality Coordinators.

Each Coordinator was asked if they had read the last Inspection report and had undertaken measures based on the report. Some 57.1% answered that they had read the report, while 50% of that subgroup declared to have undertaken measures based on the report recommendations. Afterwards, the Quality Coordinators were asked to identify standards within each clustered group.

The mean value of standards that the Quality Coordinators could identify from the 32 BSHQ was 12.7, SD=3.4 or 39.7%, the lowest value was 8 standards or 25%, while the

highest value was 18 or 56.3%. The presentation of the results will protect the identity of the Quality Coordinators by removing name identifiers from their respective MFMC (Figure 23).
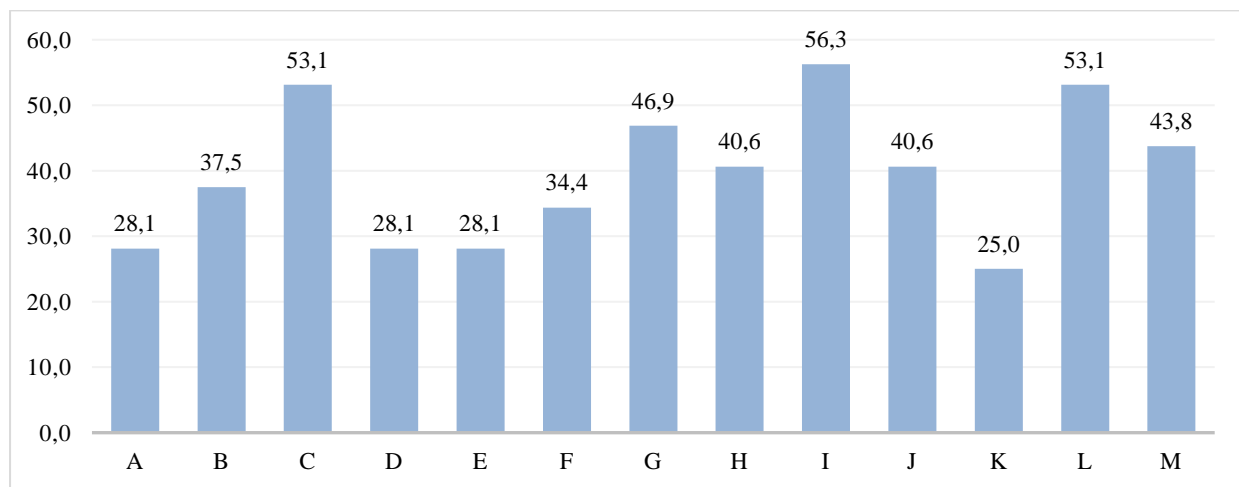
Figure 23. Knowledge of 32 BSHQ by the Quality Coordinators, 2018 (%)

From the figure, we can notice that eleven Quality Coordinators recognised less than half the standards while only three knew more than 50% but less than 60% of them. Interestingly, the Coordinators acknowledged other issues that were not a part of BSHQ inspections but were essential to them, such as reporting to the Health Information System, prescription of antibiotics, wheelchairs for impaired patients, licenses for health personnel, data safety, patient privacy, personnel records, personnel performance and archive for a (primarily paper-based) medical history of the patients.

By clustered categories of standards, the highest number of Quality Coordinators identified Health Documents standards (Mean=10.7, SD=2.1), while the least identified Other legal requirements (Mean=1.8, SD=3,5). The differences in means between the standard category groups have statistical significance for p=0.0342 and F=2.668 (Table 23).

Table 23. Most identified clustered groups of BSHQ by the Quality Coordinators, 2018

Standard category	(N)	Mean	Std. Dev.	Std. Error
Patient information	7	3.4	2.6	0.95
Health documents	3	10.7	2.1	1.2
Medicines	4	4.8	5.2	2.6
Hygiene	6	5.7	4.5	1.8
Medical waste	2	10	1.4	1.0
Work resources	3	2.7	2.5	1.5
Professional ID	2	4.5	2.1	1.5
Other	5	1.8	3.5	1.6

ANOVA Summary					
Source	Degrees of Freedom DF	Sum of Squares SS	Mean Square MS	F-Stat	P-Value
Between Groups	7	233.7883	33.3983	2.668	0.0342
Within Groups	24	300.4298	12.5179		
Total:	31	534.2181			

5.7. Impact of training on Quality Coordinators' knowledge of the BSHQ

Seven selected Quality Coordinators were subjected to training sessions by the Health Inspectorate to define the impact of this organised activity of the Health Inspectorate on quality awareness of the Quality Coordinators (see Chapter 5).

The mean knowledge of 32 BSHQ by these seven Quality Coordinators before educational sessions was 11.4 standards (SD=2.9) or 35.7% attainment, and these values rose to 23.4 standards (SD=8.3) after the sessions or 73.2%. A paired two-sample t-test discovered statistically significant differences in mean values of the standards knowledge before *($\bar{x}$=11.4, SD=2.9)* and post-training *($\bar{x}$=23.4, SD=8.3)*, *[t(6)=3.658, p=0.011], 95% CI[3.9728, 20.0272],* with a large effect size d=1.4 (Figure 24). (115)
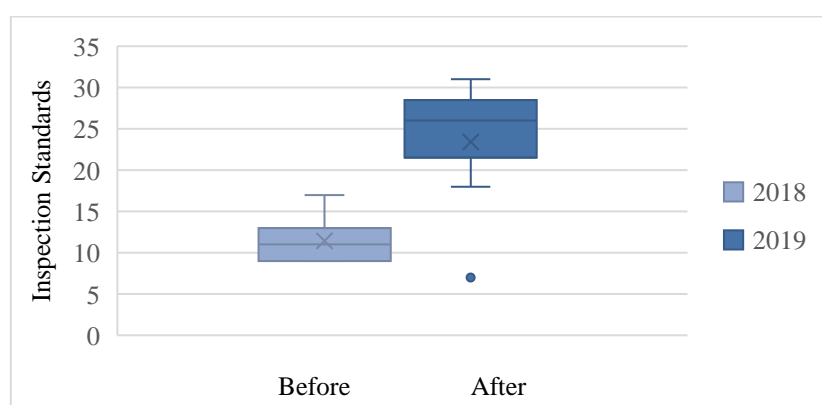

Figure 24. Quality Coordinators' knowledge of 32 BSHQ before and after the training (N=7)

Individually, 6 of the 7 Quality Coordinators have shown drastic improvement in knowledge afterwards, and these values are higher than the individual values of the untrained 7 Quality Coordinators. However, one has shown a decline in knowledge score from 37.5% to 21.9%, representing the lowest value among all Quality Coordinators (Figure 25).
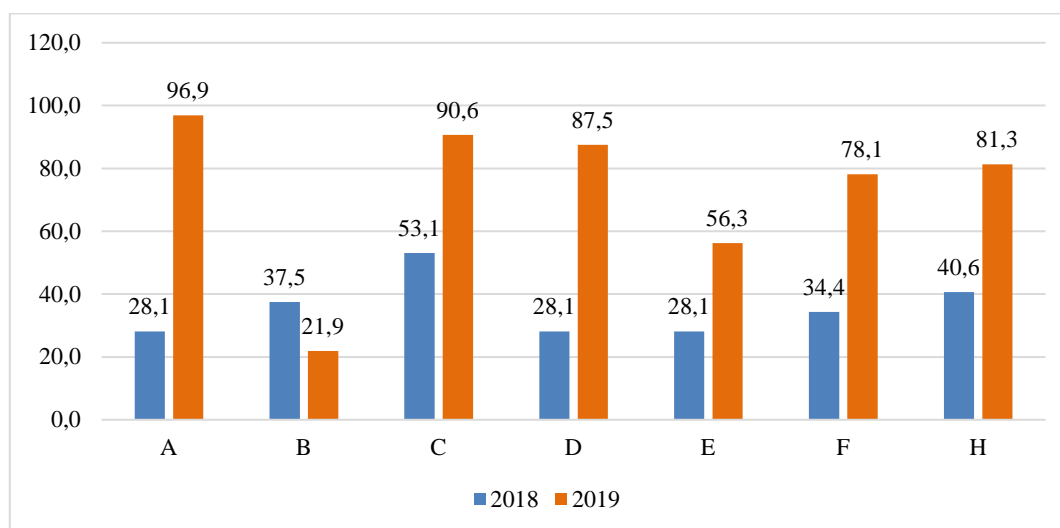
Figure 25. Comparison of knowledge of BSHQ before and after training (%)

Before the training, standards from the clustered group of Health Documents were the most known by the Quality Coordinators $(\overline{x}=2.6, SD=0.5)$, while standards from the group of Work Resources were known the least $(\overline{x}=0.3, SD=0.5)$. After the training, standards from the Medicine group were known the most $(\overline{x}=3.3, SD=1.1)$ while standards from the Other group were known the least $(\overline{x}=3.0, SD=2.0)$. Paired t-test revealed a significant difference in knowledge before and after the training for all standards groups, except for Health documents and Medical Waste (Table 24).

Table 24. Quality Coordinators' knowledge of standard groups, before and after the training

Clustered groups Of Quality standards	(N)	QC knowledge (N=7)						Sig	95% Conf.Int.	
		Before the training		After the training						
		Mean	Std. Dev.	Mean	Std. Dev.	df	t	2-tailed	Lower	Upper
Patient information	7	1.7	1.4	5.6	2.1	6	4.117	.006	.397	2.666
Health documents	3	2.6	.5	2.4	.8	2	-.420	.689	-.898	.594
Medicines	4	1.6	.5	3.3	1.1	3	3.032	.023	.146	2.095
Hygiene	6	2.3	1.1	4.0	.8	5	3.286	.017	.207	2.226
Medical waste	2	1.4	.5	1.4	.8	1	.000	1.000	-.741	.741
Work resources	3	.3	.5	2.0	1.2	2	4.076	.007	.388	2.644
Professional ID	2	.4	.8	1.4	.8	1	2.646	.038	.050	1.899
Other	5	.6	.5	3.0	2.0	4	3.232	.012	.194	2.198

Before the training, the only individual standard that all Quality Coordinators knew was Patient History (Health documents cluster). At the same time, none of the Quality Coordinators recognised the following 9 (of the 32) individual standards: the display of the name of the institution (Patient Information cluster), Complete anti-shock therapy with displayed instructions (Medicines), Clean bedsheets (Hygiene), Possession of necessary medical equipment and Functionality of the equipment (Work Resources), Infrastructure, Staff presence list, and Prohibition of advertising medicines and milk formulas in a healthcare organisation (Other). After the training, three standards were known by all Quality Coordinators: Display of organisational working hours (Patient information), Patient history (Health documents) and Availability of soaps (Hygiene), while there was no standard not known by at least three Quality Coordinators.

5.8. Focus group discussion with Quality Coordinators after the training

When discussing **motivation** to serve as Quality Coordinators, intrinsic and extrinsic motivations were noted. Some showed autonomy *"It was my own decision, and I am not even being paid that half of the coefficient"* (participant 2); others showed competence *"I saw the opportunity to improve quality in my organization"* (participant 3). Other participants revealed extrinsic motivation such as external rewards *"…It was a salary increase"* (participant 5) or ego-involvement *"I wanted to be successful in other people's eyes"* (participant 7) (116).

When asked about **on-the-job experiences**, respondents had a high assessment of their job performance. For example, six of seven say they perform their regular duties, although one objected to performing Quality Coordinator duties, not being interested in serving in this position anymore. On inspection reports, three read the report, and only one acted on published recommendations. Although motivated, performance does not keep up with motivation; there is a lack of congruence between perceived job performance and actual job performance. Further, results reveal that clinical audits, peer reviews, and managers' support positively affected job performance. Others who reported a lack of cooperation from their manager or other staff described their work as challenging: "*When Director does not respect us, nor does the staff, so nobody listens to us"* (participant 2). Working part-time as Quality Coordinator and with the remaining time in other capacities as health personnel are considered impediments to performing Quality Coordinator duties, *"I am in the middle of*

some quality related project, and I have to leave everything, even tell people to leave, because I have to get back to patients" (participant 4) (116).

Positive and negative factors influence **the quality of service in healthcare organisations.** Most of the participants appreciated the professional training provided by the Health Inspectorate, one stating, "*These meetings have sent a message back to the organisation that there is a need for cooperation....*"(participant 4). Support provided by international non-governmental organisations, usually through equipment and training, was also valued. Negative influences included the lack of resources, lack of managerial support, and insufficient on-job training. Lack of resources included outdated facilities, limited working spaces, and insufficient storage for mostly paper-based medical records: "*Our storage is full, documents are stacked in corridors, everybody can reach them, what kind of data privacy is there?*" (participant 6). Also noted were deficiencies in sanitary maintenance and lack of transportation, "*…there is a lack of vehicles, so as Quality Coordinator, I rarely visit other facilities under our authority, and I have a minimal idea what is going on in them...*" (participant 1). Respondents identify as quality problems the lack of medical equipment, lack of staff – especially nurses, and dysfunctional health information system, "*…It would be different if I could retrieve from the system how many antibiotics did a certain doctor prescribe, but I cannot, the system does not function*" (participant 5). Manager support was another factor, "*Director invites me to the managerial meeting, and says, 'Just tell me what you need!', then the others know that I got director's support, they listen, and things get better*" (participant 7). On the contrary, "*Our director is new, does not understand anything about quality, I tried, I saw no interest, and now things are idle*" (participant 1). Lastly, the lack of adequate on-job training for Quality Coordinators was a predominant comment as a motivator to support quality since the financial reward was not appreciated, "*As far as that half extra point in salary, it is meaningless*" (participant 2) (116).

Suggestions for quality improvement were related to Quality Coordinator job standards, the Health Inspectorate itself, and general healthcare categories. Those mentioning job standards believe that they should be selected by the Ministry of Health (MoH) and not the home organisation; that they should have a strong working relationship with the MoH, such as regular reporting and meetings, *"I do not even remember when we had a meeting with Quality Division in the MoH" (participant 3).* One reported a need for further quality-related training to build skills for their work. "*This training was enjoyable; it was so good to exchange experiences,*" mentioned participant 4. The other stated, "*It is so empowering to be*

capable of overtaking our role and responsibilities" (participant 7). Also, they felt that the job description should be updated so they could work only one shift instead of the current shift work. Quality Coordinators focusing on the Inspectorate believed in having more visits from Health Inspectorate, most of them stating that "…*their comments are always welcome*". Some believed that harsher measures by the Health Inspectorate are effective in quality improvement "*Health Inspectorate should use the stick!*" (participant 1). Finally, in general terms, decentralisation of municipal healthcare governance was not considered the best option, or as declared, "*There should be a direct link Ministry of Health – Municipal healthcare*" (participant 6) (116).

When asked to **evaluate this educational experience**, all participants shared positive thoughts about personal feelings, experience, development, and support: "*It is good that other people know that we have support from the Health Inspectorate*". However, one participant worried about financial reimbursement for the official travel "It would be nice to have covered expenses for travel.".

5.9. Final Inspections

After the training of the Health Inspectorate with the Quality Coordinators, final inspections were conducted. Overall, the percentage of fulfilment of BSHQ of the 14 selected MFMCs between 2016-2019 has shifted toward higher percentages (Table 25, Figure 26). In 2016, most of the MFMC (8 or 57.1%) were in the range of 81-90%, while in 2019, most of the MFMC (10 or 71.4%) were in the range of 91-100%.

Table 25. MFMC fulfilling BSHQ, 2016-2019

Fulfilment of BSHQ	2016 n	%	2018 n	%	2019 n	%
51-60 %	1	7.1	0	0.0	0	0.0
61-70 %	3	21.4	2	14.3	1	7.1
71-80 %	0	0.0	1	7.1	1	7.1
81-90 %	8	57.1	5	35.7	2	14.3
91-100 %	2	14.3	6	42.9	10	71.4
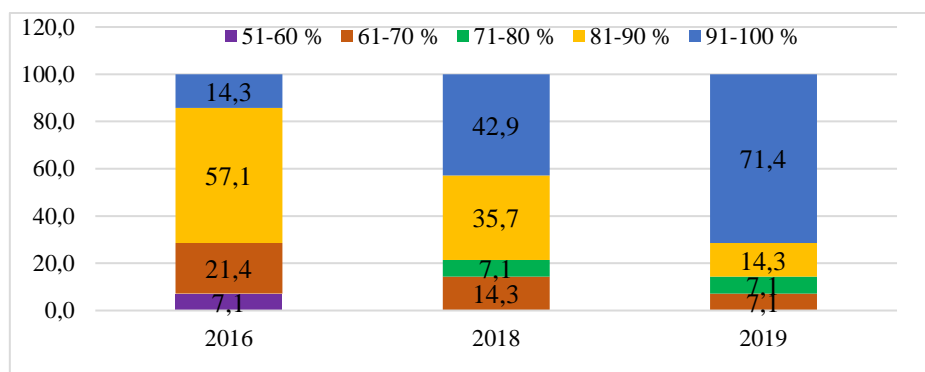
Figure 26. MFMC fulfilling BSHQ, 2016-2019 (%)

After final inspections, the average number of BSHQ that the MFMC were adhering to was 28.4 standards or 88.8% (SD=3.1), ranging from a minimum of 20 or 62.5% for MFMC Mamushë to a maximum of 31 or 96.9% for each MFMC Fushë Kosovë, Gjilan and Junik (Figure 27). This overall average value is higher than in 2018, when it was 26.9 or 84.2% (SD=3.1). The differences between the groups are statistically significant (two-tailed paired t-test, P-value=0.0076, 95% CI= -1.07 to 0.18).

The minimum percentage recorded during final inspections was the same for follow-up inspections (62.5% in 2019 and 2018, while 52.1% in 2016 – all three for MFMC Mamushë). However, the maximum percentage rose, after a slight decline in follow-up inspections, to its initial inspections value but for different MFMCs (96.9% for MFMC Prishtinë in 2016, 93.8% for MFMC Prizren and Fushë Kosovë in 2018, and 96.9% for MFMC Fushë Kosovë, Gjilan and Junik).

Figure 27. Fulfilment of BSHQ in final inspections, 2019 (%)

Over the years 2016-2019, as shown in Figure 28, 11 MFMC have improved their adherence to BSHQ in the final year compared to the initial year. Over the years, six MFMCs have continuously improved their adherence to the BSHQ - Fushë Kosovë, Gjilan, Junik, Mitrovicë, Obiliq and Shtime. The highest improvement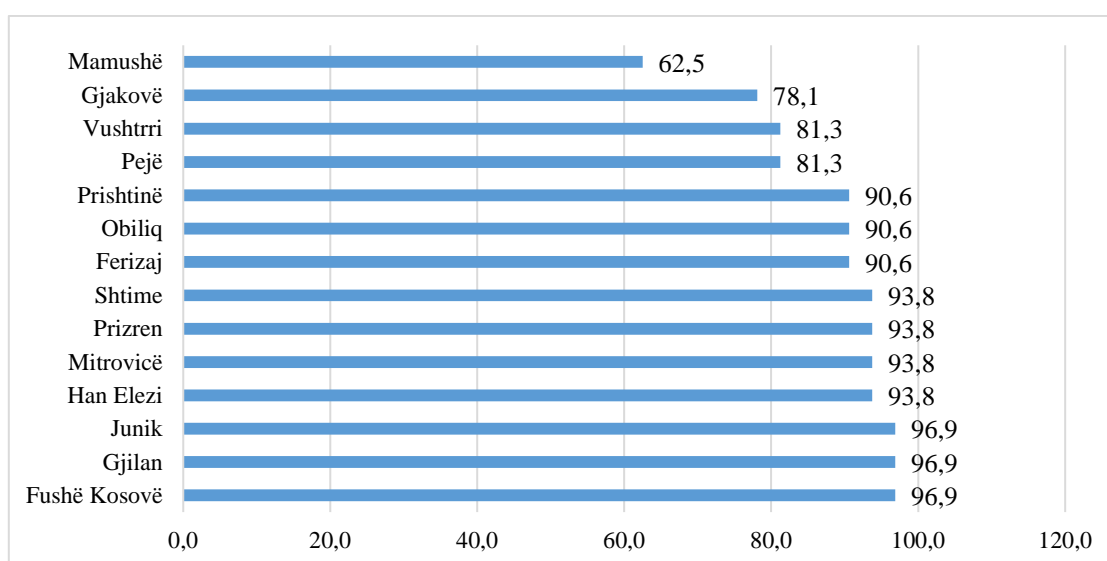, of 28.1%, was noted for both MFMC Obiliq (from 62.5% to 90.6%) and MFMC Junik (from 68.8% to 96.9%). Further, four MFMC improved in follow-up inspections compared to initial inspections but have stagnated in final inspections and remained at the same improved value – Ferizaj, Mamushë, Prizren and Vushtrri. Finally, four MFMC that have shown a decline in adherence to BSHQ between initial and follow-up inspections, in final inspections have shown variable behaviour – they maintained the same lower value (Prishtina), increased its value in comparison to follow-up inspection to a value lower than the initial inspection (Gjakovë, Pejë) or higher than the initial inspection (Han i Elezit).
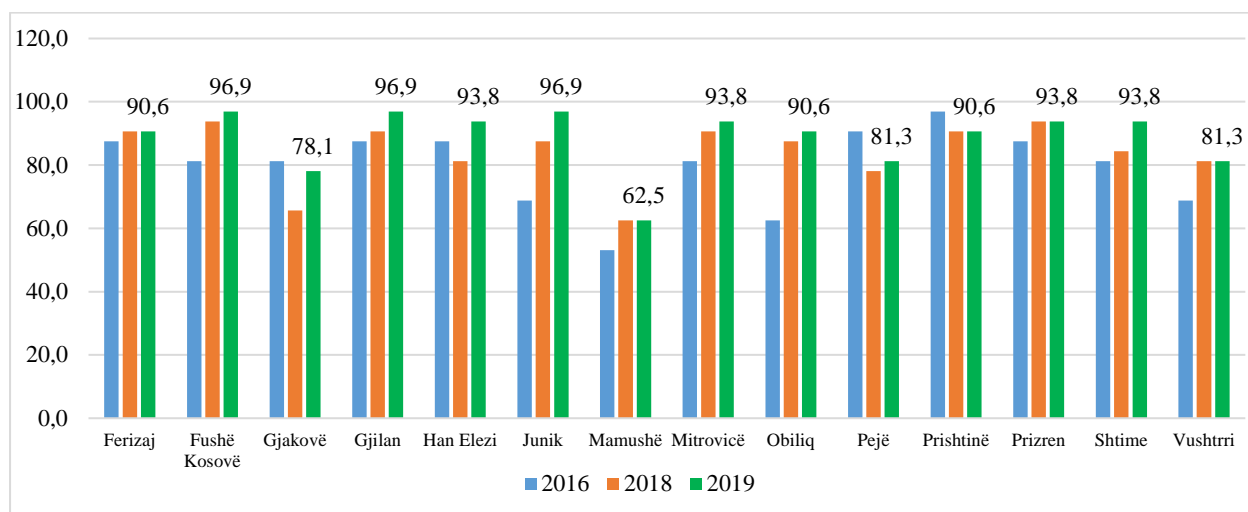
Figure 28. Comparison of the fulfilment of BSHQ 2016-2019, (%)

By clustered groups of quality standards, presented in Table 26, the groups that had the highest mean number of MFMC fulfilling that particular clustered group in 2019 were the Medical Waste (Mean=14.0, SD=0.0), while the lowest average was again found for the clustered groups of Hygiene (Mean=10.7, SD=2.7) and Work Resources (Mean=11.3, SD=4.6). The differences between the means of the eight independent standards groups are not statistically significant (F-Stat=0.994, P-value =0.4592).

Table 26. Fulfilment of clustered groups of BSHQ by 14 MFMC, 2019

Standard category	N	Mean	Std. Dev.	Std. Error
Patient information	7	13.0	0.8	0.3
Health documents	3	12.7	1.5	0.9
Medicines	4	12.8	1.9	0.9
Hygiene	6	10.7	2.7	1.1
Medical waste	2	14.0	0.0	0.0
Work resources	3	11.3	4.6	2.7
Professional ID	2	13.0	1.4	1.0
Other	5	13.0	1.7	0.8

As shown in Figure 29, over the years, six of the eight clustered groups of standards has shown continuous increased mean score (Patient Information, Health documents Medical Waste, Work resources, Professional identification and Other legal requirements); from them, the highest increase of the mean score was found for Health Documents, by 26.2% (or from 64.3% MFMC in 2016 to 90.5% of the MFMC in 2019). The remaining two clustered groups of standards that have shown a decline in their mean percentages during follow-up inspections have improved their percentages to a level lower than initial inspections (Hygiene, from 78.6% in 2016 to 76.2% in 2019) or a level higher than the initial inspections (Medicines, from 87.5 in 2016 to 91,1% in 2019).
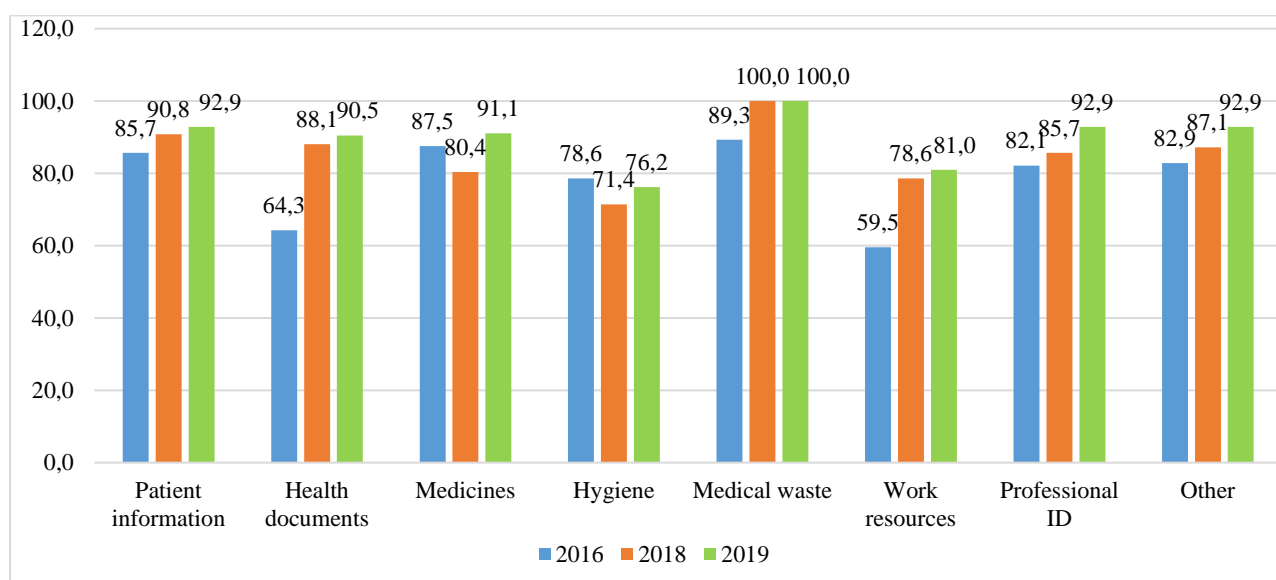
Figure 29. Comparison of the fulfilment of BSHQ by groups of standards, 2016-2019 (%)

Within the Patient Information group, the mean value for the Patient information standards cluster in the final inspections is 13.0, SD=0.8 (Table 26). The most fulfilled standard was To place the name of the organization, achieved by 14 MFMC, while the least achieved standard was Working hours are written and the Name of doctors in offices, for each 12 or 78.6% of the MFMC (Table 27). Over the years, five standards have displayed higher values than initial inspections - Name of institution, Working hours, Name of doctors in offices, Smoking prohibition sign and display of Telephone line for patient complaints. From them, the highest increase, of 28.6%, was noted for placing the Telephone line for patient complaints, from 71.4% to 100.0%. The standard of the List of services with prices has remained at the same level in all three measurements (92.9%) while one standard has suffered a decline by 7.1% - Name of service/office, from 100% to 92.9% (Figure 30).

Table 27. Fulfilment of Patient Information standards, 2019

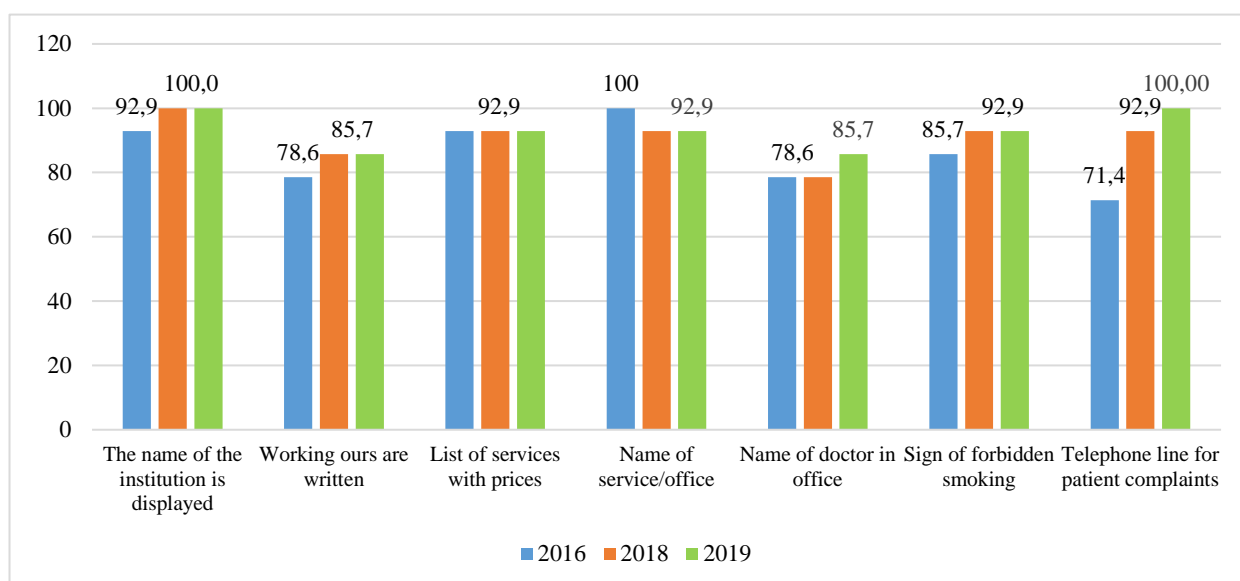| Patient Information	n	%
The name of the institution is displayed	14	100.0
Working hours are written	12	85.7
List of services with prices	13	92.9
Name of service/office	13	92.9
Name of doctor in office	12	85.7
Sign of forbidden smoking	13	92.9
Telephone line for patient complaints	14	100.0

Figure 30. Comparison of the fulfilment of the Patient Information standards, 2016-2019 (%)

The mean value for the Health documents cluster in the final inspection is 12.7, SD=1.5 (Table 26). The Patient history was the least fulfilled standard within the group, 11 MFMCs or 78.6% of them, while complete Unique Patient Documentation was found in all 14 inspected MFMCs (Table 28). Over the years, the values for all three standards increased; the highest, 42.9%, is for Unique Health documentation (from 57.1% to 100%) (Figure 31).

The mean value for the Medicines cluster in final inspections is 12.8, SD=1.9 (Table 26). Within the Medicines clustered group of standards, Anti-shock therapy and Instructions for its use were the standards fulfilled by all 14 MFMCs, while the Supply of medicines from the essential list was fulfilled in 10 MFMCs or 71.4% of them (Table 28). Over the years, two standards within this group have remained at the same maximal score, Anti-shock therapy and Instructions for its use. Expired medicines standards remained the same after follow-up inspections, presenting a decline of -7.1% from the initial inspection (from 100% in 2016 to 92.9% of the MFMC in 2018 and 2019). The standard of Supply of medicines from the essential list was mainly improved (28.6% in 2018 to 71.4% of the MFMC in 2019) (Figure 32).

Table 28. Fulfilment of Health documents and Medicines standards, 2019

Health documents	n	%
Patient registry	13	92.9
Unique health documentation	14	100.0
Patient history	11	78.6
Medicines	n	%
Supply from the essential list	10	71.4
Expiry date	13	92.9
Anti-shock therapy complete	14	100.0
Instructions for antishock therapy	14	100.0
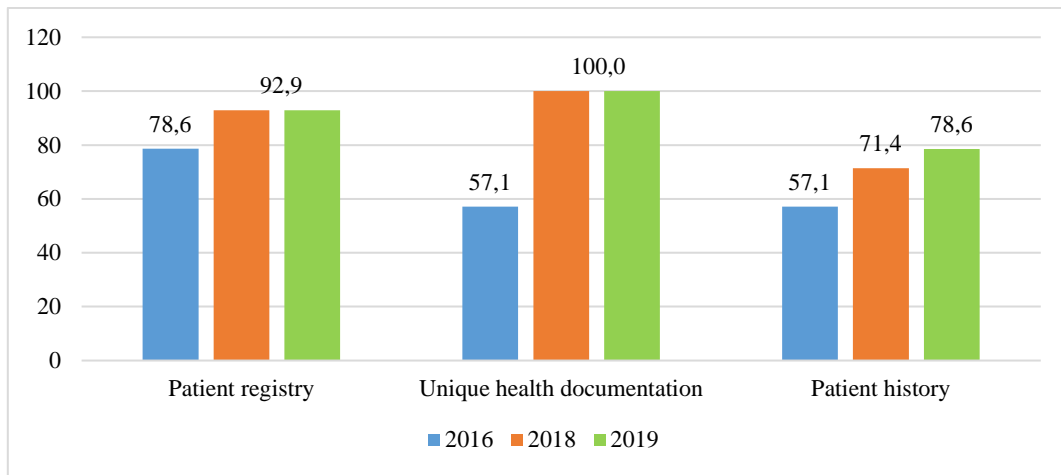
Figure 31. Comparison of the fulfilment of the Health documents standards, 2016-2019 (%)

Figure 32. Comparison of the fulfilment of the Medicines standards, 2016-2019 (%)

The mean value for the Hygiene cluster in final inspections is 10.7, SD=2.7 (Table 26). Within the Hygiene group of standards, the highest score was for the Overall hygiene of the institution, 14 MFMC or 100%, while the lowest score was for means To dry hands, only 6 MFMC or 42.9% (Table 29), both categories having higher values than in follow-up inspections. Compared to follow-up inspections, four standards have the same score, Soap availability, Running and warm water, functional Toilets and available/clean Bedsheets. The remaining two standards improved their score, the institution's overall hygiene (from 92.9% in 2018 to 100.0% in 2019) and materials to Dry hands (from 21.4% in 2018 to 42.9% in 2019). Over the years, all standards have increased their percentages, except for Soaps and Toilets (Figure 33).

Table 29. Fulfilment of Hygiene and Medical waste standards by 14 MFMC, 2019

Hygiene	n	%
Of the overall institution	14	100.0
Soaps in every sink	11	78.6
To dry hands	6	42.9
Water (warm)	11	78.6
The functional toilet is clean, all supplies	10	71.4
Clean bedsheets	12	85.7
Medical waste	n	%
Safety boxes	14	100.0
Disposal manner	14	100.0
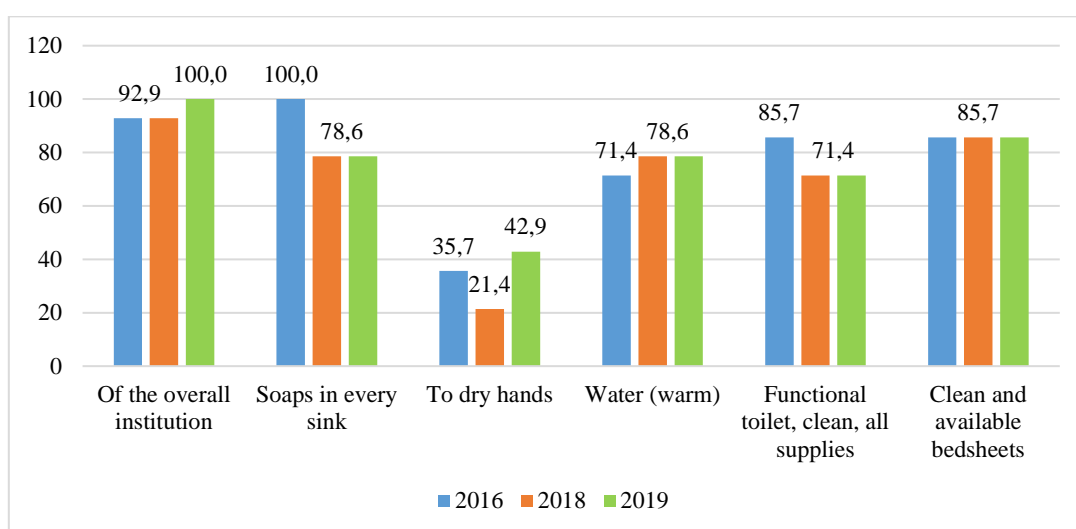
Figure 33. Comparison of the fulfilment of the Hygiene standards, 2016-2019 (%)

The mean value for the Medical waste cluster in final inspections is 14.0, SD=0.0 (Table 26). Within the Medical waste group of standards, both standards (Safety boxes and Regulated Disposal of waste) were found in all 14 MFMC or 100.0% of cases (Table 29). Compared to the follow-up inspections, both standards retained their score, which is an improvement from the initial inspections (Figure 34).
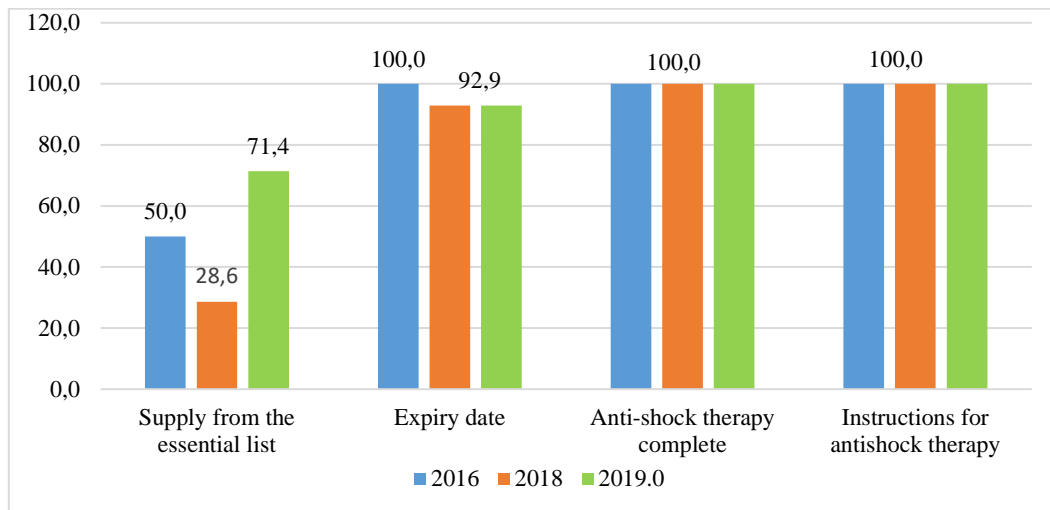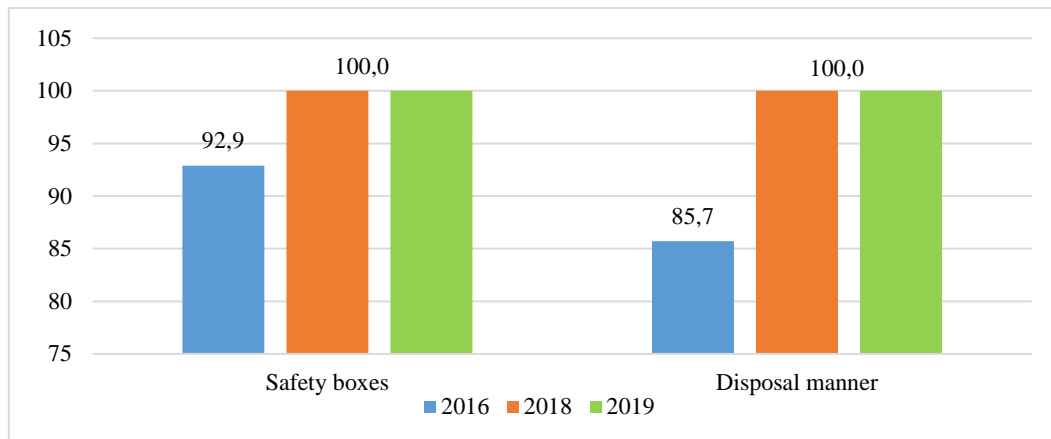
Figure 34. Comparison of the fulfilment of the Medical waste standards, 2016-2019 (%)

The mean value for the Work resources cluster in final inspections is 11.3, SD=4.3 (Table 26). Within the Work resources cluster, both the Necessary medical equipment and working Medical equipment were found in 14 MFMCs or 100.0% of cases. However, Sufficient staff was found only in 6 MFMCs or 42.9% of cases (Table 30). Compared to the follow-up inspections, the two standards have maintained the same percentage score, while Medical Equipment improved its percentage score from 92.9% to 100.0% of the MFMC. Compared to 2016, all three standards showed an improved percentage score (Figure 35).

The mean value for the Professional identification cluster in final inspections is 13.0, SD=1.4 (Table 26). Within the Professional identification group, proper wearing of uniform was found in 14 MFMC or 100.0% of cases, while Identity badges were found in 12 MFMC or 85.7% of cases (Table 30). Compared with follow-up inspections, the Uniform standard has maintained the same percentage value while the Identity Badges standard has improved from 71.4% to 85.7%. Both standards have shown improvement in comparison to 2016 (Figure 36).

Table 30. Fulfilment of Work resources and Professional identification standards, 2019

Work resources	n	%
Necessary medical equipment	14	100.0
Medical equipment working	14	100.0
Sufficient staff	6	42.9
Professional Identification	n	%
Uniform	14	100.0
Identity badges	12	85.7
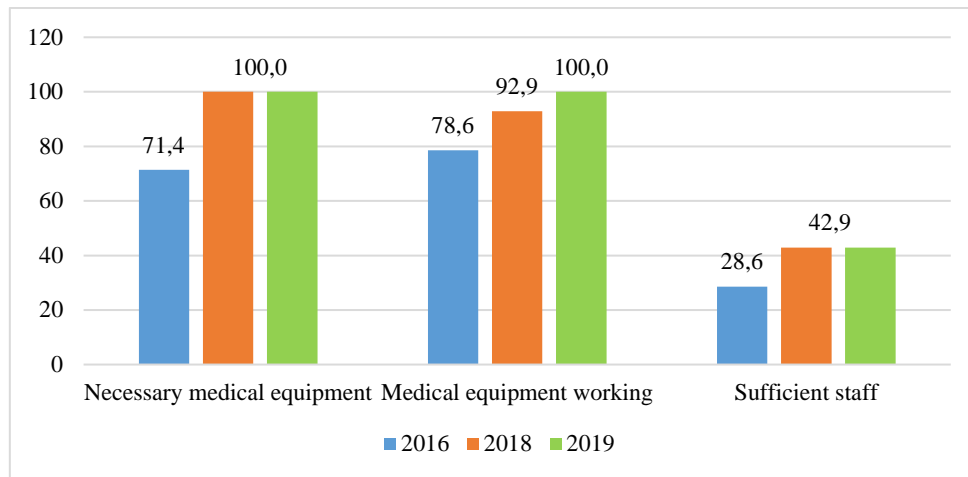
Figure 35. Comparison of the fulfilment of the Work resources standards, 2016-2019 (%)
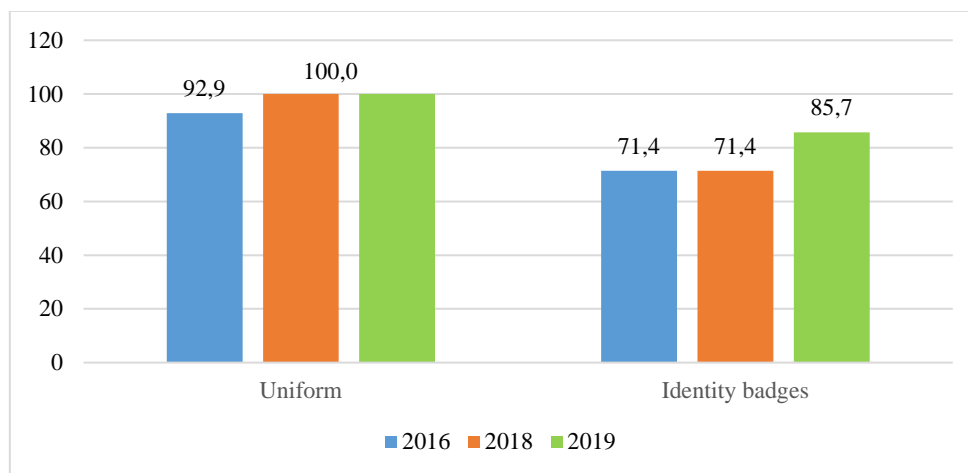
Figure 36. Comparison of the fulfilment of the Professional identification standards, 2016-2019 (%)

The mean value for the Other legal requirements cluster in final inspections is 13.0, SD=1.7 (Table 26). Within the Other legal requirements group, three standards were fulfilled in 14 MFMC or 100.0% of cases - No advertisement of milk formula and medicines, Attendance Sheet and the Overall infrastructure. Access for the disabled was still found the least, in 10 MFMCs or 71.4% of cases (Table 31). Compared to the follow-up inspections, all standards improved their scores, except for the Overall infrastructure and Ban on advertisement of milk formula and medicines – whose maximal scores were retained. Compared to 2016, all standards showed an improvement percentage except for the presence of staff in working places, which displayed erratic behaviour ending with a lower percentage than in the baseline year (Figure 37).

Table 31. Fulfilment of Other legal requirements standards, 2019

Other legal requirements	n	%
The overall infrastructure is good	14	100.0
Access for disabled - stairs, elevator, light	10	71.4
Staff in their working places	13	92.9
Attendance sheet	14	100
No advertisement for milk formula and medicines	14	100.0

Figure 37. Comparison of the fulfilment of the Other standards, 2016-2019 (%)

6.   DISCUSSION

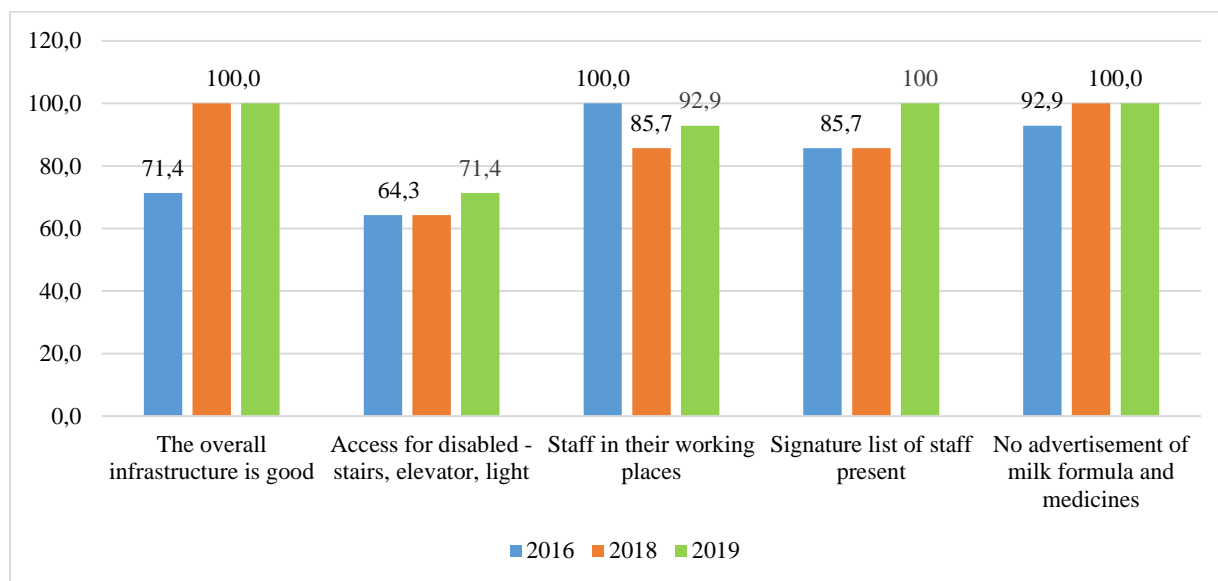The introduction presented the definitions of quality in healthcare, the Donabedian framework for assessing the quality of care, and five frameworks for external quality improvement. All the presented frameworks can complement each other as they assess different regulatory-related features and vary their approach in generalisation, specificity, and theoretical foundation. Therefore, we could combine these complementary frameworks to allow a broader assessment of factors and measures to facilitate successful regulation-based quality improvement. From all of the presented material, it is vital to notice that there is no common framework for regulation or regulatory role in quality improvement, which corresponds to the idea that regulatory structures and functions are tailored to the countries imposing them, but no particular model can fit all. Taking the liberty provided by this approach, the Taxonomy of quality-enhancing regulatory interventions model may help describe the quality-enhancing structure in the Republic of Kosova, which will answer the first research question of this study. The model was selected because a) it has been tested for different European healthcare regulatory systems in different countries; b) it helps define elements of the healthcare quality improvement structure in the country, their scope of responsibility and regulatory power; c) it enables analysis of possible interventions to strengthen regulation in healthcare; and e) it allows studying of the regulatory structure itself, as it excludes environmental factors which it does not affect. This study analyses the institutional and professional approach to regulatory interventions in Kosova. With this approach comes a re-conceptualization of the development of regulatory interventions in Kosova at the macro-level to guide future recommendations for strengthening it. Further, the Donabedian framework is employed to analyse adherence to structural standards at the micro-level using empirical, normative and structural indicators. This model will provide further insight into the number and types of structural indicators used to assess health care organisations' quality and improvement. Finally, the other frameworks explained in the chapter suggested that the regulator's output impact healthcare organizations (31); that responsive regulation means starting with the lightest reactive measure by the regulator, such as information and education (38); that concentrating on the management system promotes improving the gap between the regulation and outcome (46); and, that the regulatory visits over an extended period impact the continuous improvement of the level of attainment to the quality standards, despite the level decline in between the visits (44). Such a researcher's

approach allows the evaluation of healthcare organisations' capability to improve under the direction of the main regulatory body in Kosova. The study evaluated compliance with the BSHQ, the improved capacity, and the management system's role in quality improvement in the healthcare organization in Kosova.

6.1. Discussion on factors influencing the quality of the MFMC

If we look at the final results, each institution has greatly improved adherence to standards across MFMC over the years. Considering the varying conditions making comparisons of the MFMC is challenging; year by year growth in regulatory compliance and awareness is encouraging. Some of those conditions include vastly different numbers of patients served, facilities of varying size and age, external and internal institutional pressures for each MFMC, the institutional pressures internal to each MFMC, and general trends toward self-awareness for improvement (117).

One recent study outlines a similar array of contributory factors to the overall efforts to improve quality in the Iranian system, notable for its sizable public health sector. Mosadegrad (2014) notes the effect of proper planning, education and training, availability of resources, and effective management of those resources as critical factors exerting pressure on quality improvement (117). A vital component of a healthcare system is the experience of the patient and the aesthetic and physical aspects of the health facility delivering care (118). With ageing and understaffed institutional boundaries, it is harder for institutions to deliver adequate healthcare, making standard attainment difficult. It is also important to note that stakeholder expectations may affect healthcare outcomes if they are not met by a proper healthcare delivery system (118).

The largest MFMC has a 20 times greater population served than the smallest, at nearly 200,000 persons, meaning standards' enforcement and awareness of what is happening on the ground take on greater urgency with higher facility depreciation. Quality improvement for a facility serving 200,000 is more demanding than one serving 5,000. The demands of professional service make the role of Quality Coordinator quite challenging without institutional support and adequate monitoring for the job. Cycles of measurements must be taken to determine compliance; therefore, allowances must be made for the time needed and the general value placed on the role itself. The mere selection of metrics for quality improvement has its intricacies and variables, which must be managed successfully for the

institution to grow and continuously improve (119). Staffing adequacy, constantly an issue in a fluctuating job market, may profoundly impact institutional quality (120). Sometimes it takes a crisis in quality management to move funds and interest to the sites themselves.

External pressures, numerous to be listed herein, are led by the continuous political atmosphere of Kosovo, a country still lacking official UN recognition and EU status. Since these are municipal care facilities, there is a risk that each election will result in a party change which could destabilise the system as personnel rotate in and out. Since no national primary healthcare quality strategy exists, these municipal elections may spur a different direction for primary healthcare expenditures and initiatives. Khan (2018) notes the power of politics to interfere with quality management when he points out two critical influences as institutions attempt to reform. One relevant point in this study is the need for accurate and up-to-date patient data, particularly on health outcomes (121). It cannot be said that Kosovo has any centralized patient medical data, a notable area of growth for policymakers. Informed decision-making, including funding, is inhibited without such data points, which can be disaggregated to determine MFMC quality. The second is the failure to acknowledge that the "substantial political challenges noted in acting against low-quality health care providers are rarely acknowledged" (121). Further, political obstacles as external factors affecting quality management may take the unusual form. For example, Khan (2018) describes direct political threats made against those who suggested reforms (121); even America's vaunted Dr. Anthony Fauci and his immediate family have been subject to harassment and vilified for his recommendations involving low-quality providers (122). Another example is when Dutch Prime Minister Mark Rutte noted that his country found itself in a "diabolical dilemma," describing the ethical and political choices his cabinet faced in response to the Coronavirus pandemic that made health care policymakers targets for societal frustration (123).

Adding to the observations made about the importance of internal factors such as staff competence and training by Mosadegrag (2014), cross-national comparisons provide vivid examples of widespread variation in clinical practice in developing countries (124). Peabody directs our attention to one study in which researchers observing clinical practice observed that three out of four cases were "not adequately diagnosed, treated, or monitored and that inappropriate treatment with antibiotics, fluids, feeding, or oxygen occurred in 61% of cases." (125). An institution might note this statistic, remove barriers to training, and align staff to better clinical practices.

Surprisingly, institutional improvement is further confounded by the challenging notion that in looking at two sets of doctors, the top 5% of doctors from Macedonia, a neighbouring country to Kosovo, performed as well or better than the average Californian doctor on observed care delivery, making a case that adherence to best practices was not restricted to wealthier countries (126)

Internal and external forces impose intense pressures and render the simplest tasks considerably more difficult. Not to forget that in an immense sense, public healthcare is regionalized as one part of the country does not participate in centralized efforts based on ethnic and political differences. Even the most straightforward approaches to assessing and implementing health care quality management must consider highly detailed literature reviews which point out the "range of intersecting influences that often lead to departures from narrow notions of rational decision-making" (127). Williams (2018) notes the difficulty institutions have to reach "decisions of value," as they represent the most prominent possible commitments translating to "substantial and direct implications" for cost and delivery of quality care (127).

A further possible explanation for differences in adhering to quality standards can be explained by looking at two theoretical models that underscore the foundation of this study. Decoupling is a possible explanation for the lack of adherence to quality standards. As mentioned in the System-based regulation framework, three types of decoupling can occur: a) Goals-system decoupling, in which there is a gap between a quality standard and organizational management that does not believe in nor reinforce specific standards; b) System-practice decoupling, in which there is a gap between organizational management and daily practices in the organisation, such as employees who do not follow prescribed quality directives; and c) Practice-outcome decoupling, in which there is a gap between the daily practices in healthcare organisations and positive outcomes for patients or organisation, which in our case means that despite all concerned have done what was necessary, the actions did not result in the intended goals (46)

The Life Cycle Model is another conceptual regulatory framework created by Devkaran & Farrell (2014), which can help explain the variations in adherence to quality standards within the same institutions. As defined by the framework, there are four phases of the life cycle of quality in a healthcare organisation: a) initiation phase - a slight improvement of quality standards after acquaintance with the standards; b) pre-survey phase - a significant quality improvement reaching peak level due to increased efforts of the organisation for the

reason of the proximity of the regulatory visit; c) post-regulation slump phase - characterised with a drop in compliance level, and d) the stagnation phase - where compliance plateau is characterised by variability, but a total level of compliance to quality standards is significantly higher than before the first visit of the regulator (44,45).

Institutional quality improvement requires conditions whereby institutional needs can be measured and, if needed, addressed. Because staff form the points of engagement that precede sought-after institutional reform, their support is crucial. Staff may be more motivated to address concerns if the change they report as necessary is resolved or institutionally addressed (128). They might find more significant reinforcement in a responsive system and feel more valued in such a system, leading to more thorough reporting. The institution is strengthened if everybody is motivated at the Quality Coordinator and managerial levels. The study by Chmielewska (2020) reported that the highest effect on organizational performance was related to "quality and style of supervision," pointing to the intersection between human resources and employee motivation as the centrepiece of effective institutional responsiveness (128); thus, organizations need to pay close attention to management strategies that address different motivational factors (129).

The groups of quality standards themselves are good to explore for the implications for adherence or lack thereof. For example, the lack of medicines can be attributed to poor organisational planning or stock management but could also result from delayed central procurement procedures for which the organization cannot be held accountable. Furthermore, hygiene maintenance is sometimes outsourced, and companies are unfamiliar with specific hygiene needs in delivering healthcare. Alternately, if maintenance is internal, it still depends on funds, procurement, and running or hot water availability. Finally, Health documentation is still very much paper-based, and Health Information System in Kosova is fragmented and only partially functional. The implications involve proper medicine selection, awareness of procedures and diagnoses, and allocation of resources based on the data reported in the system. For example, when comparing the MFMC by morbidity, one MFMC has high numbers of tuberculosis, cancer, and infectious diseases compared to others (see chapter 5.1). One may think that something is very unusual going on in that municipality, or it could be that they are registering and reporting their cases in the health information system while the others are not.

6.2. Discussion about Quality Coordinators

It was vital to maintain confidentiality both in the interview process and to ensure that no respondent would be tied to the data report personally; because there is only one Quality Coordinator per MFMC, it could have been possible to trace the data to the individual. By randomising the assignment of letters to cases, confidentiality was maintained.

Principal findings suggest that after relatively brief training, Quality Coordinators' knowledge of BQSH increased by identifying standards they previously ignored. Intrinsic and extrinsic motivation were identified as factors contributing to the Quality Coordinators' experience. Clinical audits, collegial reviews, and managers' presence and support were reported as positive on-job factors. In contrast, a lack of cooperation by supervisors and staff, a lack of official authority to initiate measures, and part-time work shifts were considered negative on-job factors. Support by Health Inspectorate and international non-governmental organisations were considered to positively influence the quality of service in their organisations. Simultaneously, negative influences included lack of resources, managerial support, and insufficient on-job training. Suggestions to improve the system covered the Quality Coordinators role, the Health Inspectorate role, and healthcare broadly (116).

The research data revealed in the study show that the designed infrastructure of Quality Coordinators of one per MFMC, along with the practice of them working half time as a health professional and the other time as Quality Coordinator, has impeded commitment and continuity of quality-related activities. Further, inconsistency of training activities, not only of Quality Coordinators but managers and other personnel too, has contributed to difficulties in implementing quality standards in healthcare. Also, the role of supervision was pointed out more than once during the research, as the managers' understanding of the importance of quality has had a direct impact on the work and success of the Quality Coordinators. Evidently, the Quality Coordinator's job needs personnel diversity, more significant professional preparation, and monitoring. Like any organisation, positive feedback is crucial, and when gaps and needs for changes are pointed out, they must be addressed, or the system breaks down. Understaffing and poor facilities cannot be ignored when this Quality Coordinators evaluation is taken as a whole.

6.3.   Strength and limitations

This study provides a method for measuring the adherence to quality standards from which strategic planning and financial and resource allocations can be reviewed. The framework also provides a model from which other countries, especially developing ones, may apply as quality improvement is continuously on the agenda of healthcare leaders (117). The study was done to emphasize generalizability; the same method may be used but not necessarily the same standards because they are country-specific. Also, this study provides practical tools to monitor, assess, and improve healthcare quality standards continuously. Institutional staff were willing to work harder with greater reinforcement, which is an observation any organization would want to know. Further, the study represents a novel exploration into the inner workings of Quality Coordinators. The family medicine concept applied in the public primary healthcare system aims to cover 80% of health condition treatments (130) therefore, a clear picture of Quality Coordinators' skills and needs is vital for quality improvement efforts. In addition, this research examines the perspective of significant organisational actors in maintaining quality healthcare. Being an under-researched and underserviced population, Quality Coordinators work amidst ageing facilities, limited resources, and uneven support. Furthermore, the study illustrates obstacles in assessing and implementing BQSH. It was revealed that Quality Coordinators benefited from greater comprehension of expected professional standards, which may be achieved through specific training aligned to the standards that regulate primary healthcare. Finally, this study provides decision makers with a vital new data set to inform policy decisions. With limited quantitative or qualitative data on the role of Quality Coordinator in Kosovo, this novel research becomes even more significant as there are no other comparable studies to serve as a baseline, to the author's knowledge (116).

Regarding limitations, the study did not account for size differences among MFMC, which were sometimes vast. In addition, while replicability of the study concerning MFMC is desirable within the country, it is not feasible for other countries as they may require different standards or external monitoring mechanisms. Further, due to practical issues, there was a change in the Health Inspector conducting evaluations of the MFMC, which may have caused different evaluation thresholds, and could have impacted the results. A possible limitation also involves the potential of the Hawthorne Effect (131) during the discussion with the Quality Coordinators. However, the presence of the Health Inspectors would tend to diffuse

such a researcher effect. Finally, although only a small number of Quality Coordinators were asked for data, these represent the entire universe of those working in the positions that qualify for the study, making the study robust despite the relatively small number of cases involved (116).

6.4.   Implications for research and practice

The healthcare system blends the institution, resources, and patient needs in a real-time environment. Areas, where healthcare quality may be improved are: "…supportive visionary leadership, proper planning, education and training, availability of resources, effective management of resources, employees, and processes, and collaboration and cooperation among providers." (117). All of these areas are an excellent foundation for further research into factors that affect the adherence to quality standards, affect quality improvement, and possibly explain the differences between MFMC in quality performance.

Perhaps one of the most important results to emerge from this study, which may have implications worthy of further research, is why only 57% of Quality Coordinators read the inspection report that forms the basis of their responsibilities. Such a number reveals a significant gap between regulatory needs and outcomes. That only half of that subgroup undertook to enact intervention based on the report speaks to another potential step to reconcile this gap (116).

Training is a very efficient organizational strategy when it can be shown to be effective in achieving quality improvement. The research illustrates the importance of aligned training in increasing Quality Coordinator absorption of previously ignored healthcare standards. After a brief training by the Health Inspectorate, Quality Coordinators reported far greater knowledge than in a pre-test measure. The implications are that modest training, if aligned, produces educationally significant effects. Alignment is vitally important because trained staff are instrumental to quality improvement in a primary healthcare organisation; their training should be tailored to organisational and professional needs (132). Therefore, regular and relevant training should be provided for Quality Coordinators, especially during staff rotations (116).

It is interesting to notice that while Quality Coordinators failed to recognise primarily structural standards used by the Health Inspectorate in evaluating the quality of their institutions, they considered important quality issues falling under process standards, such as

antibiotic prescription, patient privacy, and data archiving. This disparity raises a question of possible decoupling between what is relevant for quality assurers, who aim to standardise healthcare through planning, setting and communicating quality standards and monitoring their compliance (133) and what is relevant for Quality Coordinators - frontline healthcare workers. There is a need for reopening discussions and education about healthcare quality standards. The experiences expressed by Quality Coordinators in this research could be beneficial in tailoring the process to what is relevant for health personnel (116,134).

More insight is needed to link the increased Quality Coordinators' knowledge and healthcare quality. Quality Coordinators could play an essential role in communicating their knowledge to other professionals within the organisation, acting as practice facilitators or like coaches for quality improvement (135). Improved communication has been shown to improve the implementation of clinical guidelines (136,137), prevention in primary care (138,139), staff involvement in quality improvement activities, and acceptance of the change (140,141).

The role of supervision came across several times in the research, as Quality Coordinators that enjoyed this support reported higher satisfaction with their job and quality improvement measures. In the face of inevitable staffing changes, congruence within governance must include equipping primary healthcare managers with mandatory on-the-job training about quality requirements in primary healthcare (142,143). Such training would help the managers support Quality Coordinators and the rest of the personnel to continuously undertake quality improvement initiatives by ensuring the required tools and available resources while requesting accountability and evidence-based results (116).

Once the Quality Coordinators are listened to, and suggestions culled, a mechanism is necessary to take these comments and review them for possible implementation, ensuring a continuous feedback loop between expectations and performance. Conveniently, the Division of Quality in the Ministry of Health provides a natural repository for the conversations produced by such inquiries (116).

Future studies may wish to explore gender, age, and role redefinition as variables to determine whether differential behavioural effects may be observed. Because there are more females in primary healthcare (144) more female Quality Coordinators may be necessary to serve their peers. Female professionals have a more person-centred, counselling and compassionate communication style (145) active participation and joint decision making (146) possibly improving staff commitment to quality improvement actions. With the average

age of doctors approaching 57 years (147), a new generation of younger Quality Coordinators is needed to supplement these veterans, who may be in a position to teach younger candidates the intricacies and institutional histories vital for organizational success. Roles may need redefinition in a reformed system. More nurses may be tapped to perform Quality Coordinators duties, beginning with drafting and implementing policies to modify the structure of healthcare professional roles and relationships, shifting from instructional doctor-nurse relationships to complementary and supportive relationships, empowering nurses to perform higher-level duties, and improving professional collaboration with doctors (134,148).

7.   CONCLUSIONS

- The research hypothesis is confirmed, meaning that Health Inspections are an effective tool to monitor basic quality standards of healthcare. However, the final role of the Health Inspectorate is not quality control but fostering improvement. Health Inspectorate can use its formal power to ensure and enhance the culture of healthcare quality in everyday practices and request personnel and resources to be provided by the Ministry of Health and municipalities, as a prerequisite of the foundation of quality enhancement.

- Compliance of the primary healthcare institutions with basic standards of quality of healthcare at initial inspections was low: 79.7% (SD=12.1), ranging from 53.1% to 96.9%, and no statistically significant difference between the clustered group of standards (F-Stat=1.14, P-value =0.37). While statistically, the numbers look decent, these basic standards for healthcare quality should be (almost) ultimately met.

- Final inspections revealed that compliance of the primary healthcare institutions with basic standards of healthcare quality increased over time, and in 2019 the average number of BSHQ that the MFMC were adhering to was 28.4 standards or 88.8% (SD=3.1), ranging from 62.5% to 96.9%, with statistically significant differences between the group of standards (two-tailed paired t-test, P-value=0.0076, 95% CI= -1.07 to 0.18).

- Quality Coordinators' knowledge of the 32 basic standards of healthcare quality was low, with a mean of 12.7, SD=3.4 or 39.7%, and ranging from 8 to18 standards (or 25% to 56.3%); with statistically significant differences in means between the clustered groups of standards (p=0.0342 and F=2.668).

- The training was a successful mean of increasing the knowledge of seven Quality Coordinators of the basic standards of healthcare quality, with statistically significant differences in mean values of the standards knowledge before *($\bar{x}$=11.4, SD=2.9)* and post-training *($\bar{x}$=23.4, SD=8.3)*, *[t(6)=3.658, p=0.011]*, *95% CI[0.293, 2.421]*.

- Qualitative data showed that training motivated and empowered Quality Coordinators to take a proactive approach toward quality improvement, the difficulties they face in their work path, and horizontal communication.

- There is a need for investing and expanding the Quality Coordinators workforce; providing continuous relevant training for Quality Coordinators, managers, and other

staff; ensuring the availability of appropriate tools and resources to assess, improve and maintain quality; providing management support and promoting horizontal communication with other Quality Coordinators, along with the review and update of quality standards and other relevant policies, to ease and encourage Quality Coordinators functioning.

- Further research is needed into factors that affect the adherence to quality standards and factors that affect quality improvement within a healthcare organization, which could also explain the differences between healthcare organizations in quality performance. The possible factors of interest for further research include and are not limited to municipal health indicators, financial means, management, health professionals, services, and patients.

- Further research is needed to evaluate the impact of gender and age on the role and performance of the Quality Coordinators, as well as the possibility of their role redefinition and consequent modification of relevant policies.

8. ABSTRACT IN ENGLISH

Health inspectorate as a tool for quality improvement in public health institutions of primary health care in Kosovo

Ardita Baraku   Zagreb, 2025

Kosovo applies a healthcare organization quality model based on an internal mechanism - Quality Coordinators (QC), and the external mechanism - Health Inspectorate of the Ministry of Health. The hypothesis of this research was that the Health Inspectorate is an efficient regulatory tool for quality improvement in public institutions of primary healthcare (PHC) in Kosovo.

Purposefully selected 14 PHC organisations were subjected to initial, follow-up, and final inspections to monitor adherence to 32 basic standards of healthcare quality (BSHQ). QC from the same institutions were tested for healthcare quality knowledge. The lowest scores of both provided selection for seven QC who were subjected to training, and focus group discussion on motivation to serve, experiences, factors that impact quality and suggestions for improvement.

Results showed that over the years, adherence to 32 BSHQ and QC knowledge improved. QC believed that the Health Inspectorate positively influences healthcare quality. Suggestions for improvement included QC role, Health Inspectorate and healthcare in general.

In conclusion, the research hypothesis was confirmed. The Health Inspectorate can use its formal power to foster a culture of healthcare quality in everyday practices by requesting authorities to provide resources as a prerequisite for quality enhancement.

Keywords: Kosovo, developing country, quality of health care, primary healthcare, health inspectorate

9. ABSTRACT IN CROATIAN

Zdravstveni inspektorat kao alat za poboljšanje kvalitete zdravstvene zaštite u javnim ustanovama primarne zdravstvene zaštite na Kosovu

Ardita Baraku   Zagreb, 2025

Kosovo primjenjuje model kvalitete zdravstvene organizacije koji se temelji na internom mehanizmu - Koordinatorima kvalitete (QC) i vanjskom mehanizmu - Zdravstvenoj inspekciji Ministarstva zdravlja. Hipoteza ovog istraživanja bila je da je zdravstvena inspekcija učinkovit regulatorni alat za poboljšanje kvalitete javnih ustanova primarne zdravstvene zaštite (PZZ) na Kosovu.

Svrhovito odabranih 14 organizacija PZZ-a podvrgnuto je početnim, naknadnim i završnim inspekcijama kako bi se pratilo pridržavanje 32 temeljna standarda zdravstvene kvalitete (BSHQ). QC iz istih ustanova testirani su na poznavanju kvalitete zdravstvene zaštite. Najniže ocjene obje dale su odabir za sedam QC-a koji su bili podvrgnuti obuci i diskusiji u fokusnoj grupi o motivaciji za služenje, iskustvima, čimbenicima koji utječu na kvalitetu i prijedlozima za poboljšanje.

Rezultati su pokazali da se tijekom godina poštivanje 32 BSHQ i QC znanja poboljšalo. QC smatra da zdravstvena inspekcija pozitivno utječe na kvalitetu zdravstvene zaštite. Prijedlozi za poboljšanje uključivali su ulogu QC-a, zdravstvene inspekcije i zdravstva općenito.

Zaključno, hipoteza istraživanja je potvrđena. Zdravstvena inspekcija može koristiti svoje formalne ovlasti za njegovanje kulture kvalitete zdravstvene skrbi u svakodnevnoj praksi tražeći od vlasti da osiguraju resurse kao preduvjet za poboljšanje kvalitete.

Ključne riječi: Kosovo, zemlja u razvoju, kvaliteta zdravstvene zaštite, primarna zdravstvena zaštita, zdravstveni inspektorat

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11. CURRICULUM VITAE

Dr. Ardita Baraku, born in 1975, graduated from the University of Prishtina, Kosova as a Medical Doctor in 2004; completed Master studies in Health Policy, Management and Financing at the University of Maastricht, the Netherlands, in 2008; became a Specialist in Public Health in 2015; and completed Master's in Healthcare Management from Erasmus University Rotterdam, the Netherlands in 2021.

Dr. Baraku has extensive management experience in healthcare, serving in various roles including Director of Health Services for the Kosova Police, Senior Community Officer for Mercy Corps, Chief Executive of the Health Inspectorate of Kosova, and currently Executive Director of the National Institute of Public Health of Kosova. Parallelly, she has developed an academic career by lecturing on public health-related subjects at local and international universities, publishing scientific articles, participating in international conferences, and collaborating on international public health projects.

Dr. Baraku is appreciated for her work by Police Commissioner Curtis in 2007, KPS Colonel Guda in 2006, National Centre of Blood Transfusion in 2006, Lt. Colonel Atifete Jahjaga in 2004 and Deputy Police Commissioner, UNMIK Civilian Police in 2002. Dr. Baraku is a beneficiary of the MATRA Scholarship 2017 and ISQua Fellowship Award 2021.

Dr. Baraku lives in Prishtina, Kosova.

APPENDICES

Appendix: Health Inspectorate's Checklist

1. Patient information – signage   Circle one
    1. Name of institution   Yes   No
    2. Working hours   Yes   No
    3. List of services with price list   Yes   No
    4. Name of office/service   Yes   No
    5. Name of doctor on the door   Yes   No
    6. New smoking prohibition sign   Yes   No
    7. Sign for a telephone line for complaints   Yes   No

2. Health Documentation
    8. Possess and appropriately fill patient registry   Yes   No
    9. Possess and use new health forms   Yes   No
    10. Patient history is kept and appropriately filled   Yes   No

3. Medicines
    11. They have medicines from the essential list   Yes   No
    12. Medicines are within the expiry date   Yes   No
    13. Complete anti-shock therapy   Yes   No
    14. Written instructions for anti-shop therapy   Yes   No

4. Hygiene
    15. The overall hygiene of the institution is good   Yes   No
    16. Soaps   Yes   No
    17. Means to dry hands   Yes   No
    18. Water (warm)   Yes   No
    19. Functional toilet   Yes   No
    20. Clean bed sheets   Yes   No

5. Medical waste management
    21. Safety boxes   Yes   No
    22. Controlled removal of medical waste   Yes   No

6. Work resources
    23. Necessary equipment available   Yes   No
    24. Necessary equipment working   Yes   No
    25. Necessary staff working   Yes   No

7. Identification of health professionals
    26. Uniform, well-kept   Yes   No
    27. ID cards   Yes   No

8. Other legal requirements
    28. Overall condition is good   Yes   No
    29. Access for disabled (stairs, elevator, light)   Yes   No
    30. Staff at work   Yes   No
    31. Signature list, existing and in use   Yes   No
    32. Prohibition of advertisements of milk formula or medicines is respected   Yes   No

1. MFMC _____
2. Gender   M   F
3. Year of Birth _____
4. Education (circle)   Primary school
                          Secondary school
                          University graduate
                          Postgraduate studies
5. Work experience in MFMC _____ years
6. Work experience as QC   _____ years
7. A high-quality health system (based on IOM, 2001) is characterised with (circle as much as you think is necessary)
   a. Safety
   b. Effectiveness
   c. Patient orientation
   d. Timely services
   e. Efficiency
   f. Equity
8. Do you know the official job description of the QC?   Yes   No
9. Do you regularly perform your duties as the QC?   Yes   No
10. Do you regularly report to the MFMC Director on your activities as QC? Yes   No
11. Does the Director of MFMC consult you on quality issues?   Yes   No
12. Have you participated in the meeting organised by the Health Inspectorate on basic standards of healthcare quality in the year 2012?   Yes   No
13. Would you like to participate in a training organised by the Health Inspectorate on basic standards of healthcare quality?   Yes   No
14. Have you had in the past any training related to the duties of the QC?   Yes   No
    If Yes, please write what and when?

    _____
    _____
    _____

Introduction of the researcher
Background and objectives of the research
Information about the interview (structure, informed consent)
Participant information: institution and working experience at the current position.

Discussion:

Theme: Quality Coordinator job satisfaction
      1. What was your motivation to serve as Quality Coordinator?
            Is there any particular quality issue you were passionate about?
      2. What is your previous experience in this job?
            Please explain?

Theme: Factors influencing adherence to quality standards
      3. Which factors have had a positive influence on adherence to quality standards?
           Can you give examples?
           How do you feel about that?
      4. Which factors have had a negative influence on adherence to quality standards?
           Can you give examples?
           How do you handle that currently?
      5. What are your suggestions to improve the current system for better adherence to quality standards?
           Can you give examples?

Theme: Experience with the Health Inspectorate training
      7. What was your experience during this training?
           What did you like?
           What would you do differently?
           Can you give examples?
      8. was the training useful?
           Can you give examples?
           How do you handle that currently?
      9. What do you think should be improved?
           Why?
           How?
           Who could do it?
           When?

Final remarks by the participant, if any
Thank the participants
Closure words
End of interview