Eiropas Savienības fondu darbības programmas „Izaugsme un nodarbinātība” 9.2.3.specifiskā atbalsta mērķa „Atbalstīt prioritāro (sirds un asinsvadu, onkoloģijas, perinatālā un neonatālā perioda un garīgās veselības) veselības jomu veselības tīklu attīstības vadlīniju un kvalitātes nodrošināšanas sistēmas izstrādi un ieviešanu, jo īpaši sociālās atstumtības un nabadzības riskam pakļauto iedzīvotāju veselības uzlabošanai” ietvaros īstenotā projekta Nr.9.2.3.0/15/I/001 „Veselības tīklu attīstības vadlīniju un kvalitātes nodrošināšanas sistēmas izstrāde un ieviešana prioritāro jomu ietvaros” 14.nodevums – Quality Assurance Review.

Quality Assurance Review[1]

[1] Author: Elyssa Finkel (efinkel1@worldbank.org)

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1. Introduction

1. The following review provides an assessment of the policies and mechanisms currently in place in Latvia to assure and improve the quality of health care. Specifically, the analysis seeks to (i) provide an overview of current quality assurance policies and mechanisms available in Latvia; (ii) identify the Latvian system's strengths and potential areas for improvement based on the policies and mechanisms available in other European countries[2]; and (iii) based on the latter, present a range of policy options that could be pursued. While the review aims to summarize potential areas for improvement to help inform future discussions on how to strengthen the Latvian quality assurance system, it is beyond the scope of the review to conduct a comprehensive assessment of the viability and specific implementation requirements of any particular policy intervention within the Latvian health sector context.

2. This analysis was conducted as part of a World Bank Group (WBG) reimbursable advisory services agreement with the Latvian National Health Service (NHS), which aims to provide "Support to Develop a Health System Strategy for Priority Disease Areas in Latvia." The analysis draws on: a) document reviews (for example, legislation, previous quality of care reviews and studies, guidelines, and handbooks) and b) interviews conducted by the WBG in September 2015 with various Latvian health sector stakeholders. The stakeholders interviewed include: the Latvian National Health Service (NHS), Health Inspectorate, Center for Disease Prevention and Control (CDPC), Latvian Medical Association and Nurses' Association, Hospital Managers, and Patient Rights Groups (Cancer, Cardiovascular Disease and Mental Health).

3. The review is organized as follows. Section2 provides a brief summary of how to define quality assurance and quality of care. Section 3 provides an overview of the context for quality assurance in Latvia based on its performance on several OECD Health Care Quality Indicators. Section 4 describes the analytical framework that will be used to assess the quality assurance system in Latvia. Section 5 summarizes the key features of the Latvian quality assurance system. Section 6 provides an assessment of the Latvian quality assurance system's strengths and potential areas for improvement based on experiences in other European countries. Section 7 concludes with promising policy solutions to pursue.

2. Defining quality assurance and quality of care

4. Before describing the quality assurance policies and mechanisms available in Latvia, it is necessary to first define what is meant by "quality assurance" as well as "quality of care" in this context. Quality assurance has been defined by Avedis Donabedian (widely recognized as the father of quality assurance) as "all actions taken to establish, protect, promote and improve the quality of health care" (Donabedian 2003). While acknowledging that terms such as *quality improvement*, *continuous quality improvement* or *quality management* may be more apt since one cannot, strictly speaking, assure or guarantee quality, he nevertheless maintained the term quality assurance as it is more firmly established and widely used in the health care field.

5. Quality of care is a complex concept that has been extensively explored in the literature. A number of definitions of quality of care have been developed over the past several decades, reflecting

[2] The countries that will be used as comparators in this analysis include Sweden, Denmark, Norway, the UK and Estonia.

the lack of consensus on the topic and common conceptual framework to assess it. One of the more influential definitions, put forth by the Institute of Medicine (IOM) in the United States, 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" (IOM 1990). By including both patients and populations, this definition encompasses the full cycle of health care from prevention and promotion to curative, rehabilitative and palliative care. It focuses on "desired" health outcomes which reflects the importance of prioritizing patient's views and satisfaction. At the same time, it emphasizes that high quality care is in line with "current professional knowledge" reflecting the need for developing updated standards that are in line with evidence-based medicine (Legido-Quigley et al. 2008).

6. Many authors, including Donabedian, as well as organizations have described quality of care through a set of dimensions (Legido-Quigley et al. 2008; Donabedian 2003; Kelley and Hurst 2006). A number of OECD countries have adapted these dimensions to help formulate their health system performance assessment and quality indicator monitoring systems. The OECD recently conducted a review of these performance assessment and monitoring systems to help develop the conceptual framework for its Health Care Quality Indicators Project (Kelley and Hurst 2008). Though the number of these dimensions and their definitions have varied across countries, the most common dimensions include effectiveness, safety, responsiveness or patient-centeredness, accessibility, equity, and efficiency.

Box 1: Definitions of the dimensions of quality of care

Effectiveness: "The degree of achieving desirable health outcomes, given the correct provision of evidence-based healthcare services to all who could benefit, but not to those who would not benefit."

Safety: "The degree to which health care processes avoid, prevent and ameliorate adverse outcomes or injuries that stem from the processes of health care itself."

Responsiveness or Patient-Centeredness: "The degree to which a system actually functions by placing the patient/user at the center of its delivery of healthcare … is often assessed in terms of patient's experience of their health care. The experience of care refers to the caring communication and understanding that should characterize the clinician-patient relationship"

Accessibility: "The ease with which health services are reached. Access can be physical, financial, or psychological, and requires that the health services are *a priori* available."

Equity: "The extent to which a system deals fairly with all concerned. In this context, equity refers to the distribution of health care and its benefits among a people."

Efficiency: "The system's optimal use of available resources to yield maximum benefits or results."

Source: OECD Health Care Quality Indicators Project, Conceptual Framework Paper (Kelley and Hurst 2006)

7. In terms of assessing quality of care, Donabedian's "structure-process-outcome" framework developed in the 1980s has received widespread acceptance. This triad represents the types of information that can be obtained to assess quality in clinical care (Donabedian 2003). "Structure" represents the conditions under which care is provided and includes aspects such as facilities and equipment, human resources, and organizational characteristics. "Process" includes the actual clinical procedures and activities conducted by medical personnel as part of prevention, diagnosis, treatment or

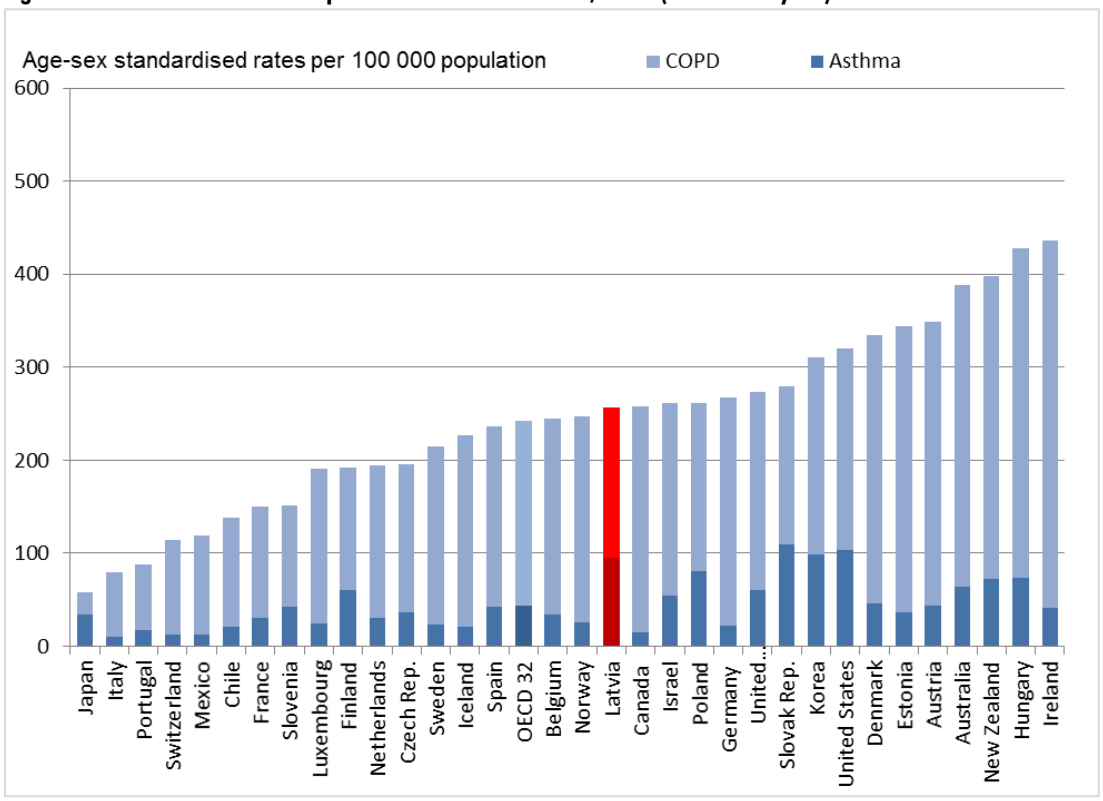
rehabilitation care. Finally, “Outcome” represents the changes in patient or population health status, knowledge, behavior or satisfaction as a result of this care. A limitation of this model is that it is primarily meant to be used to assess the quality of clinical practice, where there is a pre-determined relationship between the different elements under structure, process and outcome. While it is generally applicable in this context, it may not be suited to the assessment of other activities that may have an impact on quality of care.

3. Context

8. As Latvia has yet to join the OECD, currently slated for 2016, it has begun calculating and reporting on a few of the OECD Health Care Quality Indicators. Relative to other OECD countries Latvia health care system performs at an average rate for some of these indicators (for example, hospital admissions), whereas it its clearly at the lower end of the spectrum for others (for example, 30-day mortality following a hospital admission for an AMI).

9. Hospital admissions for particular conditions, including (among others) asthma, COPD, diabetes, and congestive heart failure, can be used as measures for quality in primary care. Much of the care to manage and prevent complications from these conditions can be delivered at the primary care level. Thus, high-quality primary care should be able to prevent hospital admissions for these conditions. Latvia’s combined age-sex standardized rate of asthma and COPD admissions are close to the OECD average (Figure 1). Similarly, Latvia has an average rate of diabetes admissions (Figure 2). Comparisons among OECD countries, however, must be taken with caution since a variety of factors including disease prevalence, differences in coding practices, access to hospital care, and levels of health spending may explain some of the differences in observed admission rates.

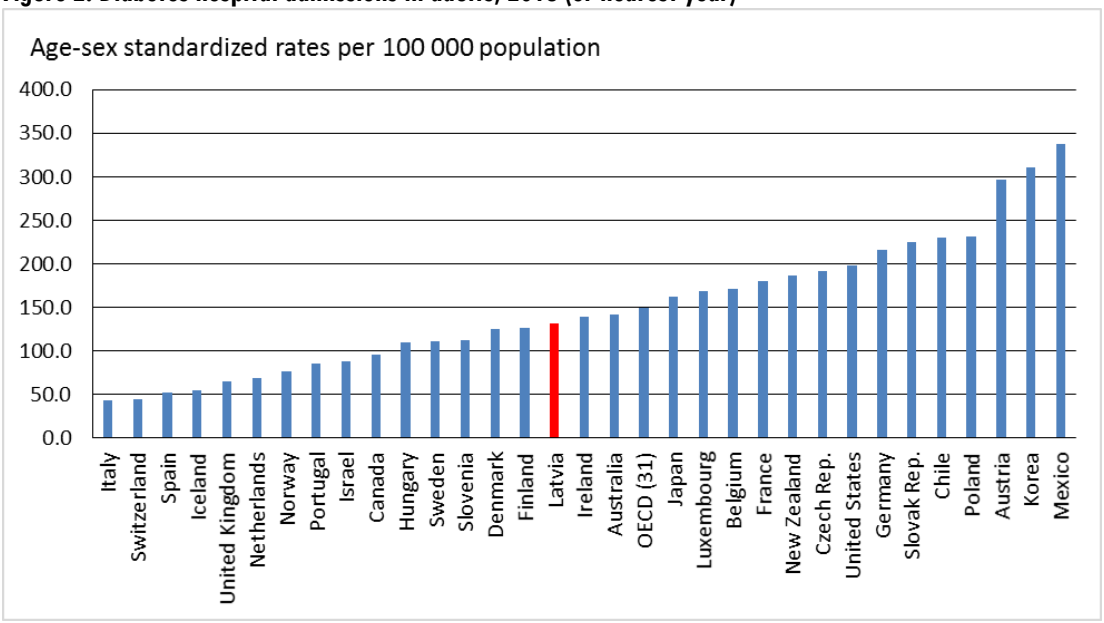
Figure 1: Asthma and COPD hospital admissions in adults, 2013 (or nearest year)



Source: OECD Health at a Glance, 2015

Notes: Data for Switzerland, Chile, Slovak Rep., US, New Zealand and Hungary are from 2012; data for Japan, Netherlands, and Belgium are from 2011; all other data are from 2013.

Figure 2: Diabetes hospital admissions in adults, 2013 (or nearest year)

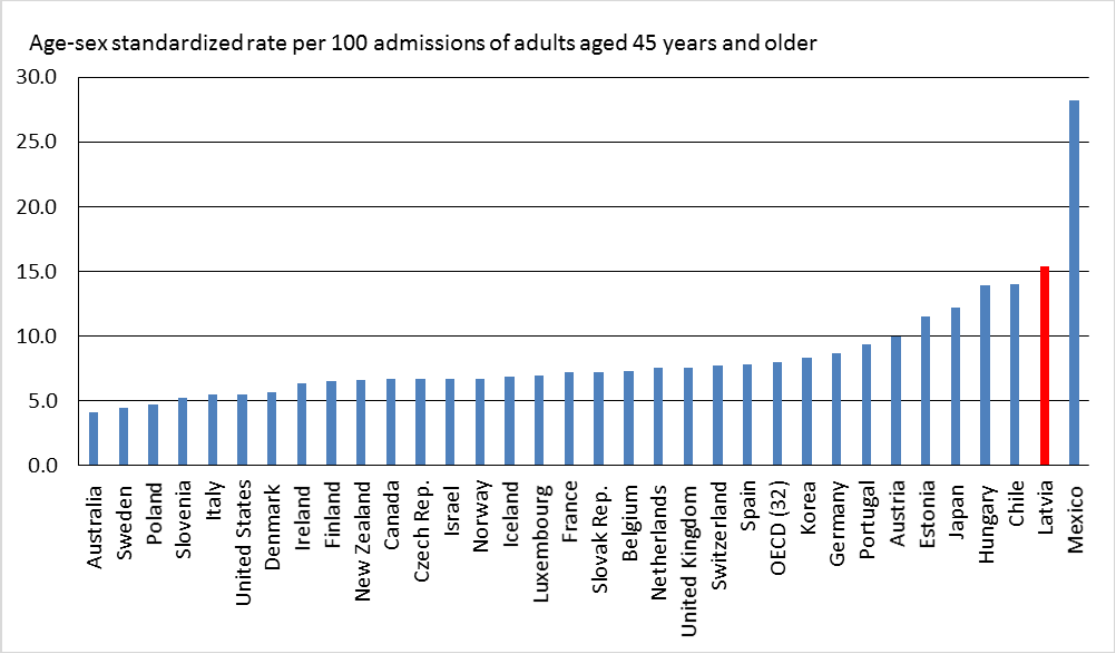


Source: OECD Health at a Glance, 2015

Notes: Data for Switzerland, Iceland, Hungary, Luxembourg, New Zealand, US, and Slovak Rep. are from 2012; data for Netherlands, Japan, and Belgium are from 2011; data for Chile are from 2010; all other data are from 2013.

10. Thirty-day mortality after admission to a hospital for an AMI or stroke based on admission data is a reflection of the quality of acute care – including timely transport and effective medical intervention. In addition to quality of care, differences in hospital transfers, average length of stay and severity may influence these rates (OECD 2015). Latvia has one of the highest rates of 30 day mortality for AMI and ischemic stroke compared to other OECD countries (Figures 3 and 4).

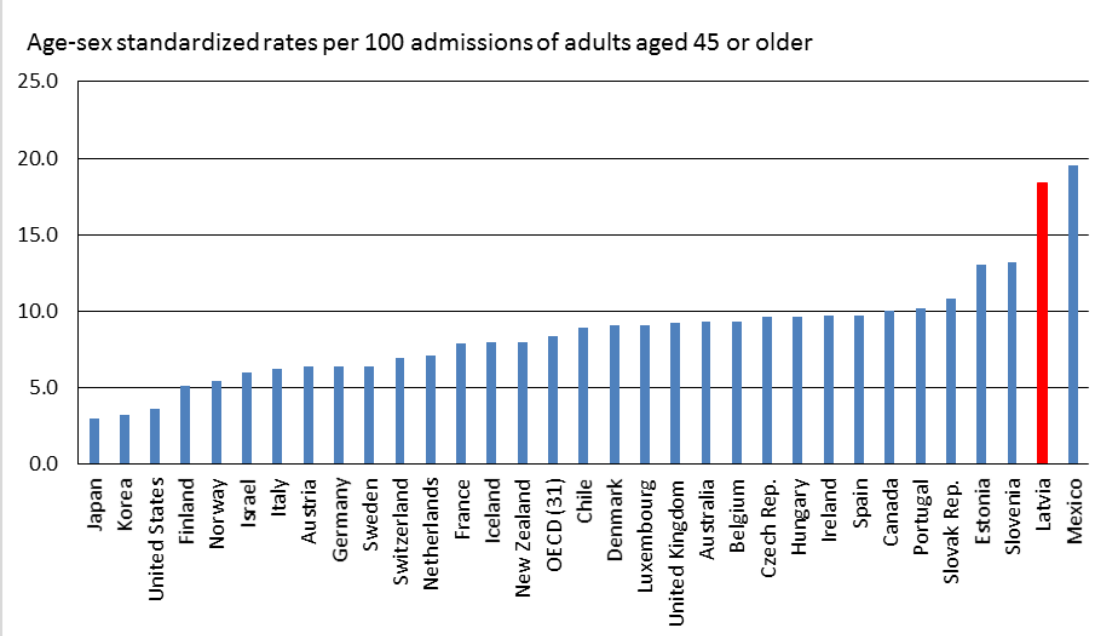
Figure 3: Thirty-day mortality after admission to hospital for AMI based on admission data, 2013 (or nearest year)



Source: OECD Health at a Glance, 2015

Notes: Data for Luxembourg, Slovak Rep. and Chile are from 2012; data for Netherlands and Japan are from 2011; all other data are from 2013.

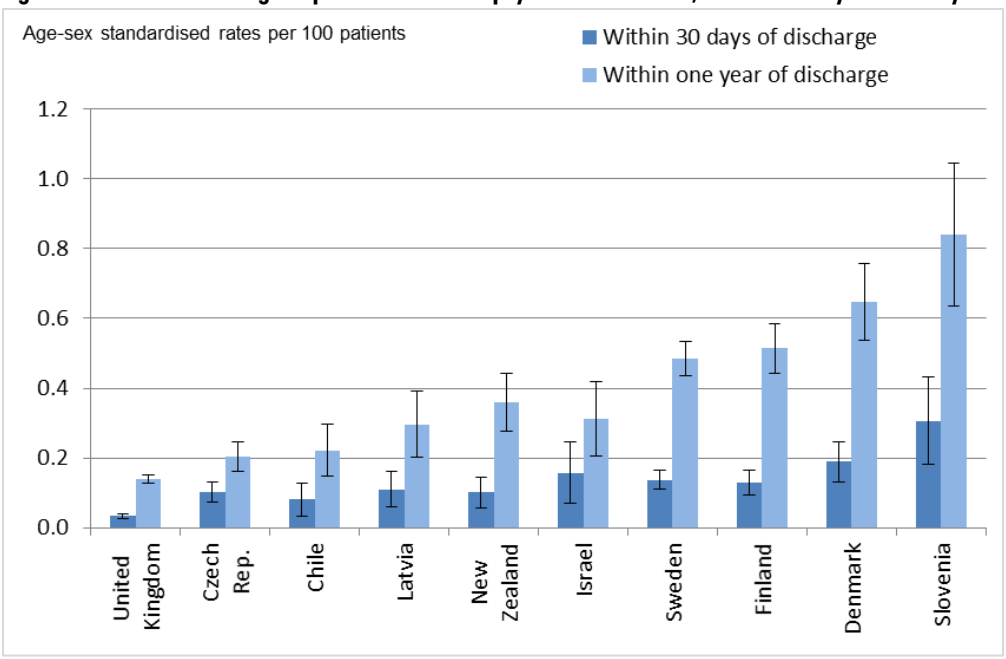
Figure 4: Thirty-day mortality after admission to hospital for ischemic stroke based on admission data, 2013 (or nearest year)



Source: OECD Health at a Glance, 2015
Notes: Data for Luxembourg, Slovak Rep. and Chile are from 2012; data for Netherlands and Japan are from 2011; all other data are from 2013.

11. The rate of suicide following hospitalization for a psychiatric disorder illustrates the quality of mental health care in community settings, as well as the quality of coordination with inpatient care during and immediately after discharge, when patients are particularly at risk (OECD 2015). Latvia appears to have the fourth lowest rate among OECD countries with available data, after the UK, the Czech Republic, and Chile (Figure 5).

Figure 5: Suicide following hospitalization for a psychiatric disorder, within 30 days and one year of discharge, 2012



Source: OECD Health at a Glance, 2015

12. Cancer survival reflects the quality of cancer care systems, spanning from prevention, diagnosis and treatment. While Latvia's survival rate for breast cancer is on par with the OECD average at about 85%, the survival rates for cervical and colorectal cancer are lower than the respective OECD averages (Table 1). Screening rates for all three cancers are relatively low in Latvia compared to OECD averages.

Table 1: Cervical, breast, and colorectal cancer, five-year relative survival, 2008-2013 (or nearest period)

	Latvia (%)	OECD (%)
Cervical cancer five-year relative survival rate, 2008-2013	58.5	66.0
Breast cancer five-year relative survival rate, 2008-2013	84.2	84.9
Colorectal cancer five-year relative survival rate, 2008-2013	58.3	62.2

Source: OECD Health at a Glance 2015
Notes: All three values for Latvia are from the 2008-2013 year period, however the values for some OECD countries (included in the average) are from varying periods.

13. Finally, while Latvia does not report on any OECD quality indicators for maternal and child care, infant, child and maternal mortality in Latvia are well-above the averages for the EU and Nordic countries (Table 2), suggesting a high likelihood that there are quality of care issues in these areas.

Table 2: Infant, child, and maternal mortality, 2013 (or nearest year)

	Latvia	EU	Nordic Countries
Infant deaths per 1000 live births	6.28	3.83	2.59
Probability of dying before age 5 per 1000 live births	7.14	4.59	3.09
Maternal deaths per 100 000 live births	24.28	4.99	4.83

Source: WHO Health for All database, 2015
Notes: Nordic countries include Denmark, Finland, Iceland, Norway and Sweden and their autonomous regions.
Infant deaths per 1000 live births years: Latvia (2012), EU (2012), Nordic Countries (2013).
Probability of dying before age 5 per 1000 live births years: Latvia (2012), EU (2012), Nordic Countries (2013).
Maternal deaths per 100,000 live births: Latvia (2013), EU (2013), Nordic Countries (2013).

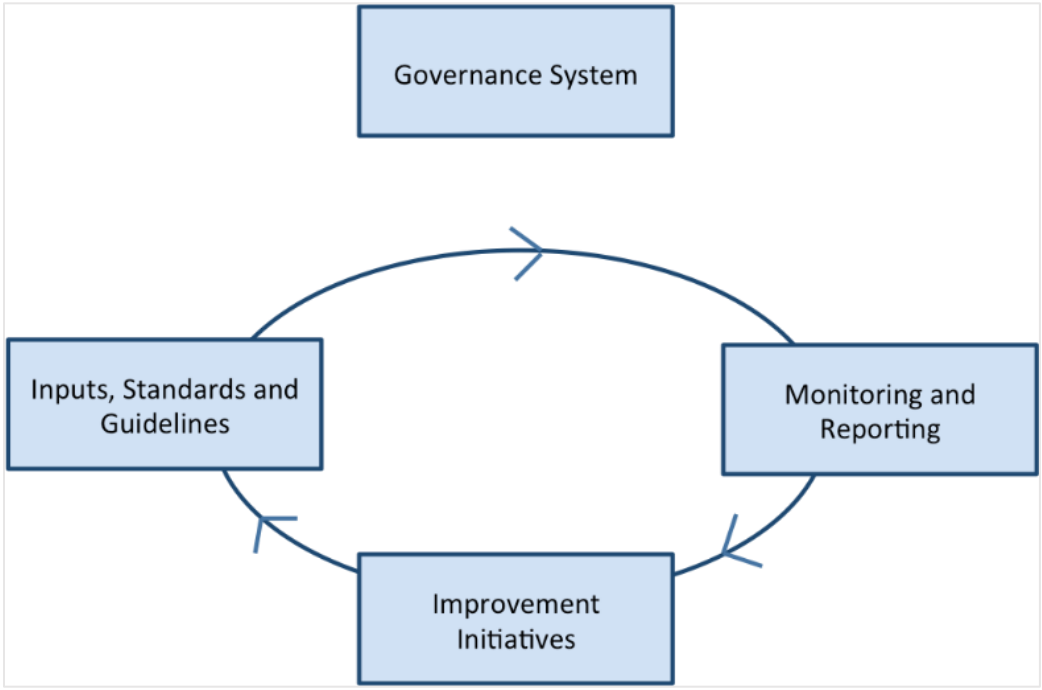
4. Analytical Framework

14. The analytical framework that will be used to assess Latvia's health sector quality assurance system builds on others that have been previously developed by the OECD and WHO (OECD 2014; Shaw & Kalo 2002; Legido-Quigley et al. 2008). These frameworks classify quality assurance policies and mechanisms along dimensions such as their type, objective, and compliance requirement (that is, whether they are voluntary, mandated by law, or incentivized with pay-for-performance schemes). The resulting framework is organized around five key components of quality assurance systems, each of which plays a key role in sustaining the quality improvement and assurance cycle for health care (Figure 6). These five components are:

i) A governance system for quality assurance
ii) Quality assurance of health system inputs
iii) Standards and guidelines of health care practice
iv) Monitoring and reporting on quality of care
v) Quality improvement initiatives

15. This cycle is governed by a system which consists of a legal framework and various health sector institutions with designated quality assurance responsibilities. The cycle begins with mechanisms to assure the quality of health system inputs as well as the setting of agreed upon standards and guidelines for the provision high quality health care. This is followed by monitoring and reporting activities to identify any deficiencies in health system inputs and assess adherence to standards and guidelines. Finally, targeted improvement initiatives and activities are implemented in response to any weaknesses in quality of care identified through monitoring and reporting, which may lead to modifications in inputs, standards and guidelines, thereby "closing the quality loop."

Figure 6: The quality assurance and improvement cycle for service delivery



Source: Adapted from Shaw & Kalo 2002 and OECD 2014

5. Overview of the quality assurance system in Latvia

A. Governance system for quality assurance

16. Developing a governance system for quality assurance involves the designation of responsibilities for performing and overseeing quality assurance activities to various health sector institutions. Ideally, this would include one institution, such as the Ministry of Health, or government agency with an active leadership function that is able to articulate a clear and comprehensive vision or strategy for quality assurance in the health sector and disseminate this to the public, providers, and purchasers. The designation of responsibilities should also be supported by a legal framework specifying various quality assurance roles and activity requirements among health sector institutions.

Roles and responsibilities for quality assurance in Latvia

17. Various institutions in Latvia are responsible for performing quality assurance activities (Table 3). The Ministry of Health (MoH) is the primary government institution responsible for planning and regulation of the health system. In this capacity, it is responsible for developing national health policies and legislation, which provide the foundation for quality assurance of health care in Latvia. The Ministry is also beginning to take a leadership role on quality assurance by commissioning a concept note for the development of a unified quality assurance system. A description of the concept note, containing the main principles and activities to be included, was approved by the Minister of Health on September 28nd 2015. The procurement process to select a firm that will be developing the concept note is set to begin next year with a final selection due by June 2016. The development of this quality assurance system will be supported by funding through the European Union's "Growth and Employment" Operational Program (Groene 2014).

18. Other institutions playing a significant role in the quality assurance of health care in Latvia include the Health Inspectorate, the State Agency of Medicines (SAM), and the National Health Service (NHS). The Health Inspectorate is the agency that is responsible for monitoring and ensuring compliance of health care institutions with the service provision conditions specified in contracts with the NHS as well as with the mandatory requirements of the laws and regulations established by the MoH. The SAM's quality assurance activities include assessing and registering medical products and devices; providing permits for clinical trials of medical products and devices; overseeing pharmacovigilance, hemovigilance and vigilance of medical devices; assessing and supervising centers for acquiring and storage of tissues, cells and organs, blood rooms of medical treatment institutions, blood preparation divisions, and the State Blood Donor Centre; and licensing of pharmaceutical companies. Furthermore, the NHS, the national purchaser of health care services, also performs some quality assurance activities, including organizing the evaluation of draft of clinical guidelines, registration of clinical guidelines in an online database, payment for quality in primary care, and development of the national e-health system.

Table 3: Quality assurance responsibilities of health sector institutions in Latvia

Institution	QA Responsibilities
Ministry of Health	• Development of national health policy and legislation related to quality of care
Health Inspectorate	• Inspections of medical treatment institutions • Supervision and inspections of availability of health care services and use of public funding • Inspections of the quality of health care and capacity checks (on request) • Maintenance of the Register of Medical Institutions and the Register of Medical Persons and Medical Support Persons • Supporting the Medical Treatment Risk Fund through inspections • Supporting the national cross-border healthcare contact point
National Health Service	• Family physician quality bonus scheme • Organizing the evaluation of draft clinical guidelines and registration of clinical guidelines in online database • Evaluation and registration of medical technologies • Inpatient and outpatient performance assessment • Monitoring of waiting times • Development of E-health System • Evaluation of pharmaceuticals for inclusion in positive list • Administration of Medical Treatment Risk Fund
State Agency of Medicines	• Conformity assessment and registration of medicinal products and medical devices; quality expert-examination of medicinal products • Permits for the performance of clinical trials of medicinal products and medical devices and supervision of their procedures • National competent authority for pharmacovigilance, medical devices vigilance and hemovigilance • Conformity assessment and supervision of centers for acquiring and storage of tissues, cells and organs, blood rooms of medical treatment institutions, blood preparation divisions, and the State Blood Donor Centre • Conformity assessment and issuance of special permits (licenses) for pharmaceutical activities • Licensing of pharmaceutical companies
Latvian Medical Association, Latvian Nurses'	• Certification and recertification

Association and the Union of Professional Organizations of Medical Practitioners	• Clinical guideline development
Pharmacists' Society of Latvia	• Maintains a pharmacist and pharmacist's assistant register • Certifies the length of professional experience for pharmacists and pharmacist's assistants • Recognizes the continuous education process for pharmacists and pharmacist's assistants
Center for Disease Prevention and Control	• Monitoring of health behaviors • Monitoring of OECD quality indicators • Obtaining, summarizing, and analyzing public health data and statistical information of health care (e.g., disease registers, death register, newborn register, state statistical reports.)
Health care facilities	• Radiation Safety monitoring • Equipment Safety monitoring • Occupational Safety monitoring • Patient safety monitoring • Development of quality management system • Supervision of epidemiological safety requirements • Reporting adverse events and complications • Conducting pharmacovigilance and hemovigilance

Legal Framework

19. Latvia has a developed system of laws which guide quality assurance activities in the health sector. The Medical Treatment Law is the principal law outlining the quality assurance responsibilities of various health sector institutions with the purpose of ensuring "qualified prophylaxis and diagnosis of diseases or injury, as well as qualified medical treatment and rehabilitation of patients." The law covers a number of areas including: general requirements for practicing health care professionals, health care facilities and the institutions responsible for certifying them; the rights and responsibilities of health care professionals; as well as the rights of patients with mental illnesses and conditions under which they may be involuntarily committed to psychiatric treatment.

20. Additional laws relevant for quality assurance include (i) the law on Patients' Rights, covering issues such as patient's rights to information and informed consent, high quality and timely medical treatment, data protection, and compensation for harms caused during or as a result of medical care and (ii) the Pharmacy Law, which prescribes the functions and objectives of the state institutions in the field of pharmacy as well as basic requirements for provision of safety, quality, and effectiveness of medicine and pharmaceutical care.

21. Aside from these laws, a number of regulations of the Cabinet of Ministers also guide various quality assurance programs and activities (Table 4).

Table 4: Relevant Cabinet of Ministers regulations for quality assurance

Quality Assurance Program/Activity	Cabinet of Ministers Regulation
Family Physician Quality Bonus Scheme	• Regulation No.1529 "The Procedure of Organization and Financing of health care" (adopted on 17 December, 2013).
Development of Clinical Guidelines	• Regulation No.469 "The Procedures for the Development, Evaluation, Registration and Implementation of the Clinical Guidelines" (adopted on 25 May, 2010).
Quality Assurance of Medical Treatment Institutions	• Regulation No.60 "Regulations Regarding the Mandatory Requirements for the Medical Treatment Institutions and Their Structural Units" (adopted on 20 January, 2009) • Regulation No. 574 "Basic Requirements for a Hygienic and Counter-Epidemic Regimen in a Medical Treatment Institution" (adopted on 11 July 2006) • Regulation No. 220 "Acquisition, Storage, Use, and Disposal Registration of Medicinal Products in Medical Treatment Institutions and Social Care Institutions" (adopted on 27 March 2007) • Regulation No. 170 "Registry of Medical Institutions" (adopted on 08 March 2005) • Regulation No.1529 "The Procedure of Organization and Financing of health care" (adopted on 17 December, 2013) • Regulation No.47 "Pharmacovigilance Procedures" (adopted on 22 January, 2013) • Regulation No.1040 "The Procedures for Health Care Practitioner who has determined complications caused by vaccination" (adopted on 27 December, 2005) • Regulation No.1037 "Regulations Regarding the Quality and Safety Standards for the Collection, Testing, Processing, Storage and Distribution of Human Blood and Blood Components, as well as Compensation for Expenditures for the Renewal of the Lost Volume of Blood" (adopted on the 27 December, 2005) • Regulation No.1176 "Procedures for utilization of Human Tissues and Cells" (adopted on 22 October, 2013)
Quality Assurance of Health Professionals	• Regulation No.943 "The Certification Process of Medical Personnel" (adopted on 18 December, 2012) • Regulation No. 268 "Regulations on the medical personnel and students who acquire the first or second level professional higher education programs for medical, therapeutic expertise and their theoretical and practical knowledge content" (adopted on 24 March 2009). • Regulation No. 192 "Registry of Medical Practitioners and Support Personnel" (adopted on 24 February 2009) • Regulation No. 454 "Procedures for the Registration of Pharmacists and Pharmacist Assistants" (adopted on 27 April 2004) • Regulation No. 290 "Procedures for the Issuing, Re-registering and Revoking of Professional Qualification Certificates of Pharmacists" (adopted on 23 March 2010)
Quality Assurance of Medical Technologies	• Regulation No.891 "The Procedures for the Clinical Trial of Medical Devices Intended for Human Use) (adopted on 21 September, 2010) • Regulation No.468 "The Procedures for the approval of medical technologies used in medicine and implementation of new medical technologies" (adopted on 28 June, 2010). • Regulation No.581"The Procedures for Registration, Conformity Assessment, Distribution, Operation and Technical Supervision of Medical Devices" (adopted on 2 August, 2005) • Regulation No. 376 "Procedure for the Registration of Medicines" (issued on 9 May, 2006) • Regulation No.289 "Regulations Regarding the Procedures for Conduct of Clinical Trials and Non-interventional Trials of Medicinal Products, Labelling of Investigational Medicinal Products and Evaluation of Compliance of the Clinical Trials with the Requirements of the Best Clinical Practices" (issued on 23 March, 2010)

B. Quality assurance of health system inputs

22. A second key component of a quality assurance system includes mechanisms for assuring the quality of health care system inputs, such as human resources and physical infrastructure. These mechanisms include certification and registration of health care professionals with periodic re-certification requirements, as well as registration of health care facilities. While registration of health care facilities and certification of health care professionals are required by law, re-certification may be done on a voluntary basis.

Certification, recertification, and registration of health professionals

23. The certification and recertification of health professionals is the responsibility of the respective professional associations identified in the Medical Treatment Law(Table 5), which have the right to suspend or cancel certificates if it is seen as necessary. All health care professionals in Latvia are registered in the register of medical practitioners by the Health Inspectorate, with the exception of pharmacists and pharmacist's assistants who are registered with the Pharmacists' Society of Latvia. To receive a certificate after completion of an education program which complies with education requirements prescribed by legal regulations, the medical practitioner takes a qualifying exam and pays a fee to receive certificates from their respective professional associations. Certifications for sub-specialties are granted in a similar manner. A pharmacist certificate confirms their fulfillment of the requirements specified in the Pharmaceutical Law and grants the right to manage a pharmacy. Information about certification of a medical practitioner is available from the register of medical practitioners (information is updated by the Health Inspectorate) and information about certification of a pharmacist is available from the register of pharmacists (information is updated by the Pharmacist Association).

Table 5: Associations responsible for certifying health care professionals

Health Care Professions	Certifying Association
Doctors and dentists	Latvian Medical Association
Nurses, midwives, dental nurses, dental hygienists	Latvian Nurse's Association
Doctor's assistants, geneticists, speech therapists, psychotherapists (without medical education), social workers, public health specialists, masseurs, functional specialists, etc.	Union of Professional Organizations of Medical Practitioners of Latvia
Pharmacists	Pharmacists' Society of Latvia

24. The validity period of a certificate for medical practitioners is 5 years, and after five years, recertification is required. Medical practitioners who would like be recertified must submit an application and summary of their professional activities in their respective primary specialties, sub-specialties, additional specialties or medical or diagnostic methods, reflecting the scope, intensity, and quality of work carried out during the validity period of the certificate. Medical practitioners must also submit a copy of a document confirming payment for the recertification process to the certification institution. The certification institution then evaluates the professional and scientific activities of the applicant.

25. During the validity period of the certificate, health care professionals must also acquire 250 continuing education points in basic specialties, sub-specialties, or additional specialties of *physicians*

and *dentists,* as well as in the basic specialty of *physiotherapists*. All other medical practitioners, including nurses, must obtain 150 continuing education points in basic specialties, sub-specialties, and additional specialties. For medical or diagnostic methods, 100 continuing education points are required. At least 60 percent of points must be obtained through scientific and professional activities and continuing education. Physicians, dentists, physical therapists may obtain the required 250 points by lecturing medical students, taking part in scientific conferences, seminars, and trainings, publishing research in magazines, or engaging in international or national consultation boards, professional associations, certification commissions, or donation projects. The Latvian Medical Association organises five interdisciplinary conferences per year which may be used by physicians to acquire points. Nurses may obtain 150 points by participating in various activities including conferences, seminars and trainings. The Latvian Medical Association, Latvian Nurses' Association, or the Union of Professional Organizations of Medical Practitioners in Latvia must approve the visited conferences, seminars, and training courses by indicating number of points in each activity. As an alternative, a medical practitioner may also take a recertification exam, although 90 percent of physicians complete their re-certification through the point system.

26. After changes in the classification of specialties, there are now specialties for which new certificates (as well as recertification) are no longer issued (including, nurses of preschool institutions and schools). Until 31 December 2016, during the certificate validity period, medical practitioners have the right to continue their professional activity and obtain a certificate in another speciality. Starting in 2017, medical practitioners will not have the right to carry out professional activities in these discontinued specialties. The Latvian Nurses Association has particular concerns with respect to medical nurses who have received a preschool or school nurse certificate, as only 25 percent of practicing school nurses have obtained a certificate in any other valid specialities.

27. The Union of the Professional Organisations of Latvian Medical Practitioners certifies medical support practitioners - for example, geneticists, speech therapists, social workers, functional specialists, and masseurs. Medical support practitioners are registered in the Register of Medical Practitioners and Medical Support Practitioners by the Health Inspectorate. Medical support practitioners who would like to obtain a certificate must submit the following to the Union of the Professional Organisations of Latvian Medical Practitioners: documents regarding their education, an overview of professional activities, and receipt confirming payment for the certification process. Medical support practitioners take a certification exam. Recertification is carried out by the Union of the Professional Organisations of Latvian Medical Practitioners, which reviews the overview of professional activities and qualification improvements during the previous five years submitted by the medical support practitioner and confirms that these add up to at least 50 hours per year. Pharmacists who work in pharmacies are repeatedly certified by taking part in a continuous education process recognized by the Latvian Pharmacist Association.

Certification of medical and diagnostic methods

28. The Latvian Medical Association and the Latvian Nurses' Association also issue a certificate of medical and diagnostic methods. This document certifies the professional proficiency of the relevant medical practitioner and indicates that he or she is entitled to independently apply the medical or diagnostic method indicated in the certificate.

Registration of health care facilities

29. Since 2009 the Health Inspectorate registers all health care facilities on the basis of compliance with relevant laws and regulations. According to the Medical Treatment Law, all service providers regardless of legal status, must comply with the requirements listed in the Regulation of the Cabinet of Ministers of the Republic of Latvia No.60 "Regulations Regarding the Mandatory Requirements for the Medical Treatment Institutions and Their Structural Units." This includes requirements with respect to structural features, staffing and qualifications of medical personnel, hygiene, quality of medical equipment and clinical processes. Pharmaceutical companies are licensed and registered by the SAM.

30. Until 2009, all health care institutions could be accredited according to these minimum requirements. That is, facilities could have paid a fee to be inspected to see if they were compliant with the requirements stipulated in the legislation, and, if compliant, they would have received a certificate. However, since 2009, the accreditation system has been discontinued and determination of compliance has been incorporated into the surveillance responsibilities of the Health Inspectorate. Prior to 2014, compliance was based solely on self-reports from the respective medical institutions as well as planned random checks conducted by the Health Inspectorate after registration. Currently, a health care facility is included in the register only after the visit of inspector who checks whether the facility complies with all mandatory requirements.

C. Standards and guidelines of health care practice

31. Health care standards and guidelines are fundamental requirements for good quality assurance systems. These typically consist of comprehensive, evidence-based clinical guidelines and pathways, which serve as the criteria for quality monitoring activities. Having an established function of conducting health technology assessments and consistently updating clinical guidelines and pathways are essential to ensuring that they reflect evidence-based practice.

Clinical guidelines

32. Latvia currently has a decentralized system for guideline development with professional organizations of medical practitioners, medical treatment institutions, and institutions of higher education that implement academic and second level vocational study programs in medicine entitled to develop draft guidelines. Many professional organizations publish guidelines that they have either developed themselves or adapted from international sources on their websites. In addition, since 2010 these stakeholders can submit draft guidelines to the NHS to be registered in a database, which is available on the NHS website.

33. The clinical guidelines registered by the NHS may be original, adapted or translated and must comply with the requirements laid out in the Cabinet Regulation No. 469 on the Procedures for the Development, Evaluation Registration and Implementation of Clinical Guidelines. Requirements include benefits, side-effects and risks which may arise by following the guidelines; the target group of application of the guidelines, specifying diagnoses or groups of diagnoses in accordance with the ICD-10; and information sources of evidence and criteria for selection. The credibility of evidence supporting guidelines must be stated according to four levels (A, B, C or D), with level A indicating a high credibility of evidence obtained in several good quality randomised clinical trials on which a meta-analysis has

been performed and level D indicating only evidence obtained during observation of a series of cases or unanimous recommendation by experts.

34. There are currently 27 clinical guidelines registered in the database published on the NHS website – of which three address cardiovascular diseases and 12 address oncological diseases. These guidelines were added over the years since the register was established in 2010, including 8 in 2011, 4 in 2012, 5 in 2013, 4 in 2014 and 5 in 2015. There are currently no requirements for periodic updating of these guidelines and no monitoring systems directly assessing adherence to these guidelines. In general, the guidelines are recommendations that may be followed rather than a mandatory, gold-standard approach. Thus, there are no systems in place to measure compliance with these guidelines. Funding available for the development of these guidelines is generally low.

35. The NHS is also responsible for preparing the Rational Pharmacotherapy Recommendations in line with its reimbursement system of medical products and medical devices for outpatient treatment, which are also available on the NHS webpage.

Pathways or disease management programs

36. Latvia currently has no integrated care pathways or disease management programs in place for the for the four priority disease groups.

D. Monitoring and reporting on quality of care

37. Monitoring quality of care can be performed either by external entities or by providers themselves. Participation in external quality assessments (for example, audits or random checks) and the performance of some quality monitoring activities by providers are typically mandated either by law or in purchaser contracts. Monitoring typically consists of monitoring adherence to quality standards for clinical practice and medical facilities.

Monitoring by the Health Inspectorate

38. The Health Inspectorate is the main institution responsible for monitoring quality of health care and conducts three broad categories of monitoring: (i) inspections of medical institutions, (ii) supervision and inspections of the availability of health care services and use of public funding, and (iii) inspections of the quality of health care and capacity checks (on request). In addition to the agency's headquarters in Riga, there are four territorial branches of the Health Inspectorate which are responsible for conducting surveillance activities. There are 46 inspectors total (3 technical supervision inspectors, 18 inspectors conducting surveillance of medical institutions, 12 inspectors conducting surveillance of compliance with contracts, and 13 doctors - medical experts conducting surveillance of health care quality).

Inspections of Medical Institutions

39. The inspection of medical institutions consists of inspections to determine compliance with requirements prescribed by various laws and regulations (Annex 1). These requirements cover a variety of areas including structural features, staffing and qualifications of medical personnel, hygiene, quality of medical equipment, and clinical processes. In addition, the Regulation of the Cabinet of Ministers No.

60 “Regulations Regarding the Mandatory Requirements for the Medical Treatment Institutions and Their Structural Units” Article 17 specifies that all medical institutions should develop and implement a quality management system that includes the following: “regular quality control of medical services provided; consideration of patients` claims and recommendations; analysis of treatment results; and improving the quality of medical services.”

40. Control of compliance with these regulations is conducted in three ways: (i) planned inspections every year in accordance with specific priorities (that is, focusing on institutions with a specific profile, a specific medical unit type or checking compliance with specific laws and regulations); (ii) inspections beyond these planned controls which are typically conducted after the receipt of information or documents (from mass media, citizens, the Ministry of Health, NHS or other institution) on particular medical institutions; (iii) follow-up inspections to confirm compliance after specific recommendations have been provided; and (iv) combined inspections. The number of each of type of inspection varies every year, though the majority tend to be planned inspections (Table 6). The priorities for planned controls are usually selected through risk-analyses of information from prior inspections as well patient complaints, which have been entered into an electronic system since 2012. Although planned controls are conducted annually, not all institutions are inspected. Institutions in Riga, which represent close to half of all institutions in the country are inspected less often. On average, inpatient facilities are inspected every 4-5 years, while outpatient facilities are checked every 6-7 years. Typical types of non-compliance cases include non-compliance with regulations on hygiene and prevention of epidemics, proper operation and maintenance of medical devices, the absence of an established quality management system with required features, inappropriate medical documentation, and low effort in ensuring accessibility of services for patients with disabilities.

41. Sanctions for non-compliance with laws and regulations range from issuing of warnings and administrative fines in accordance with the Latvian Administrative Violations Code, to referral to law enforcement or suspension of activities if it is determined that non-compliance poses a significant threat to the health and safety of patients. Follow-up inspections may be conducted to ensure compliance after specific recommendations have been provided.

Table 6: Controls of medical institutions

Year	Planned control	Beyond the plan control	Follow-up controls
2012.	465	137	231
2013.	512	158	185
2014.	716	211	205
2015 (Half –year)	420	95	100

Source: Health Inspectorate

Inspections of the availability of health care services and use of public funding

42. Inspections of this type examine waiting times for care as well as compliance with conditions set in contracts between medical institutions and the NHS and legal acts. The inspections may be conducted on the basis of internal suggestions as a result of risk-analyses or of external suggestions (from the NHS, MoH, State Revenue Service, other institutions, patients or mass media). About 250 inspections are conducted each year (Table 7). In 2014, two-thirds of these were as a result of external suggestion. The

most frequently observed violations include missed payments, improper manipulations according to legal acts, simultaneous charges to the patient and NHS for the same procedure, and irregularities in the availability of services (such as long waiting times or requirements for patients to pay for services).

43. If a violation is found, a warning statement is issued to the institution. When indicated, sanctions may include requirements to refund patients or the NHS, fines, and withholding of payment from the NHS. If there are several violations, the NHS may be asked to terminate its contract with the institution.

Table 7: Supervision and inspections of the availability of health care services and use of public funding

	2012	2013	2014	2015 (Half-year)
Checks of health care services and government spending checks	277	256	254	153
Checks conducted as a result of an internal risk analysis	126	169	167	53
Checks as a result of an external suggestion	151	87	87	100

Source: Health Inspectorate

Supervision and inspections of the quality of health care and capacity checks

44. Inspections of health care quality are usually prompted by complaints. The majority of complaints are received from natural and legal persons, law enforcement institutions, the Ministry of Health, and from persons who are in prisons. These inspections are conducted by 13 doctors employed by the Health Inspectorate. During these inspections, the doctor analyzes patients' medical records and, if necessary, may request a written explanation from the patient's medical practitioner. In more complex cases, more exhaustive investigations may be conducted based on historical medical records and published medical literature on use of clinical guidelines and medical technologies. In cases where there is no need for a more exhaustive investigation and inspection is not carried out, a reply letter is sent to the patient. Most complaints filed are related to the following medical fields: neurology and neurosurgery, primary health care, trauma, surgery, physical therapy, obstetrics and gynecology, and dentistry. In general about 1000 complaints are filed annually by patients, with 600 of these requiring more in depth inspections by a doctor or medical expert. As shown below, about 200 are proven to be justified submissions each year (Table 8). Since October 25th, 2013, patients are able to apply for compensation for damages caused by medical treatment from the Medical Treatment Risk Fund, which is administered by the NHS (see Quality Improvement Initiatives below).

Table 8: Information about complaints on health care quality

Year	Number of Applications Examined	Justified submissions
2012.	993	193 (19%)
2013.	1127	207 (18%)
2014.	1049	204 (19%)
2015. (Half-year)	432	95 (22%)

Source: Health Inspectorate

Monitoring by the NHS

45. The NHS is responsible for monitoring waiting times for inpatient and outpatient care on a monthly basis, and makes this information available to patients through their website. Waiting times are reported as the shortest waiting time for a given medical specialty within an institution as of the first day of the month. In cases where there is more than one physician practicing a particular specialty within an institution, only the shortest waiting time among these physicians is reported. In general, however, it appears as though information on waiting times is incomplete, which may reflect the fact that the NHS relies on facilities to voluntarily report waiting times on a monthly basis.

46. The NHS also monitors on inpatient and outpatient performance and publishes reports annually on its website, including indicators on utilization patterns (for example - inpatient bed days and average length of stay, share of outpatient visits by diagnosis group), mortality indicators, readmission rates and traumas occurring during medical procedures.

47. Finally, since 2005 NHS has been monitoring quality in primary care as part of its mandatory quality bonus scheme for family physicians. The numbers and types of indicators included in the scheme have changed over time. Currently, the NHS monitors 13 indicators, on which about 10-15 percent of capitation is contingent. These indicators cover a range of areas including routine health check-ups in adults and children, cancer screening, diabetic patient monitoring, monitoring and assessing cardiovascular disease risk in patients with hypertension, care for asthma patients, reducing the number of ambulance calls made by patients with specific diagnoses, and performing procedures within the scope of their competencies as defined by the regulations.

48. In 2014, there were 1302 GPs participating in the bonus scheme for the full year, which constitute 92-98% of all GPs in the country.[3] The percentage of GPs meeting the target for each indicator in 2014 ranges from just 13 percent for indicator 3 (percentage of children vaccinated according to the vaccination calendar) to 75 percent for indicator number 4 (percentage of patients who have had an annual check-up, ages 2-18) (Table 9). The low level of achievement for indicator 3 may be due to the fact that children tend to receive these services from pediatricians instead of family doctors. Less than 20% of GPs have achieved the targets for breast cancer screening, cardiovascular disease risk assessment, and peak-flow measurements for asthma patients.

Table 9: Percentage of GPs achieving target by performance indicator, 2014

Performance indicator	Target range	% of GPs meeting target	Median GP performance
1. Percentage of new patients with routine health check-up within 3 months of registration	75-90	45	72.5
2. Percentage of adult patients who have had check-up per annum	65-75	31	60.5

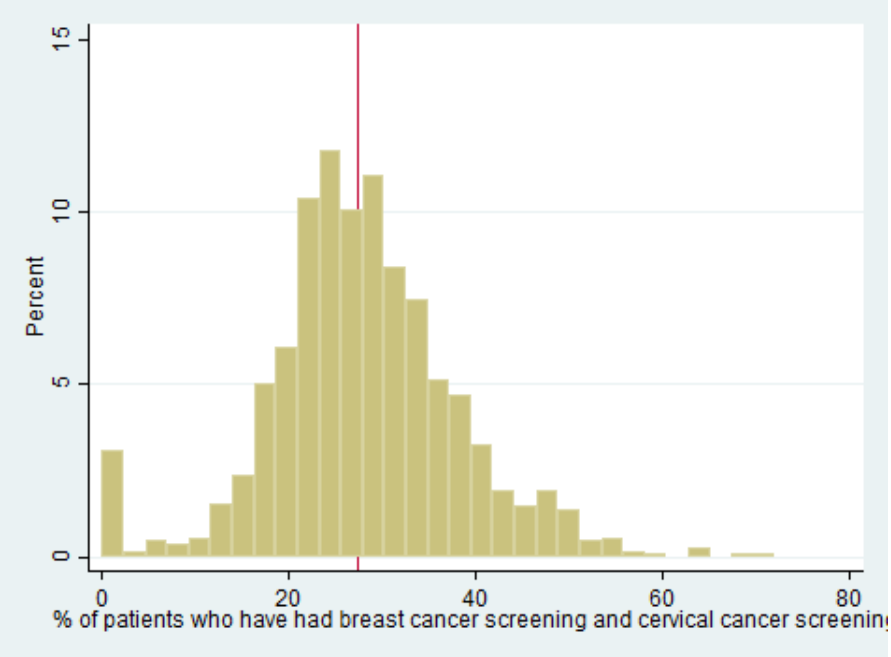
[3] The following data sources provide different estimates of the total number of GPs active in the country in 2014:
a. GP capitation payment data: 1369 GPs who received capitation in 2014 (i.e. who had contract with the state).
b. Insured persons registry: 1349 GPs.
c. NHS outpatient data: 1320 GPs who provided services paid by state.
d. Health care persons registry (Health Inspectorate data): 1411 GPs.

3. Percentage of children who have been vaccinated according to vaccination calendar	92-98	13	58.2
4. Percentage of patients who have had check-up per annum, age 2-18 years	75-95	75	83.3
5. Percentage of patients who have had breast cancer screening and cervical cancer screening check-up	36-50	19	27.3
6. Percentage of patients who have had colorectal cancer screening check-up, age 50 - 74	8-25	43	5.3
7. Percentage of patients with type II diabetes who have had measured glycated hemoglobin tests	75-90	40	60.6
8. Percentage of patients with type II diabetes who have had a record of micro-albuminuria testing	50-75	38	36.6
9. Cardiovascular disease risk assessment	60-90	17	4.5
10. Percentage of arterial hypertension patients who have had a low-density cholesterol test	70-90	24	60.4
11. Percentage of asthma patients who have had at least one measurement of peak expiratory	75-90	18	41.7
12. Number of SEMS visits to patients with definite diagnosis, if patient has not been hospitalized	110-100	63	84.5
13. GP provides various range of manipulations and services	25-50	35	19.1

Source: National Health Service database on GP quality payments

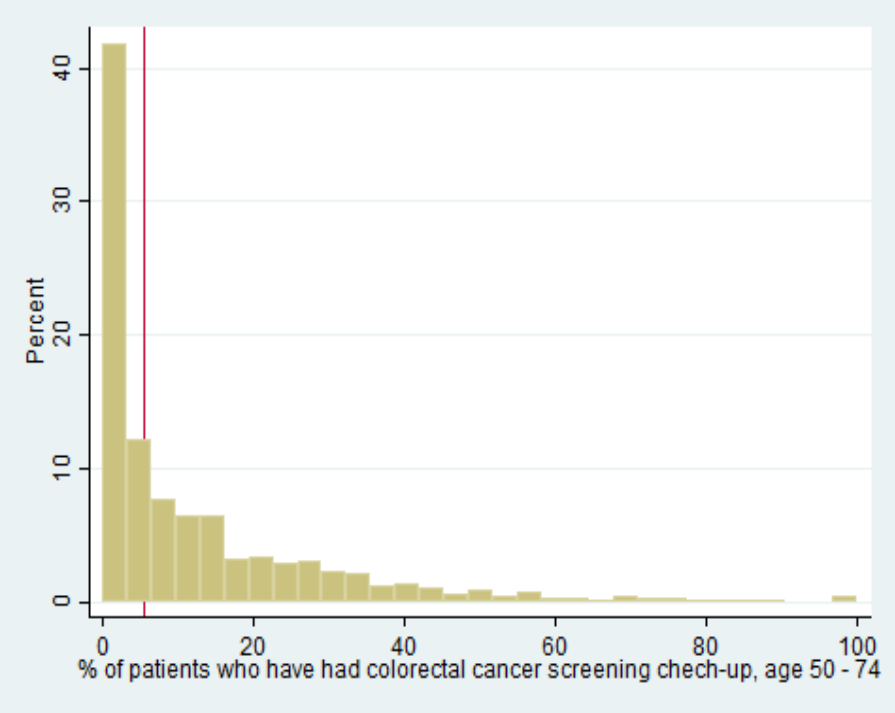
49. The distributions of GP performance for each indicator are shown in Annex 2. The median values for cancer screening indicators (indicators 5 and 6) are relatively low with 50 percent of GPs screening 27 percent of their eligible patients or less for breast and cervical cancer. The median GP screens only 5% of eligible patients or less for colorectal cancer.

Figure 7: Distribution of GP performance: Indicator 5



Source: National Health Service database on GP quality payments

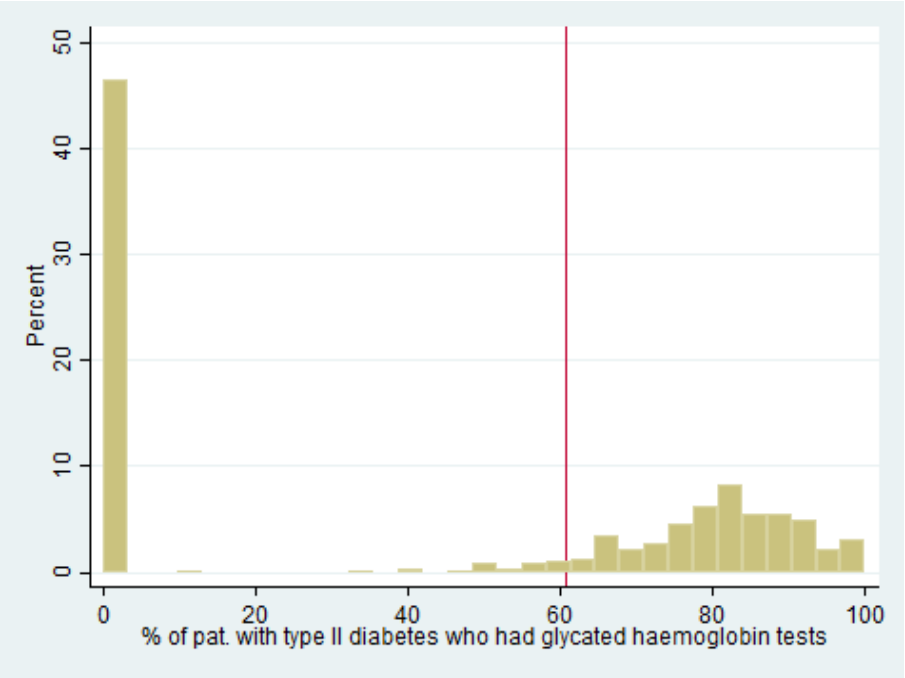
Figure 8: Distribution of GP performance: Indicator 6



Source: National Health Service database on GP quality payments

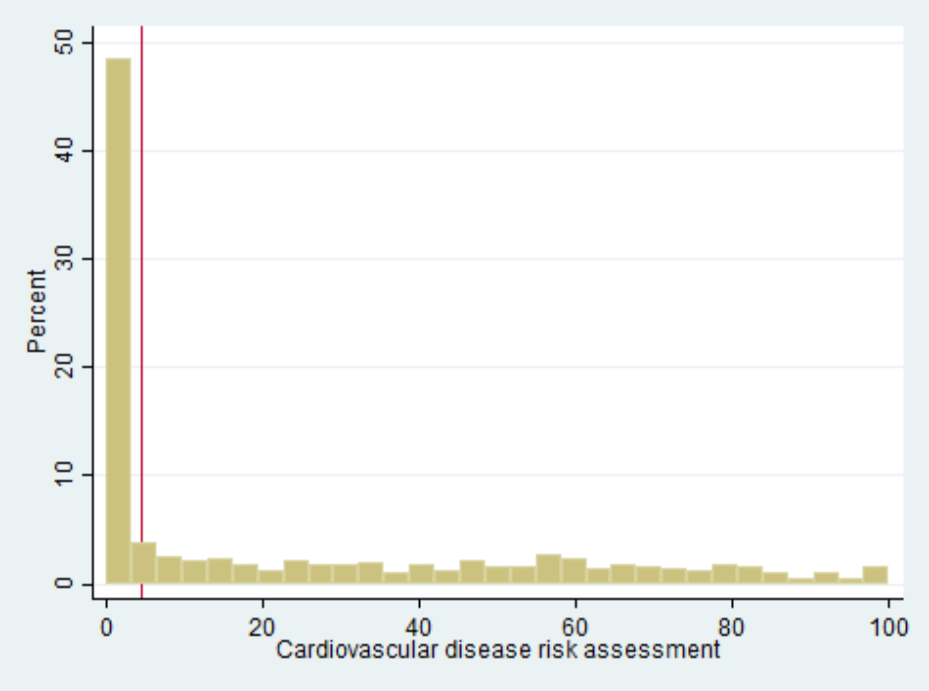
50. While the median GP has 60 percent of his/her type II diabetes patients completing glycated hemoglobin tests, there is a large mass of providers around zero. For cardiovascular disease risk assessment, the median completion rate is low (4.5 percent of patients).

Figure 9: Distribution of GP performance: Indicator 7



Source: National Health Service database of GP quality payments

Figure 10: Distribution of GP performance: Indicator 9



Source: National Health Service database of GP quality payments

51. While, the percentage of GPs achieving all 13 indicators is very low at about 0.23%., the number of GPs achieving zero indicators is also low at about 2.69% (Table 10). In general, GPs appear to be experiencing difficulty achieving a majority of the indicator targets, with close to 50% of GPs meeting only 4 indicator targets or less.

Table 10: Number of indicator targets achieved by GPs, 2014

Number of Indicator Targets Achieved	Number of GPs	Percent (%)	Cumulative (%)
0	35	2.69	2.69
1	102	7.83	10.52
2	168	12.9	23.43
3	209	16.05	39.48
4	219	16.82	56.3
5	143	10.98	67.28
6	125	9.6	76.88
7	87	6.68	83.56
8	82	6.3	89.86
9	57	4.38	94.24
10	37	2.84	97.08
11	24	1.84	98.92
12	11	0.84	99.77
13	3	0.23	100
Total	**1302**	**100**	

Source: National Health Service database of GP quality payments

52. In-person interviews conducted for this analysis have indicated that some family physicians are dissatisfied with the bonus program, including claims that many of the indicator targets are very difficult to achieve. However, it appears that there are low completion rates even for very basic tests for hypertension and diabetes.

Monitoring by the CDPC

53. The CDPC is the main institution responsible for monitoring population health. Each year it collects data from municipalities, health care providers, and surveys and publishes a statistical yearbook on health statistics on over 800 indicators including morbidity and mortality data. It collects data from providers for several registers including cancer, tuberculosis, diabetes, mental disorders, drug abuse, occupational diseases, injuries, congenital abnormalities, multiple sclerosis, HIV/AIDs, infectious diseases, causes of death, medical births, and state genome registers. These registers contain information on incidence and prevalence and for certain chronic diseases, as well as on indicators of disease management (i.e., HBA1C level and body mass index for diabetes patients).

54. In addition, the CDPC conducts a national survey on health behaviors in adults (15-64) which include patient-reported indicators on quality of care. These indicators reflect levels of good clinical practice (for example, most recent blood pressure, blood sugar and cholesterol checks in adults), waiting times for care, as well as patient satisfaction with care and information provided by family doctors (Box 2).

Box 2. Sample of quality-related topics covered in national survey on health behaviors in adults:

- Overall satisfaction with family doctor
- Evaluation of family doctor's kindness and helpfulness, ease of communication, and competence
- Family doctor's likelihood of seeing patient at their appointed time
- Convenience of family doctor's contact hours
- Having a waiting time of longer than one week to receive care in a family doctor's office, medical specialist's office or hospital and frequency of this occurring in last 12 months
- Satisfaction with information provided by family doctor about patient's disease diagnosis, possible consequences and complications, treatment plan, alternative treatment methods, and side effects of prescribed medication or treatment methods
- Satisfaction with information provided by family doctor on the availability of state-paid health care services in other healthcare institutions, necessity and opportunities to receive preventive vaccinations, state covered medication and procedure of payment
- Frequency of difficulty to get a referral letter to a medical specialist from family doctor
- Frequency of problems on getting medication prescriptions (including state-paid medications) from family doctor

55. Furthermore, although Latvia is not a member of the OECD, the CDPC nevertheless calculates and reports on various indicators included in the OECD Health Care Quality Indicators (HCQI) Project (Table 11).

Table 11: HCQI indicators reported by CDPC, 2014

Name	Measurement unit
Patient-based (in-hospital and out of hospital) AMI and Stroke 30 day mortality	Age(-sex) standardized rate per 100 patients aged 45 years old and over
Admission-based AMI and Stroke 30 day in-hospital mortality;	Age(-sex) standardized rate per 100 patients aged

	45 years old and over
Deaths from suicide 30 days and 1 year after discharge among patients diagnosed with mental disorders	Age(-sex) standardized rate per 100 patients
Five year relative survival rates for breast, cervical and colorectal cancer	Age standardized survival (%)
Hospital admissions for asthma, COPD and diabetes without complications.	Age-(sex) standardized rate per 100 000 population

Monitoring by Providers

56. With the exception of a few areas (radiation safety, occupational safety and medical equipment safety), information on the monitoring of quality of care that is conducted by providers is largely lacking. Medical institutions are required to develop a quality management system that includes at least the following measures: (i) regular quality control of medical services provided; (ii) consideration of patients' complaints and recommendations, (iii) analysis of treatment results; and (iv) improvements in the quality of medical services. Moreover, providers are also required to develop management programs for patients with rare and complicated diseases. Although the Health Inspectorate checks compliance with this legal requirement, the activities are not standardized amongst institutions, and information on these activities is not regularly collected. A survey was first conducted by the MoH to review the provider quality management systems in 2012, though the information obtained has yet to be updated.

57. Medical institutions are required to monitor adverse events and serious complications, as well as conduct pharmacovigilance and hemovigilance. However, only a few institutions have implemented a no-blame reporting and learning system for adverse events, and there is no system for monitoring adverse events at the state level. Similarly, regulations also require medical institutions to monitor healthcare associated infections as part of their hygienic and anti-epidemic regimen plans, though there is no national monitoring system for these infections. Some acute care hospitals have, however, voluntarily participated in the first European Center for Disease Control (ECDC) Net Point Prevalence Survey of Healthcare-Associated Infections and Antimicrobial Use (2011-2012). The second ECDC survey will be conducted in 2016.

E. Quality improvement initiatives

58. Quality improvement initiatives may include national policies and programs as well as initiatives carried out by providers themselves. Some examples of quality improvement initiatives at the national level include accreditation of provider organizations, health technology assessments, establishment of organizations responsible for protecting and advancing patients' rights (for example, ombudsman's office, patient rights groups), and use of e-health systems and pay-for-performance schemes. Provider quality improvement initiatives may include staff trainings, use of checklists, and discharge planning in hospitals.

National Quality Improvement Initiatives

Accreditation

59. A national accreditation system for medical treatment institutions run by a separate agency was abolished in 2009 due to the high administrative burden it created. Currently, the Health Inspectorate assesses compliance with minimum requirements specified by laws and regulations.

60. Though not a replacement for an official accreditation program, an annual competition for a quality prize is run by the Latvian Society for Quality and Latvian Health Economics Association, in which health care institutions or divisions of a health care institution are invited to participate. A fee is required for participation in the competition, but in return the institutions/divisions may receive external evaluations and training.

Health Technology Assessment

61. The NHS is responsible for assessing and approving medical technologies that will be covered by the state budget. Once pharmaceuticals and medical devices are registered with the State Agency of Medicines[4], the respective manufacturing companies can apply for inclusion in the NHS positive list for reimbursement of medicinal products and medical devices for out-patient treatment. These applications must contain information on criteria including burden of disease, therapeutic value, impact on the health budget and, for pharmaceuticals, results of cost-effectiveness assessments carried-out in accordance with the Regulation of Cabinet of Ministers No. 899 of 31 October 2006 "Procedures for the reimbursement of Expenditures for the Acquisition of Medicinal Products and Medical Devices Intended for Out-patient Medical Treatment" annex No3 "Guidelines for Economic Evaluation of Pharmaceuticals". Each application is evaluated by the NHS with respect to safety, potential impacts, and efficiency and economic justifications for use. More than 1000 pharmaceuticals are included on the positive list as well as a limited number of medical devices, and the list is revised four times per year. The NHS occasionally conducts its own cost-effectiveness evaluations, though most are conducted externally by pharmaceutical or marketing companies prior to application.

Contracting and paying for quality

62. Aside from the quality bonus scheme for family physicians there are no other contracting or payment mechanisms to encourage quality improvement.

Protecting and Advancing Patients' Rights

63. Since October 25th, 2013, patients can apply for compensation for damages caused by medical treatment from the Medical Treatment Risk Fund, which is administered by the NHS. This fund aims to provide an opportunity for patients to protect their rights and access compensation more quickly than through the justice system. In turn, health care professionals have the opportunity to protect themselves against the risks related to their professional activities and their consequences. Contributions to this fund are covered by the State through tariffs for those medical institutions that are contracted by the NHS.

64. The principles and process of evaluating applications to the risk fund are defined by the Cabinet Regulation No. 1268 "Medical Treatment Risk Fund Rules". In cases where claims of harm to the patient are substantiated through health care quality inspections, the inspector provides a summary of the inspection as well as an estimate of the extent of damage as a percentage to the NHS. On the basis of this information, the NHS determines whether the patient shall receive a payment from the Fund.

[4] The State Agency of Medicines (SAM) maintains a register of approved pharmaceuticals and medical devices, and is responsible for the quality, safety and effectiveness evaluations of these products. However, due to its complexity, a review of quality assurance mechanisms for pharmaceuticals and medical devices were determined to be outside the scope of the current study.

65. Patients must submit an application to the fund not more than 24 months after the detection of the damage and not more than 36 months after the date of the damage. Once an application has been submitted, patients must receive a decision within 6 months, and in cases where additional information has to be requested, the evaluation period can be extended up to 12 months from the date of application.

66. Since the risk fund began operation in 2013, the number of applications has been growing as patient awareness about the possibility to apply for compensation through the fund has increased (Table 9). The most common fields of application have consisted of traumatology, neurology, gynecology, and childbirth assistance. The total amount paid from the fund as of October 6th, 2015 is 647,673.23 EUR. The largest compensation to a single patient was 106,717.23 EUR.

Table 12: Applications to the Medical Treatment Risk Fund and decisions provided as of October 1, 2015

	Received applications	Accepted positive decisions	Accepted negative decisions	Refusal to examine in Treatment Risk Fund competence[5]
Year 2013 (starting from 25th October)	1	0	0	0
Year 2014 1st half-year	40	0	0	3
Year 2014 2nd half-year	54	3	21	7
Year 2015.1st half-year	82	21	15	8
Year 2015 2nd half-year 3 months (from July to September)	45	15	13	4
TOTAL:	**222**	**39**	**49**	**22**

Source: National Health Service

67. In addition, a number of patients' rights groups as well as the Office of the Ombudsman are active in Latvia. These groups serve as advocates for patients, and provide information campaigns on proper prevention and treatment of particular diseases as well as on effective communication skills for patients and providers in order to improve the quality of clinical encounters. Available funding for these rights groups is, however, limited and thus restricts the potential range of impact of these activities. The Ombudsman's main role is to receive patient complaints and work as an advocate for patients in discussions with both providers and the Health Inspectorate.

Development of National E-health System

68. The NHS is leading the development of the national e-health system in Latvia. The objectives of this system are to increase access to and more efficient use of health care information by both patients and providers, thus resulting in enhanced quality and patient empowerment. The e-health portal will provide patients with access to their health records in order to improve their involvement in the health care system. In the future, the system will also be a main source of information and data for national population health statistics monitoring, including disease registers. Modules that are currently being developed for launch in the beginning of 2016 include electronic health records and e-prescription. Use of E-prescription and sick-leave certificate systems will be compulsory as of December 1st, 2016.

[5] Reasons for refusal include: applications for date of damage before October 25th, 2013; applicants without a certificate of succession; applications that do not concern the risk fund according to law; and flaws in applications that prevent the initiation of an administrative case.

Expert Committee on Maternal Mortality

69. Latvia has a Maternal Mortality Confidential Analysis Expert Committee (10 October 2012 Order No.110 of the Ministry of Health) which is operating under internal regulation No.6 of the Ministry of Health, *Regulations of the Maternal Mortality Confidential Analysis Expert Committee* (5 September 2012) and which conducts confidential analyses of maternal mortality cases. Identified flaws are brought up and discussed in the meetings of the Association of Latvian Gynaecologists and Obstetricians.

Provider Quality Improvement Initiatives

70. Although providers are required by law to maintain a quality management system, it is unclear to what extent quality improvement initiatives are being implemented at the provider level.

6. Current Strengths of the Latvian Quality Assurance System and Potential Areas for Improvement

71. As shown in the previous section, Latvia has several building blocks for a sound quality assurance system. A particularly strong component is the quality assurance of inputs, where Latvia has various quality assurance policies and mechanisms in place. For example, it has a mandatory recertification system for health care professionals to help ensure that qualifications are kept up to date, as well as a system of conducting regular inspections of medical institutions to assess compliance with laws, regulations and to address patient complaints. In terms of other components, Latvia has also begun to officially register clinical guidelines on a national level through the NHS, there is routine collection of health data by the CDPC through registries, and there is a pay for performance scheme in primary care based on 13 quality indicators. Finally, while not yet implemented, a national e-health system is currently being developed, and the Ministry has commissioned a concept note for a unified quality assurance system in Latvia. Although the presence of these policies and practices is encouraging, there may be room for further improvement in these and other areas, as discussed in more detail below.

A. Governance System for Quality Assurance

72. There is currently no clear and comprehensive strategy on quality assurance for health care in Latvia, reflecting a lack of strong leadership on this issue at the Ministry level**.** Having a clear strategy would create the necessary conditions for the development of detailed action plans on quality, as well as for better coordination and assessment of the quality assurance activities carried out by various health sector institutions against specific goals and targets. Several countries in Europe have developed national strategies on quality. In Norway, for example, a national strategic framework for quality improvement was developed in 1995, and a more recent national strategy for quality improvement in health and social services was developed for 2005-2015. Similarly, in Denmark**,** a national strategy for quality was first developed in 1993 and was revised in 2002. In both of these countries, regional governments (and even municipality governments in Norway) also have responsibilities for developing their own quality strategies for the health care services they provide, covering areas such as standard setting, supervision, and support.

73. Instituting a leadership role within the Ministry of Health to develop a quality assurance strategy and oversee its implementation will be essential to ensuring accountability for adherence to quality standards as well as to supporting further development of quality improvement initiatives in Latvia.

Latvia's Ministry of Health is taking a first step in this direction by commissioning a concept for a unified national quality assurance system. Developing the quality assurance strategy will likely involve convening stakeholders to develop a consensus on priorities for strengthening quality assurance, conducting systematic reviews of evidence regarding policy solutions to address these priorities, and assessing the feasibility of solutions given current capacities and resources for change.

74. According to the WHO *Guidance on developing quality and safety strategies with a health system approach,* a strategy will be more likely to be successful if it (i) is developed by combining research evidence with negotiations with key stakeholders to ensure it is appropriate and acceptable for the local situation and (ii) implemented in stages, taking into account the resources available and the knowledge and experience in the country about quality (WHO 2008). The guidance also defines an index based on a set of criteria to judge a strategy's success (shown in Box 3 below). Moreover, it is recommended that the development of the QA system follow a phased approach - gradually increasing the complexity and scope of interventions as the quality assurance capacity of a country grows (WHO 2008).

Box 3. WHO Quality and Safety Strategy Success Index

Politically-based: the strategy development and implementation process engages key stakeholders and enlists them in the common aim with their different contributions (multiple stakeholders). The process is presented and allowed research and evidence to be discussed and allowed conflicts to be minimized between what is politically feasible and what the research and evidence indicates. The cost and savings of the strategy are estimated and tracked and a defined budget allocated and its use reported.
Scoring: The strategy does not address this at all = 0. Does this well = 5.

Resource-realistic: how well has the strategy provided extra resources for developing expertise in quality, time for personnel to give improving quality, and finance for investment in change.
Scoring: The strategy does not address this at all = 0. Does this well = 5.

Institutionalized: the strategy will survive individuals, because it is established as a national policy, a central policy of all organizations, and has a structure and process for implementation which has defined responsibilities including reporting and accountability. It also actively creates a quality and safety culture.
Scoring: The strategy does not address this at all = 0. Does this well = 5.

Systemic: the strategy takes into account the systemic nature of a service (outcomes for patients depend on how the parts relate – changing one part has many effects which are difficult to predict). It uses tests actions and pilot schemes on a small scale before changes are fixed and spread.
Scoring: The strategy does not address this at all = 0. Does this well = 5.

Multi-level and multiple component: the strategy describes actions at each level of the system and the actions to remove hindrances and give support which the level above takes to provide the facilitating context for the level below.
Scoring: The strategy does not address this at all = 0. Does this well = 5.

Systematic: the strategy ensures the use of proven quality tools and methods such as PDCA or RCA to ensure that the time given to quality work is effective.
Scoring: The strategy does not address this at all = 0. Does this well = 5.

Research- and evidence-informed: the strategy uses and requires at certain points research into effectiveness, data about local problems and measures for feedback about the effectiveness of change in the process of improvement.
Scoring: The strategy does not address this at all = 0. Does this well = 5.

Strategies scoring less than 40% of the possible total are unlikely to be successful, and strategy success can be increased by working on areas with low scores to decide actions which could increase the score.

Source: Guidance on developing quality and safety strategies with a health system approach (WHO 2008).

B. Standards and guidelines of health care practice

Clinical guidelines

75. Although some professional associations do develop and publish guidelines, it is unclear to what extent they are used in Latvia. Only 27 guidelines have been registered by the NHS since 2010, which may reflect a lack of capacity among qualified organizations and institutions to develop and submit guidelines for registration by the NHS. Without clear criteria and standardized methods for guideline topic selection, selection of evidence, formulation of recommendations, and updating of existing guidelines, there may be substantial variations in the quality of guidelines that are produced by professional associations and may also run the risk of conflicting recommendations. To evaluate the quality of guidelines that have been developed in Latvia (both those registered by the NHS or published on professional associations' websites), the Appraisal of Guidelines for Research & Evaluation (AGREE) instrument may be used. This tool scores guidelines based on a total of 23 items in the following 6 domains: scope and purpose, stakeholder involvement, methodological rigor, clarity of presentation, applicability, and editorial independence (Bero et al., 2013).

76. To help standardize the guideline development process in Latvia, a resource manual on guideline development and adaptation (beyond the criteria specified in the regulation) could be created through consultations with various health sector stakeholders and international experts. The Estonian Handbook for Guideline Development (World Health Organization, 2011), the WHO Handbook for Guidelines Development (2014) as well as the NICE Interim Methods Guide for Developing Service Guidance (2014), can be used as examples for the production of a similar resource in Latvia. As in the case of Estonia, this handbook may also provide guidance on developing an implementation plan along with indicators and mechanisms (e.g. clinical audit) to monitor progress, as well as guidance on when and how to update guidelines.

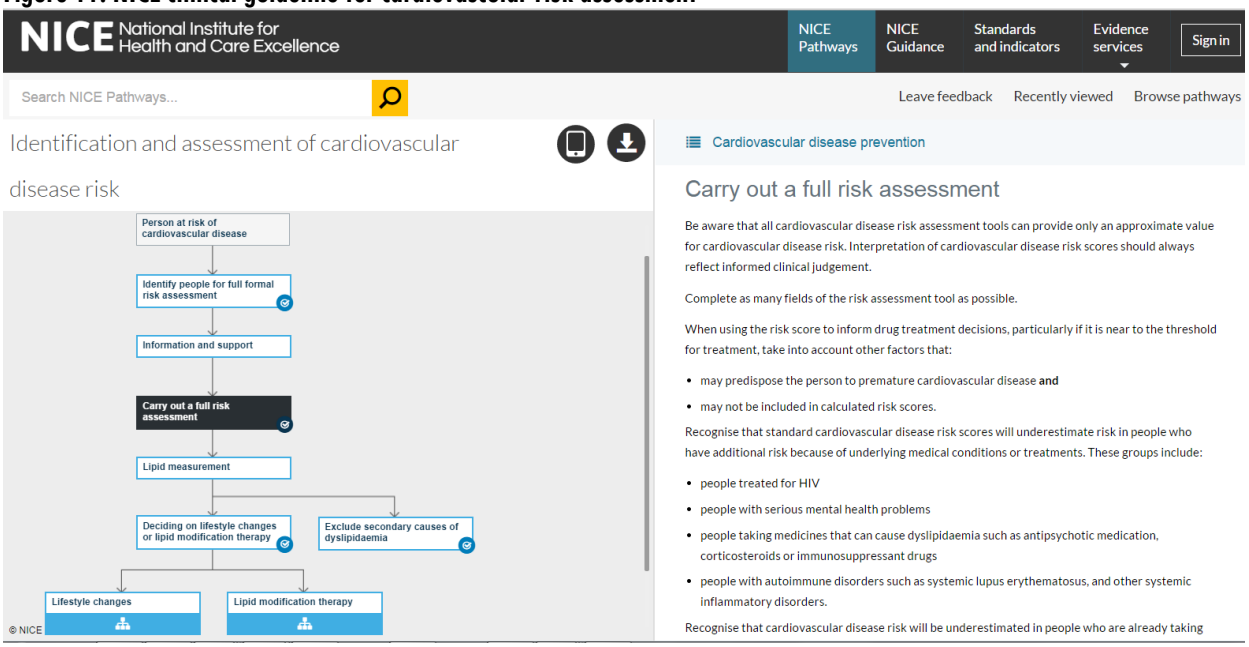
77. Unlike countries such as Sweden and the UK, which develop guidelines through multidisciplinary consensus processes relying on systematic reviews of evidence including formal technology assessment studies on cost-effectiveness, Latvia may find it difficult to develop national guidelines "from scratch" because of limitations in time, expertise and/or financial resources. In such situations, it may be more practical to primarily base local guideline development on reviews and recommendations from existing guidelines, and only occasionally develop guidelines *de novo* (Bero et al. 2013). Estonia, for example, which faces the obstacle of limited technical and human capacity to conduct systematic reviews for the development of guidelines due to its small population, has included guidance on identifying, evaluating and adapting existing guidelines from international sources in its Handbook for Guideline Development.

78. The Estonian Handbook presents a hierarchy of recommended sources, with the highest priority being clinical guidelines that were created by independent national authorities, such as the National Institute for Health and Clinical Excellence (NICE) in the UK, based on systematic reviews or transparent evidence summaries (Bero et al., 2013). NICE has been widely recognized for producing over 200 high-quality, evidence-based clinical and public health guidelines, which are available to the public on its

website. The NICE guidelines are especially useful since they are presented in a very user-friendly fashion (both in manual and decision-pathway formats) which can be easily incorporated into e-health decision-support systems (Figure 11). Other reputable sources include the Scottish Intercollegiate Guidelines Network (SIGN), the Agency for Healthcare research and Quality (AHRQ, in the USA), the National Guidelines Clearing House (NCG, in the USA), the Guidelines Advisory Committee (GAC, in Canada), the Australian National Health and Medical Research Council (NHMRC) and the New Zealand Guidelines Group (Attia, 2013).

79. Additional resources – both financial and human resources - may be required to strengthen available capacity for evaluating the quality of current guidelines as well as for developing new guidelines in the future. These resources could be used to support current guideline developers (professional associations, medical education institutions, etc.) in expanding their work programs. However, to further streamline the guideline development process, investments could also be directed towards the establishment of a national coordinator responsible for overseeing the activities of expert working groups formed to develop and evaluate new clinical guidelines. Examples of such coordinators in other countries include the Estonian Health Insurance Fund in Estonia, the National Board of Health and Welfare in Sweden, and NICE in the UK.

Figure 11: NICE clinical guideline for cardiovascular risk assessment



Pathways and Disease Management Programs

80. Latvia has currently not taken any steps to develop integrated care pathways or disease management programs, which could enhance coordination and continuity of care for patients with specific chronic diseases. Both pathways and disease management programs tackle not only the clinical aspects of diagnosing and treating patients (according to clinical guidelines), but also the organizational challenge of providing high-quality care. Integrated care pathways map the steps that patients with a specific condition should take in their journey through the health care system, as well as the various interventions they should receive at each stage (Calvan et al. 2011). They also provide information about costs, optimal care settings for the delivery of specific services, and the necessary support services and

structures that should be available. While the definitions of disease management programs vary substantially they typically involve (i) an integrated approach to care for a specific disease across providers including physicians, hospitals, laboratories and pharmacies; (ii) patient education and (iii) monitoring of patient outcomes to allow for early detection of potential complications (Nolte et al. 2014).

81. In Denmark, for example, patient pathways have been developed on the national level in the areas of cancer and heart disease and on a regional level in the field of psychiatry, which cover both the organizational and clinical standards for diagnoses and treatment (OECD 2013). The aim of the cancer and heart disease pathways were to reduce processing times (including referral time) in order to ensure quicker diagnoses and onset of treatment.

82. Denmark has also launched disease management programs for chronic obstructive pulmonary disease (COPD), diabetes, heart disease, and musculoskeletal diseases, which describe the coordinated interdisciplinary and inter-sectoral processes to manage these conditions. These programs are financed through funds pooled by the Ministry of Health and distributed to municipalities and regions that implement them. The programs are also supported through guidance provided by the Danish Health and Medicines Authority, the supreme authority for health care and regulatory control of medicines in Denmark, on areas such as general models for management of chronic diseases, recommendations on use of patient self-treatment, and quality assurance of patient education programs.

83. Developing integrated care pathways and disease management programs in Latvia could contribute to significant improvement in quality of care within its priority disease areas. Future guidelines, pathways, and disease management programs should ideally be developed jointly in order to provide a comprehensive approach to care improvement for each condition.

C. Monitoring and reporting on quality of care

Quality Indicator Monitoring

84. Beyond the OECD health care quality indicators and the indicators monitored as part of the family physician bonus scheme, Latvia performs very little routine monitoring and reporting on quality. Quality indicators can be used for benchmarking between institutions as well as with other countries, which can then allow for proper self-assessment and initiation of quality improvement initiatives.

85. Many European countries have defined aggregated sets of quality indicators as objective measures of quality and performance across the health system. For example, Sweden has several national health care quality registers containing data on health care outcomes and treatment for a number of illnesses. There are over 800 quality indicators contained in these registers, which reflect provider performance based on clinical guideline recommendations. Reporting on these indicators is voluntary, through financial incentives are sometimes used by county councils or other agencies to encourage a high level of reporting. A yearly report on these indicators provides transparent comparative information on performance between regions, county councils, and providers, which helps to stimulate public debate on health care quality and efficiency as well as support local and regional efforts to improve quality. National assessments on specific areas of care are also conducted using these

indicators, which provide specific recommendations on measures that should be taken to improve quality (OECD 2013).

86. In Denmark, a National Indicator Project (NIP) was established as a mandatory disease-specific quality system for all hospitals. There are also over 60 national clinical databases providing information on quality of care with regard to prevention, diagnostics, treatment, and rehabilitation. The indicators for each database are developed and maintained by health care professionals based on standards in the international literature. All of these databases publish annual reports, and results from a large percentage of the registries are sent monthly to the regional online information systems accessible to clinicians, administrators, management and politicians in the regions (OECD 2013).

87. With the CDPC managing several disease and health care-related data registries as well as reporting on some OECD quality indicators once every two years, there may be a good basis for initiating a quality indicator monitoring program in Latvia focusing on a few priority diseases. Financial incentives may be required to stimulate reporting among providers. As national indicator programs tend to be more common and effective in countries with well-established national data systems, plans for further development of Latvia's national e-health system could incorporate modules that would facilitate collection of data on these indicators.

Peer Review/Clinical Audit

88. Aside from national indicator monitoring, peer reviews or clinical audits (conducted by medical professionals) have been used in several countries to assess adherence to quality standards (Legido-Quigley et al. 2008). These reviews typically involve the reviewer providing feedback on a peer's performance and identifying opportunities for improvement. In Estonia, for example, the Estonian Health Insurance Fund conducts five clinical audits per year on selected topics. Audits generally last up to one year, during which a team of nominated and contracted auditors (medical professionals) evaluate selected topic areas in a sample of providers against established standards. The methods used include analysis of medical records, observation, and interviews or surveys of patients. The results of the audits are shared with all participants, and since 2013, providers are contractually required to develop improvement plans based on audit results. In the UK, participating in annual peer reviews is becoming a pre-requisite for remaining licensed to practice (Legido-Quigley et al. 2008). If appropriately funded, a clinical audit program could be organized on a national level either through the NHS or Health Inspectorate.

Adverse Event Reporting and Learning System

89. Monitoring of adverse events, near misses, and safety hazards in the care of patients could be strengthened in Latvia. Some hospitals have established adverse event reporting systems, however, it is unclear to what extent these systems are used to contribute to quality improvement initiatives. Reporting and learning systems on adverse events have become increasingly available in many European countries, as they are being seen as a cornerstone to safe practice and to sustaining a safety culture within health care organizations. In Denmark, for example, a national no-blame reporting system for adverse events in health care has been in place since 2004. This system covers all levels of the health care system and requires all health care professionals to report any adverse events they become aware of in connection with patients' care. Reports are analyzed by regions or municipalities and afterwards forwarded to the National Agency for Patient's Rights and Complaints. This agency then advises stakeholders and supports learning initiatives from the adverse events nationally. Importantly, the

health care professionals reporting these events are protected from any punitive actions from their employers, supervisory actions from national health care authorities, or criminal sanctions by courts.

90. The feasibility of implementing a national reporting and learning system in Latvia will need to be assessed. The WHO has developed draft guidelines on reporting and learning systems which seek to facilitate the improvement or development of reporting systems that can improve patient safety (WHO 2005). These guidelines caution, however, that before a country decides to establish a national reporting and learning systems, it should carefully consider: (i) what the objectives of the system are; (ii) whether they can develop the capacity to respond to reports; and (iii) the resources that will be required. Indeed, there are several factors that hinder the effectiveness of even the most developed reporting and learning systems, including fear of punitive action and lack of understanding about what should be reported, how the reports will be analyzed and how they will ultimately lead to improvements in patient safety (Mahajan 2010). Lack of systematic analysis of reports and provision of direct feedback have been shown to be major barriers to clinician engagement in reporting.

91. In scenarios where there are insufficient resources to establish the necessary infrastructure for reporting systems and/or the capacity to analyze reports, provide feedback, and oversee safety improvement initiatives, the WHO guideline recommends lower-cost alternatives to collect information on potential adverse events, near misses, or safety hazards. On a national level, alternatives may include malpractice claims analysis, surveillance, and routine data collection. At the provider level, alternatives could include safety walkrounds, focus groups, focused review, failure modes and effects analysis, and screening. A safety walkround consists of senior leaders visiting front-line staff in different units or departments and asking about specific adverse events, near misses, and safety hazards. The leaders then prioritize problems and develops solutions with the clinicians which are fed-back to staff. Focus groups are facilitated discussions with staff or patients and families where they can share insights and concerns about quality and safety within the organization in an open learning environment. Focused reviews are medical record reviews that target specific types of events (for example, adverse drug events). Failure modes and effects analysis is a widely used tool for identifying vulnerabilities in system processes by mapping risks or “failure modes” and potential “effects” to identify priority areas for action. Finally, screening is a method to restrospectively identify possible adverse events by reviewing routine data and scanning for common “triggers” or specific conditions that may lead to an adverse event (WHO 2005).

Monitoring health worker hours

92. Discussions with health care managers in Latvia revealed that there was no system in place to monitor the working hours of health workers within different medical institutions and their movement between them. As a result, managers run the risk of scheduling workers that have exceeded recommended working hour periods without rest (specified in the EU’s working time directive[6]), presenting a threat to patient safety. The employing unit (for example, a hospital or other organization) should monitor worker hours for payroll purposes, which can be used to gauge regular hours worked by

[6] The EU’s Working Time Directive (2003/88/EC) requires EU countries to guarantee the following rights for all workers: (i) a limit to weekly working hours, which must not exceed 48 hours on average, including any overtime; (ii) a minimum daily rest period of 11 consecutive hours in every 24; (iii) a rest break during working hours if the worker is on duty for longer than 6 hours; (iv) a minimum weekly rest period of 24 uninterrupted hours for each 7-day period, in addition to the 11 hours' daily rest; (v) paid annual leave of at least 4 weeks per year; and (vi) extra protection for night work (e.g. average working hours must not exceed 8 hours per 24-hour period, night workers must not perform heavy or dangerous work for longer than 8 hours in any 24-hour period, etc.).

each worker. Worker hours may also be monitored as part of a comprehensive computerized health workforce information system, which will have records for each employee, including a unique identifier (for example, a social security number or registration number) which will allow tracking of each worker. The WHO has recently published a recommended "minimum data set" for these health workforce information systems. Information from these sources can then be aggregated to provide national level data.[7]

93. In other countries, the Ministry of Labor is typically responsible for monitoring adherence with the EU's working time directive on a national level. As a result, there may be an opportunity for collaboration between the Ministries of Health and Labor on this issue in Latvia. The NHS can also include a requirement for providers to report regular working hours for all staff members in their contracts.

D. Quality improvement initiatives

94. Latvia currently has room to expand on quality improvement initiatives at the national level. These may include developing a national accreditation program or encouraging participation in international accreditation programs, strengthening capacity for conducting health technology assessments (HTAs), as well as introducing new and improved financial and contractual mechanisms to help improve quality. In addition, quality improvement at the provider level could be further supported through the development of national resource centers for knowledge, practical guidance, and technical assistance on potential interventions.

Accreditation

95. Accreditation has been widely accepted as an important mechanism to grant institutions recognition for achieving a certain standard of quality. In some countries, it has been used as a market signal for both consumers as well as health care financiers to help support decisions on whether to seek care or contract with a certain health care institution. Accreditation is often confused with licensing, a mandatory process that all health care institutions must participate in order to provide care, where inspectors assess the institutions against mandatory requirements for infrastructure and inputs. In contrast, accreditation programs tend to be voluntary, conducted by peers against optimal standards of process and outcome and focus on education, self-development, improved performance, and reducing risk (Shaw and Kalo 2002).

96. The majority of accreditation programs in Europe are either partially funded or managed directly by government, although some longer established programs are independent (Spain and UK) (Shaw and Kalo 2002). Denmark, for example, has a sophisticated accreditation system in place since 2005 called Den Danske Kvalitatsmodel (DDKM) which is managed by the Danish Institute for Quality and Accreditation in health care (IKAS) and has been implemented in all public hospitals, pharmacies, and pre-hospital units. This system aims to include indicators on structure and processes but also on disease-specific indicators. The DDKM is currently based on 104 generic disease standards and includes 455 indicators. In Estonia, the Family Physicians Association has set up a committee that runs an annual, voluntary accreditation system A number of international accreditation programs are also available,

[7] Monitoring workers' hours in each institution and across institutions would also generate data on full-time-equivalent workers, which is information that is critical for human resource and capital investment planning and which is currently missing in Latvia.

including Joint Commission International, Accreditation Canada and the Australian Council on Health Care Standards International.

97. Although the Health Inspectorate in Latvia performs inspections according to mandatory requirements specified by laws and regulations as part of its medical institution registration process, encouraging participation in an accreditation program (either one that is established within the country or an international program) would allow medical institutions to be held to a much higher quality standard. If appropriate financial and human resources could be secured, a national accreditation program could be established (for example, within the Health Inspectorate). Financial incentives may also be necessary to promote the participation of medical treatment institutions in such a national accreditation program or, alternatively, in an international program (e.g. JCI International).

Health Technology Assessment

98. HTAs are comprehensive, systematic evaluations of the properties and impacts of using health technology (including medicines, medical devices, vaccines, procedures and systems). These assessments are essential to the development of evidenced-based standards and policies. For example, the Swedish Council on Technology Assessment in Health Care, an independent national authority tasked by the government with assessing health care interventions, conducts regular HTAs that constitute the basis for monitoring the quality of use of medical devices and pharmaceuticals, development of clinical guidelines and setting priorities in health care. Similarly, Norway, the UK and Estonia all have institutions responsible for conducting regular HTAs. The Norwegian Knowledge Center for Health Services in Norway and NICE in the UK are both independent institutions responsible for conducting HTAs. In Estonia, the Center for Health Technology Assessment was established as part of the Department of Public Health at the University of Tartu and is staffed with about 8-10 research fellows. In 2012-2015 this Center was funded by the European Regional Development fund and since July 2015, the Center will have continued support from the Estonian Ministry of Social Affairs (University of Tartu Department of Public Health, 2015).

99. Given that the limited capacity for HTA's within the NHS, they continue to be carried out primarily by pharmaceutical and marketing companies. In order to promote better alignment of incentives, it would be in Latvia's interest to further develop the capacity for conducting HTAs at the national level, either within the NHS or a separate institution focusing specifically on HTAs.

Contracting and Paying for Quality

100. Contracting and payment mechanisms could be used to promote quality improvement in Latvia's four priority disease areas (cardiovascular disease, cancer, mental health and maternal and child health). For example, financial incentives may be used to stimulate participation in disease management programs, or to reward high quality care in both primary and specialist care settings. In Denmark, general practitioners participating in diabetes type 2 disease management programs were offered €1000 to cover the costs of services involving cross-sectoral work (for example, for referring patients to preventive treatment and ensuring adequate follow-up after hospitalization) (Wadmann 2009). Other western European countries offer similar financial incentives for their disease management programs at the patient, provider and pooler/payer levels (Table 13). Financial incentives are also used to penalize low-quality care. For example, in Germany and the UK, payments for cases that are hospital readmissions within a certain period of time may be refused.

101. As in Latvia, both the UK and Estonia have bonus scheme programs to reward general practitioners for the achievement of specific quality indicators. However, given the low performance in Latvia on some of the indicators, there may be a need to re-evaluate the design of the scheme, including the appropriateness of the indicators that are being monitored and support to GPs for meeting targets. The indicators chosen should have practical targets for family physicians to achieve that are also in line with evidence-based clinical guidelines (for example, on recommended annual tests for diabetes and hypertension patients). For example, Estonia's quality bonus scheme has 40 indicators covering the areas of disease prevention, chronic disease management and others, while England's Quality and Outcomes Framework has over 80 indicators covering both clinical and public health domains. In addition, there may be a need to test modifications to the overall design of the bonus scheme, including varying whether the bonus is a pure top-up versus a variable component of physicians' capitation budgets.

102. Contracts between payers and providers may include specific requirements related to quality. For example, in Estonia, the health insurance fund's contracts with providers include requirements for the development of a quality assurance system. Economic agreements between national, regional and local governments may also set quality targets. In Denmark quality targets set for regional and local governments include a 10% decrease in hospital standardized mortality rate and a 20% decrease in patient harm over a three year period. In Sweden, additional funds are transferred from the national government to regions and county councils in order to stimulate compliance with clinical guidelines and to reward safe care.

Table 13: Financial incentives for disease management programs in European countries

Country	Patient Level	Provider Level	Pooler/Payer Level
Austria		• €53 initial + €25 quarterly per patient enrolled in DMP	
France	• Reduced copayment if patient enrolls in DMP	• €40 annual per patient enrolled in DMP	
Germany	• Reduced copayment if patient enrolls in DMP • Additional services (e.g. self-management education) only reimbursable if patients participate in DMPs	• €75 per patient per year for coordination costs • Additional remuneration for disease specific education programs provided within a DMP	• €153 annual per patient enrolled in DMP for coordination costs

Source: Exploring Payment Schemes to Promote Integrated Chronic Care in Europe (Tsiachristas et al. 2013)

Supporting Quality Improvement at the Provider Level

103. In addition to data and information on provider performance as well as contractual and financial incentives, additional support may be necessary to stimulate quality improvement at the provider level. Typically, this involves the formation of a national resource center on quality and/or safety that provides health care organizations with collection and dissemination of national and

international experience, techniques, data, and references. These centers serve as knowledge bases for practical guidance and technical assistance to help implement quality improvement initiatives. For example, the Danish Society for Patient Safety is a non-profit organization working to ensure that patient safety is an aspect of all decisions made in Danish health care. The NGO's main focuses are: gathering, spreading and developing knowledge and initiatives, providing advice to legislators & stakeholders, arranging study tours and conferences, suggest standards for safe operation, conducting campaigns and lobbyism, creating consensus and initiating projects. Similarly the Norwegian Knowledge Centre for Health Services, which is financed by the government but is professionally independent, supports the development of quality in health services by summarizing research, promoting the use of research results, contributing to quality improvement, measuring quality of services and working to improve patient safety (OECD 2014). The US has also developed a resource center called "Choosing Wisely" to promote conversations between providers and patients about how to choose high quality and safe care. The center provides materials including information on specific tests and procedures and their appropriateness in different situations as well as communication education modules to support providers in engaging patients in these conversations.

104. A similar resource center could be established in Latvia, either within an existing institution or a newly established one. Supporting quality improvement at the provider level, however, requires that providers have the necessary ability themselves to carry out quality improvement activities. As such, provider needs for additional resources and staffing will also have to be considered.

7. Conclusions

105. There is no universal template for the design of a good quality assurance system, however there are common elements which various developed countries demonstrate to be important as evidenced in their own national strategies, policies and initiatives (Shaw and Kalo 2002). Nevertheless, the evidence for many of these elements tends to be limited and the policies and mechanisms which work in some systems may not necessarily be directly applicable in others. While this review has outlined various tools and processes available in other countries which may be beneficial to improve quality of care, the priorities among stakeholders and resource and capacity constraints in Latvia should determine which will be appropriate within the Latvian context.

106. As demonstrated in this review, Latvia's quality assurance system has a number of strengths, a large focus of which is on the quality assurance of health system inputs (health care professionals, medical treatment institutions, pharmaceuticals and medical devices). Reflecting on the Donabedian "structure-process-outcome" framework to assess quality of care, it appears that the Latvian quality assurance system places heavy emphasis on monitoring and improving *structural* features of health care (i.e., human resources, facilities and equipment), while it has fewer measures focusing on the quality of clinical and organizational *processes* in health care, as well as patient and population *outcomes*. Latvia's future quality assurance strategy should thus focus on strengthening these latter two areas. A summary of suggested responses to the issues identified in this review are summarized in the table below. As many of these recommendations entail the development of new processes, such as clinical pathways or systematic quality monitoring, implementation will likely require both an initial upfront investment at the development stage and additional resources going forward to incorporate these activities into the routine functioning of the Latvian healthcare system. That is, these

represent new activities that unlikely can be added to current personnel profiles in health care administration.

107. The success of any quality assurance strategy depends heavily on developing a quality culture at all levels of the health care sector. Indeed, many studies show that behavioral aspects (culture, attitude, training, and management of human resources) rather than technical solutions are more important when implementing quality improvement initiatives (Shaw and Kalo 2002). Developing this quality culture will require at the very least incorporating basic training on quality assurance and improvement in medical education at the undergraduate, specialty training, and continuing medical education levels, as well as in education for non-clinical personnel (e.g., information specialists, administrators, etc.). By increasing the numbers of personnel within organizations that are fully informed about and trusting in quality assurance practices, there is a higher likelihood of ultimately creating a shift in the quality culture from one that is 'reactive,' responding to problems as they arise, to one that is 'proactive,' which consistently attempts to identify and eliminate risks and patterns that may turn into quality problems later on.

Table 14: Summary of quality assurance problems, potential solutions, and enabling actions

Component	Problem	Potential Solution(s)	Enabling Actions
Governance system for quality assurance	No national strategy on quality assurance	Develop quality assurance strategy aligned with current priorities, capacity for change and resources	1. Conduct systematic reviews of evidence regarding policy solutions to address these priorities 2. Assess feasibility of solutions given current capacity and resources for change. 3. Convene stakeholders to develop a consensus on priorities for strengthening quality assurance in Latvia.
Standards and guidelines for health care practice	Lack of clinical guidelines that are registered by the NHS	Develop capacity and resources for guideline development	1. Assess feasibility of increasing capacity and resources for guideline development
	Lack of standardized process for developing/adapting clinical guidelines	Develop a handbook for clinical guidelines development/adaptation	1. Review examples of handbooks available internationally (Estonia, WHO) 2. Convene stakeholders and international experts to develop consensus on appropriate guideline development process in Latvia 3. Pilot and evaluate process recommended by handbook, and make necessary adjustments prior to launch.
	Lack of integrated care pathways and disease management programs	Develop integrated care pathways and disease management programs for priority disease areas	1. Review examples and evidence on integrated care pathways available internationally 2. Convene stakeholders to develop consensus on the design on pathways and disease management programs 3. Pilot and evaluate pathways and disease management programs for priority disease areas.
Monitoring and reporting on quality of care	No monitoring of quality indicators	Develop quality indicators for priority disease areas, at different levels (from national to institutional)	1. Review indicators available internationally. 2. Review available guidelines on priority disease areas. 3. Convene stakeholders to develop consensus on quality indicators to be monitored and process of monitoring 4. Pilot and evaluate indicator monitoring for a few disease areas. 5. Incorporate monitoring of these indicators into future plans to develop national e-health system.
	No peer review/clinical audit system to assess adherence with guidelines	Conduct regular clinical audits in priority disease areas to assess compliance with standards and guidelines	1. Review available examples and evidence (for example, Estonian clinical audit handbook). 2. Convene stakeholders to develop consensus on audit process 3. Pilot and evaluate audit process for a few selected guidelines in priority disease areas.
	No reporting and learning system for adverse events	1. Implement a national reporting and learning system for adverse events 2. Continue to implement lower cost options (surveillance and malpractice claims analysis) at the national level, while also	1. Conduct assessment of capacity and resources to implement national reporting and learning system. 2. Convene stakeholders and international experts to develop consensus on appropriate design. 3. Conduct assessment of additional lower-cost options that could be pursued.

		encouraging and supporting alternatives at the provider level (safety walkrounds, focus groups, etc.)	
	No monitoring of health worker hours	1. Collaborate with Ministry of Labor on monitoring of health worker hours 2. Include requirement for providers to report regular worker hours on NHS contracts	1. Assess current level of monitoring of worker hours at provider level 2. Agree on minimum data set and time intervals in which worker hours should be reported. 3. Assess feasibility of implementing broader health workforce information system.
Quality Improvement Initiatives	No accreditation system	1. Develop national accreditation program 2. Encourage participation in international accreditation program (e.g. , JCI International)	1. Assess feasibility of implementing national accreditation program in Latvia together with stakeholders. 2. Develop standards and process for accreditation based on review of international programs and consultation with relevant stakeholders and experts. 3. Identify potential volunteers or provide incentives for participation in an international accreditation program.
	No HTA program	Develop capacity for conducing HTAs	1. Assess resource and capacity needs to develop a national health technology assessment program (either within the NHS or a separate institution). 2. Identify potential institutions to carry out national health technology assessments (universities or other independent institution, government agency).
	No contracting and limited payment for quality	1. Revise design of quality bonus program for family physicians to ensure feasibility of achievement and compatibility with clinical guidelines 2. Introduce new contracting and payment mechanisms to encourage adherence to quality standards and quality improvement	1. Pilot and evaluate variants of provider bonus scheme, including varying whether the bonus is structured as a pure top-up versus a variable component of salary. 2. Identification of aspects of quality that can be easily measured by the NHS or an independent organization that can be routinely used as basis for contracting and experimental pilot (i.e. randomized trial) to test effectiveness of quality criteria
	No support for quality improvement at provider level	Develop national resource center to advise and support provider quality improvement initiatives	1. Assess resource and capacity needs to develop a national resource center (within an existing or newly established institution). 2. Conduct focus groups w/ doctors to identify content areas for support and develop relevant work streams accordingly.

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Annex 1. Relevant laws for Health Inspectorate Inspections

Laws:

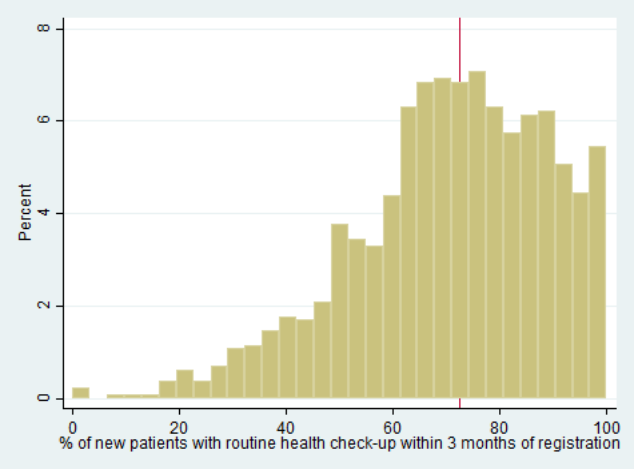
- Medical Treatment Law
- Patients' Rights Law
- Epidemiological Safety Law
- Pharmaceutical Law
- Sexual and Reproductive Health Act
- The Law "On protection of a dead human body or human tissue and organs for medical"
- Personal Data Protection Act
- Latvian Administrative Violations Code
- Administrative Procedure Law

Regulations of the Cabinet of Ministers:

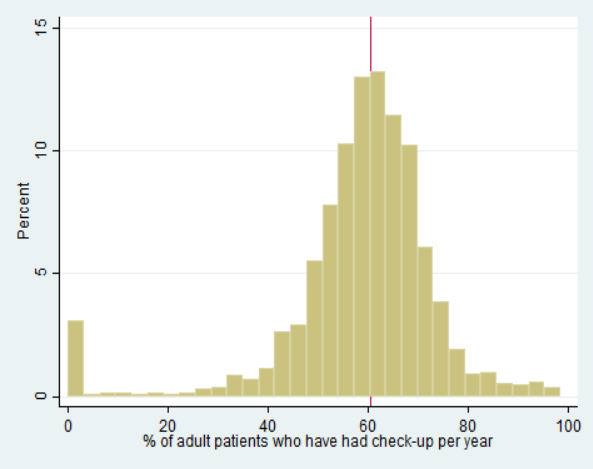
- Cabinet of Ministers Regulations 60 *Minimum Requirements for the Medical Institutions and Their units* of 20 January 2009
- Cabinet of Ministers Regulation 170 *Registry of Medical Institutions* of 08 March 2005
- Cabinet of Ministers Regulation 192 *Registry of Medical Practitioners and Support Personnel* of 24 February 2009
- Cabinet of Ministers Regulation 574 *Basic Requirements for a Hygienic and Counter-Epidemic Régimen in a Medical Treatment of* Institution11 July 2006
- Cabinet of Ministers Regulation 581 *Registration, Conformity Assessment, Distribution, Operation and Technical Supervision of Medical Devices* of 02 August 2005
- Cabinet of Ministers Regulation 220 *Acquisition, Storage, Use, and Disposal Registration of Medicinal Products in Medical Treatment Institutions and Social Care Institutions* of 27 March 2007
- Cabinet of Ministers Regulation 330 *On Vaccination* of 26 September 2000
- Cabinet of Ministers Regulation 1529 *Health Care Management and Funding* of 17 December 2013
- Cabinet Regulations. 268 "Regulations on the medical personnel and students who acquire the first or second level professional higher education programs for medical, therapeutic expertise and their theoretical and practical knowledge content" of 24 March 2009
- Cabinet Regulations. 265 "Medical documents clerical order" of 04 April 2006.
- Cabinet Regulation No. 468 "medication used in medical technology and the approval of new medical technologies implementation arrangements" of 28 June 2005.
- Cabinet Regulations. 611 "Obstetric procedures for ensuring" of 25 July 2006.
- Cabinet Regulations. 1268 "Medical Treatment Risk Fund Rules" of 05 November 2013.

Annex 2. Distribution of GP performance, by indicator.

Indicator 1



Indicator 2



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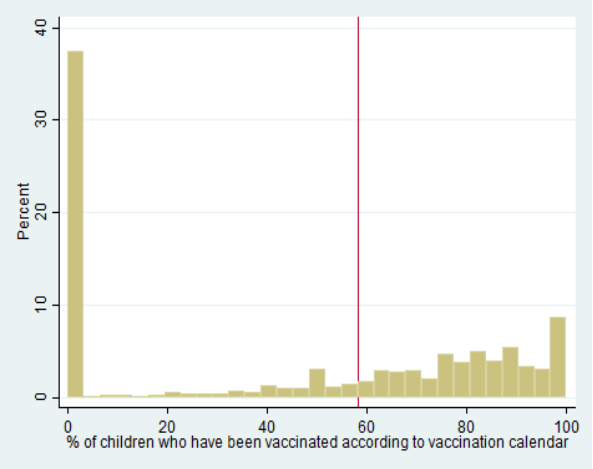

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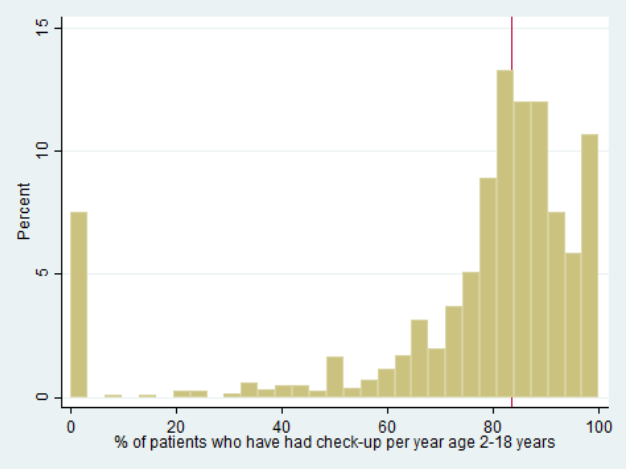

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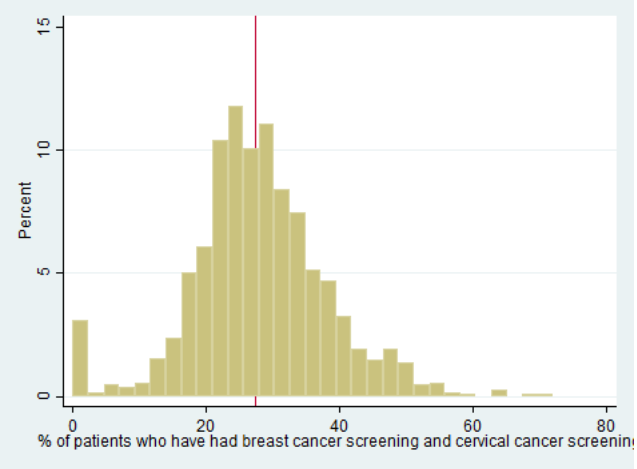

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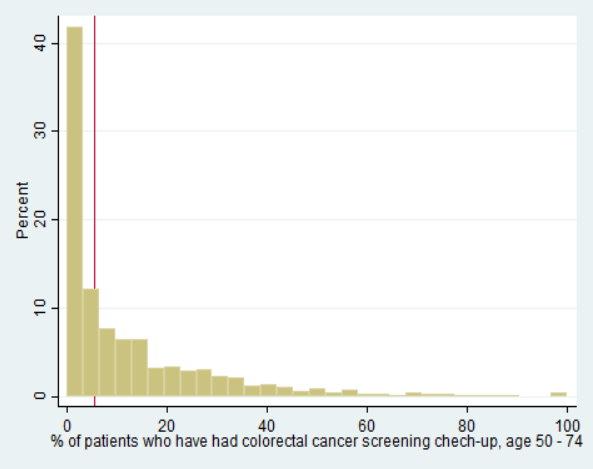
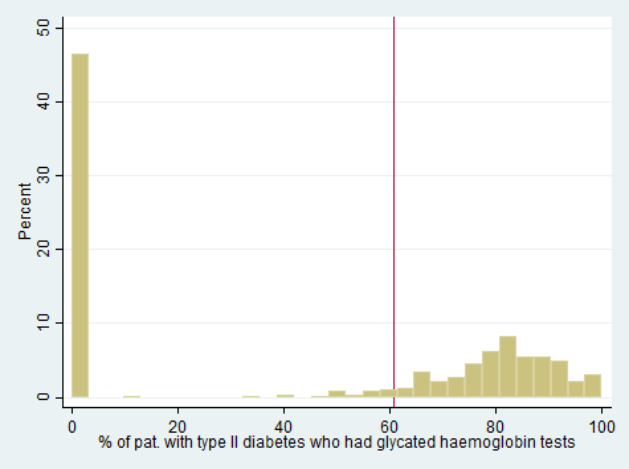
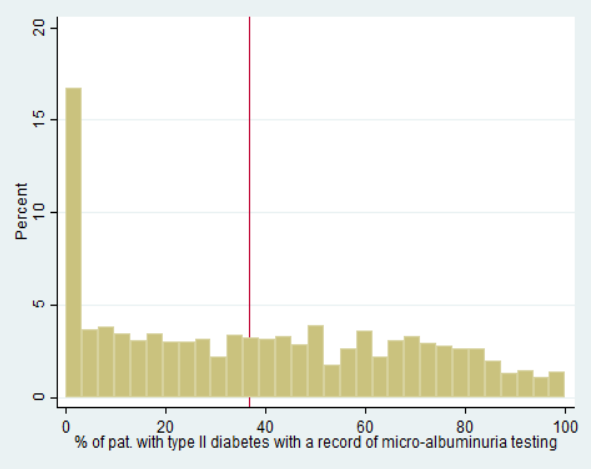


Indicator 7

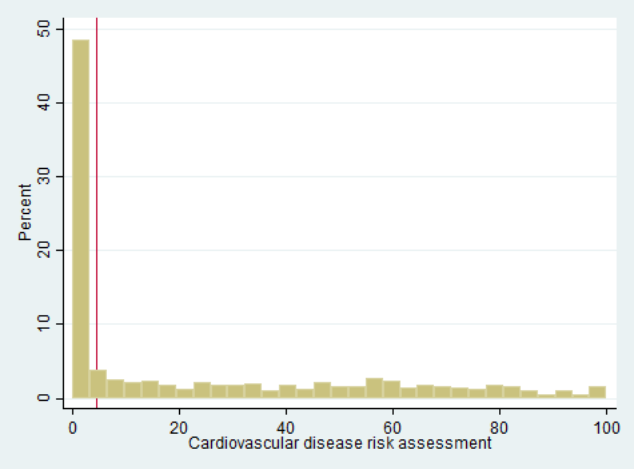
Indicator 8

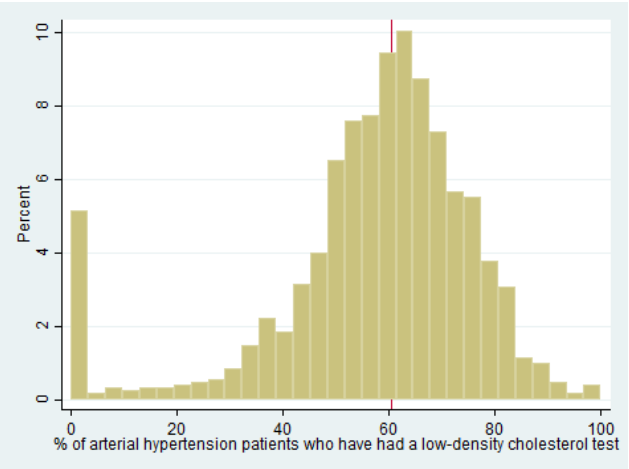




Indicator 9

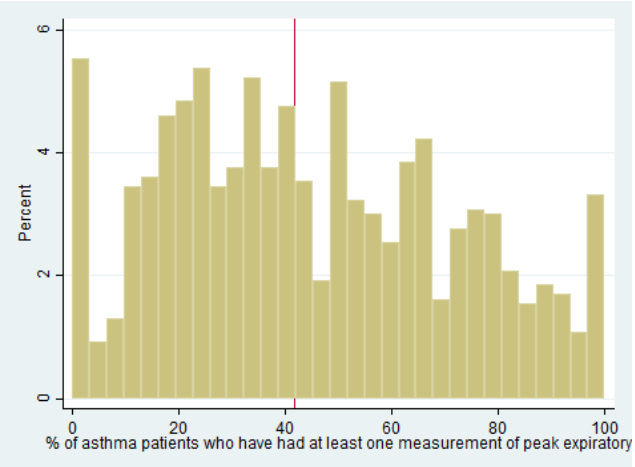
Indicator 10

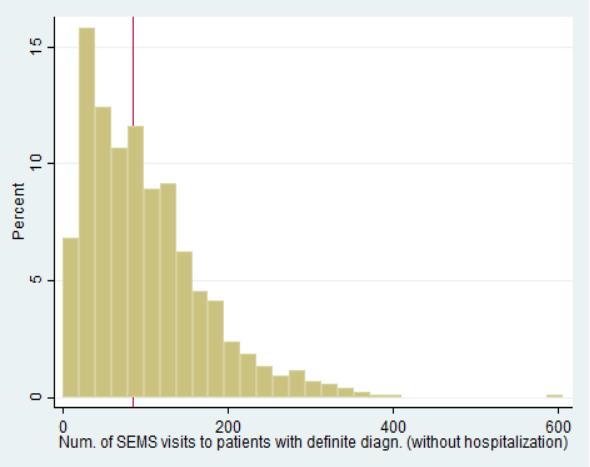




Indicator 11

Indicator 12





Indicator 13