



Peer Evaluation Report

Latvian Health Inspectorate

October 2018

European Social Fund co-financed project No. 9.2.3.0/15/I/001 “Elaboration and Implementation of Health Network Development Guidelines and Quality Assurance System in Priority Health Sectors”

Expert services in healthcare quality and patient safety domain (procurement identification
No.VM NVD 2017/36 ESF)

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Foreword and Acknowledgement

The European Partnership for Supervisory Organisations in Health Services and Social Care (hereafter – EPSO) Peer evaluation team contracted by Foundation Eurinspect (hereafter – Peer evaluation team) is pleased to present this report to the National Health service of the Republic of Latvia (hereafter – NHS).

We are very grateful for the full support and co-operation of the staff and leadership of the Health Inspectorate of the Republic of Latvia (hereafter – HI) as well as all those available for interviews with the team and for the background information provided about the system in Latvia.

Without their help this report could not have been made.

The findings and reflections of the team are not only addressed to the supervisory organisation but also to the Ministry of Health of the Republic of Latvia and to the other stakeholders of the Health Inspectorate.

We hope that all those involved in the process of improvement of healthcare in Latvia will find this report helpful and supportive.

The Peer evaluation team want to state its willingness to answer further questions and support further developments by using their knowledge and contacts if that would be useful for the Health Inspectorate.

Executive Summary

This report provides a picture of the health inspection in Latvia based on the views of a team of international experts from other countries as seen in the first week of July 2018 based on documents provided to the team and interviews with stakeholders.

The team found the Health Inspectorate of the Republic of Latvia (hereafter – HI) in a process of change. With the strong leadership of the inspectorate, supported by the staff and with the support from the Ministry of Health and the political support this change in attitude and working methods has a good chance of success.

The findings can be summarised as follows:

Improvement of patient safety outcomes

- The Health Inspectorate has an important role to play in Latvia if it could focus effectively on improvement of outcomes of patient safety and quality of care

Independent and transparent judgements

- independent, impartial and transparent judgment are key factors to make this possible

Including the stakeholders

- To fulfil this role a major change must be made towards involvement of stakeholders including patients and medical professionals
- Mediation and involvement of stakeholders such as hospitals, other healthcare providers and insurance companies could help to find solutions to help patients settling their claims and improving the health system at the same time

Inspection methods such as risk-based inspections

- Focus on the further development of inspection methods such as risk-based inspection and further empowerment of the Health Inspectorate itself are important steps forward

Complaints related to claims and Medical Risk Fund (hereafter – MRF)

- The central position of the complaints handling related to claims in the Health Inspectorate is problematic and needs to change
- The complaints and MRF process creates a high burden of work for the health Inspectorate, particularly the experts and sets an adversarial culture between the Inspectorate and the health sector

In this report, the team presents many ideas, options and international practices of “sister” inspectorate organisations. These are provided by way of examples for inspiring thought rather than being copied directly and implemented.

Further training based on a shared vision for further development seems an important next goal. The team will start this activity at the end of August 2018. One of the key factors was if the staff and workforce at the inspection level receive enough support to make a relevant change possible.

This support includes training and a flexible approach towards organisational, financial and legal settings, to make the HI do what is necessary for improvement of the level of patient safety and quality of care in Latvia.

Our recommendations are provided in detail within this report and are summarised as:

1. Re-position the HI as more independent, transparent and accountable entity
2. Move to more of a learning culture (including thematic review of common and systemic problems)
3. Empower the staff (including continuous education, training and fostering an integrated culture)
4. Improve the image of the Inspectorate with the stakeholders and consider re-branding the organisation
5. Focus on improving the quality and safety of healthcare
6. Move from compliance to more co-operative methods of inspection to be a trusted partner for stakeholders
7. Introduce self-assessment as part of the review framework
8. Introduce better risk-based profiling for prioritisation of inspections and better use of indicators
9. Redesign the complaints procedure e.g. consider introducing a triage process, categorisation and a mediation step into the process; use complaints as a tool for learning
10. Improve engagement with health institutions and groups
11. Externalise the Medical Risk Fund (MRF) function from the Inspectorate
12. Separate the (expert) function of determining if an MRF case should receive a pay-out from the assessment of the amount to be paid-out. This could include creating a schedule of payment amounts or ranges (table of compensation) based on problem and severity (i.e. remove the subjectivity)
13. Separate the expertise functions of pharmacy from the existing HI general experts.



The HI will – if supported by the right measures – certainly be able to make the change towards “hitting the target and not missing the point” as it is called in a recent article¹ from New Zealand to point at the problem of setting the right goal for inspectorates to accomplish the kind of improvement of healthcare without unintended consequences.

As the leadership within the HI in Latvia and the government level in Latvia seems to be fully aware of the challenges faced and are putting important steps in place (including this peer evaluation as an early step) to improve the focus and service of the HI and it’s part in improving healthcare outcomes for the people of Latvia, this report might be of some help and support to these developments. The peer evaluation team stands ready to provide any other assistance and advice, as well as facilitate contacts and cooperation with relevant international bodies, as needed.

¹ This expression is used by one of EPSO founding fathers Richard Hamblin called : 30 years down in the wrong rabbit hole: how we got there and how we get out, Leadership Development Centre 2018 Fellow, July 2018

1. Introduction to the report

1.1. General introduction

This report provides a picture of the health inspection in Latvia based on the views of a team of international experts from other countries as seen in the first week of July 2018 based on documents provided to the team and interviews with stakeholders

While elements of this report may appear critical, it is offered in the spirit of opportunities for learning and improvement offered by colleagues.

Readers of this report should keep in mind that this report is written with a critical inside view from other inspectorates in Europe. When we look from this perspective at the Health Inspectorate of Latvia, we see a very hard working and dedicated team of professionals who are work within tight constraints in the setting in which they work and the legal financial framework of their activities. However, we also see that with the help of the Ministry of Health and other stakeholders there are important steps to make to improve the outcomes of patient safety and quality of care in Latvia and make the inspectorate work more rewarding for themselves and for the public.

1.2. Procurement procedure and pre-procurement

As a result of its co-operative relation with the European Partnership of Supervisory Organisations in Health Services and Social Care (hereafter - EPSO) and based on a number of criteria set by the National Health Service of Latvia (hereafter – NHS) for regulations of procurement, Foundation Eurinspect was in 2017 asked by the Procurement Commission to participate in a pre-procurement process and to give input to a feasibility study as a start-up for a possible procurement procedure financed from the European Social Fund operational programme “Development and Employment”²³ on the subject of expert services in the area of healthcare quality and patient safety.

Based on this input a final procurement negotiations procedure was organised by the NHS for regulations of procurement “Expert services in healthcare quality and patient safety domain”⁴.

The actual procurement process started in 2017 and was for Foundation Eurinspect finalized by signing the contract in 31 May 2018.

² Procurement identification No VM NVD 2017/19 ESF

³ European Social Fund Operational programme Development and Employment , specific support objective 9.2.3.to support development and introduction of health network development guidelines and a quality assurance system in priority areas (cardiovascular, oncology, perinatal and neonatal period care and mental health), in particular for improvement of health of residents exposed to the risk of social exclusion and poverty’, project no 9.2.3.0./15/1/001.

⁴ ID No VM NVD 2017/36 ESF

1.3. The main Objectives / Purpose of the projects I, II and III

According to the technical description document of the above-mentioned procurement the subject of the procurement is “expert services in the area of healthcare quality and patient safety” divided into three sub-subjects:

1. Expert services in the area of medical institution supervision
2. Expert services in the area of patient complaint analysis
3. Expert services in assessing the work of the Medical Risk Fund

According to this document the aim ⁵ of this procurement is “to develop the knowledge and skills of the employees of the institution under the authority of the Health inspection and the Ministry of Health in the area of institutional supervision and patient complaint consideration and also to develop the activity of the Medical Risk Fund.”

The Latvian project is not the first project of its kind for Eurinspect foundation in co-operation with the European Partnership for supervisory organisations in Health Services and Social Care (further - EPSO). Comparable Peer evaluation projects have been undertaken for the Norwegian Board of Health and for the Danish Board of Health. In this Latvian project, comparable assessment questions used in Norway (March 2012) and Denmark (June 2014) are used as one input to help to assess the Latvian Health Inspectorate and analyse the current state and procedures of the inspection systems and methods used by the Latvian Inspectorate.⁶

The expert team, in undertaking their analysis, is of the opinion that the three projects have a high degree of coherence and therefore should be described in such a way that the report can be read as a whole and not in three separate reports as could have been done in reaction to the procurement questions. However, and for ease of reference, the answers to the procurement questions are outlined separately (in section 5 of this report).

In summary, the team was asked:

Project I

For the supervision system of the medical institutions in Latvia, to:

- Analyse the current state and procedures:
 - a. choice and application of supervision systems;
 - b. strong and weak points of supervision systems;
 - c. self-assessment methods;
 - d. indicators in supervision of medical institutions and provision of consulting support.
- Reflect on development opportunities for development and improvement of the supervision system of medical institutions in Latvia
- Present suggestions for self-assessment for various institutions and practices.

This includes the provision of at least three examples of foreign good practice by way of comparison while still being applicable to the Latvian context.

⁵ Technical Description. p.1 - appendix 1 to the procurement documents

⁶ refer section 5.1.1

Project II

To improve healthcare quality and patient safety by assessing the normative acts of the Republic of Latvia and the EU regulation in the area of patient complaints in order to identify limitations and submit suggestions for:

- a. analyses methods for patient complaints and accident causes;
- b. implementation of a patient complaint system to indicate events for improvement and development
- c. engagement of medical institutions in the process of complaint analyses
- d. prevention of patient complaints and accident causes engaging the medical institution.

This includes the provision of at least three examples of foreign good practice by way of comparison while still being applicable to the Latvian context.

Project III

To perform assessment of:

- the option of receiving compensation for harm to life or health outside a court procedure as is set in the normative acts of the Republic of Latvia and the EU regulation;
- the proportionality of the amount of harm to patient as is set in the normative acts of the Republic of Latvia.

To submit suggestions for:

- principles for creating the budget for the Medical Risk Fund, management and administration
- methods and criteria of determining the amount of harm to patient life or health as a result of healthcare service provision,
- methods and criteria which influence the amount of harm inflicted to the patient and which are applicable to the situation in Latvia.

This includes the provision examples of good practice for the above by way of comparison while still being applicable to the Latvian context.

1.4. Approach Material and Methods

The team has taken a mixed method approach to this engagement – combining analysis of background documentation, and qualitative data to provide a contextual perspective on the results and analysing the issues from multiple perspectives. The approach of the team included:

- desk analysis of existing procedures, documentation including quantitative data and normative acts of the Republic of Latvia and of the European Union regulations and OECD;
- semi-structured interviews over a concentrated period on a site visit 2nd – 5th July 2018; and
- subsequent thematic analysis and reflection of themes (provided in this report).

1.5. Structure of this report

The report begins with acknowledgements and an Executive Summary followed by introduction paragraphs in the Section 1 and Section 2 on the Settings of the Inspectorate in Latvia with a short description of

- a. the general and legal setting
- b. priorities and policy context
- c. the financial context

The next Section 3 includes several general observations (overall remarks) that affect the system as a whole and therefore relevant to all (and therefore not repeated in each of the separate sections of the report). This section has subsections covering culture, leadership, workload, inspection methods, complaints and MRF (Medical Risk Fund). These overall remarks can be seen as background information while reading the other chapters of the report.

Before providing detailed reflections of the findings of the specific projects, the team found it relevant to provide a broader context of health and social service inspection, monitoring and regulation in Europe and to pin to some of the current trends and focus points as observed by EPSO in the various EPSO member countries and regions. This Section 4 has subsections - Quality and patient safety as priority; Integrated care; Data driven and evidence-based approach; The culture of safety in a supportive environment including instruments used in a supportive approach.

In Section 5.1 the team provides reflections and answers regarding development opportunities and improvement for the supervision system of medical institutions in Latvia (Project I - Expert services in medical institution supervision system)

In Section 5.2 the team provides reflexions and answers regarding Project II - Expert services in the area of patient complaint analyses

In Section 5.3 the team provides reflexions and answers regarding Project III - Expert services in assessing the work of the Medical Treatment Risk Fund.

In Section 6 the team provides their reflections and recommendations.

The team recognises that context and culture are vital features of any Peer evaluation and, as such, has provided several reflections and options rather than strict recommendations to follow.

However, some of the reflections point in the direction of changes in the system that are necessary and can be seen as essential preconditions for a successful implementation of the report.

In order to make a meaningful and practical comparison between approaches in various countries, this report chooses where and when relevant -to give a concrete reference to alternative options in various countries, options for improvement to use as inspiration and concrete best practices. This is explicitly done without giving a full description of those systems and health systems in the countries concerned and does not imply that the examples provided should be adopted or copied without consideration of the local context.

The idea is to make use of the presented options and practices by making a tailor-made system for Latvia, fitting into the local culture and the local political legal and financial environment and context.

Appendix 3 (Description of the Latvian Health Inspectorate using the EPSO Peer Evaluation Framework) uses a best practice set of guiding questions as used for similar EPSO peer evaluations. This contains 13 areas with a set of criteria for each including those set by the International Society for Quality in Healthcare (ISQua) and ISO/IEC standard 17020:19987. It has been used to structure a first general assessment of the Latvian medical institution supervision system. For this assessment questions are answered based on the available information provided to the team, the interviews with the stakeholders (see list in Appendix 2) and staff and leadership of the inspectorate.

Appendix 4 (Selected case studies, international examples and best practices) gives an overview of good practices including links to further information. Rather than providing complete overviews of the Health Inspectorate structure, functions and processes in other countries, Appendix 4 provides selected and explicit examples relevant to the areas of and corresponding key findings from this report. In the central text of this report references are given to these studies, examples and practices.

Appendix 5 (Risk Fund Research for this project – Expert services in assessing the work of the medical risk fund) provides a detailed overview of the MRF purpose, framework, a set of international comparisons and some considerations for future models and options for the MRF in Latvia.

Appendix 6 (ERN Assessment Manual for Applicants - Self-Assessment Checklist for Healthcare e. Cure, (Active PDF)).

2. Setting of the Health Inspectorate in Latvia

2.1. General and legal

The Health Inspectorate in Latvia is a state administrative institution subordinated to the Ministry of Health of the Republic of Latvia.

The Health Inspectorate is to perform state administration functions in the field of supervision and control of the sector, in order to fulfil and implement requirements set by the laws and regulations.

It has a number of control and surveillance functions including performing core functions of the Medical Risk Fund.

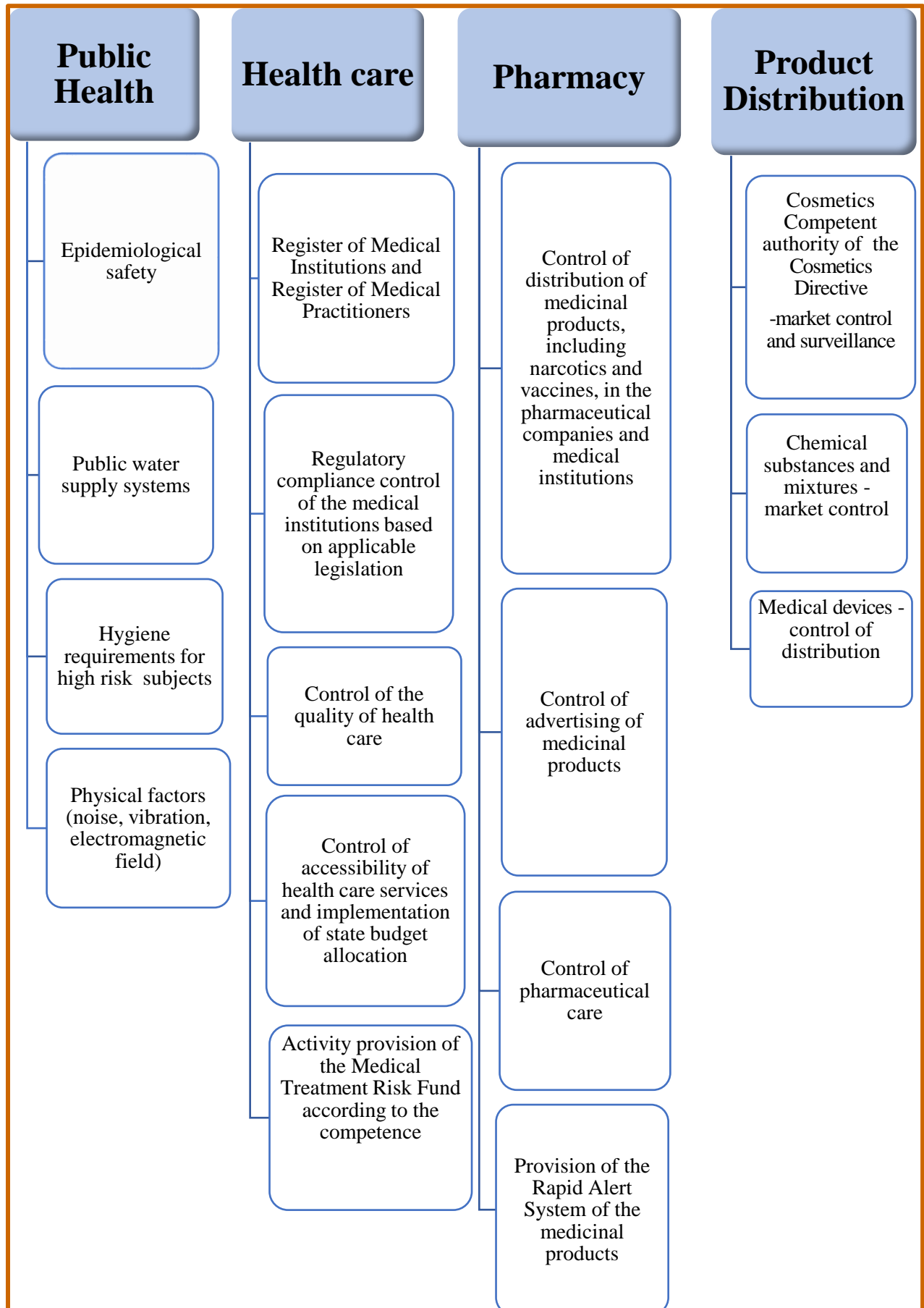
Its main purpose is to reduce the risk for society and consumer health by realizing state surveillance.

Except for the registration activities and the MRF (Medical Risk fund) activities almost all activities are compliance and control oriented as is seen in the schedule below (Overview of tasks of the Latvian Health inspectorate).

The reporting systems are mainly based on quantitative data. Qualitative data are available at an overall level, however, this does not appear to be analysed in great detail and not used for thematic analysis (i.e. assessing where are there systemic problems).

Big data is not used for analyses and goal setting.

OVERVIEW of tasks of the Latvian health inspectorate



2.2. Priorities and policy

The inspectorate has a yearly adjusted set of priorities. These priorities are mainly set by political/government strategy. The priorities are not actively influenced by the Inspectorate itself or by its stakeholders. A bottom-up discussion on priorities and goals, aims and instruments to use for improvement of healthcare is not in place.

The priorities of the inspectorate for 2018 are the following:

Control of organization of health care in children's social care institutions

Controls the compliance of psycho-neurological hospitals/departments with the obligatory requirements for medical institutions, the use of medical documentation and restrictive means.

Control of newly registered medical institutions

The development of self-assessment questionnaire for medical institutions on the provision of qualitative and safe medical services

2.3. Financial context

Latvia has a low expenditure on healthcare in relation to other comparable countries.⁷

Serious reforms have been taking place in the health system as a whole and are on its way in the inspectorate as well. The recent measures for increased funding for healthcare are expected to address some access issues. Furthermore, it seems that as well politicians (Parliament, Minister of Health and Ministry of Health) as well as other stakeholders of the HI are willing to move forward towards an environment of quality improvement.

However, public financing for healthcare remains well below the EU average and some efficiency-increasing measures are still to be implemented, including effective prevention measures, streamlining of the hospital sector, strengthening of primary care and targeting of quality management. Health outcomes are relatively poor and timely access to affordable healthcare for everyone remains a general concern. The relatively high out-of-pocket

⁷ <http://www.oecd.org/health/health-systems/Health-Spending-Latest-Trends-Brief.pdf>

payments and the division of health services into two baskets ("full" and "minimum") risks lowering access for some groups and leading to adverse health outcomes.⁸

All this suggests that Latvia is coming off a low base of healthcare expenditure, provision and outcomes. It is understandable, therefore, that there is significant work to be done by the government and its health agencies to improve healthcare. The HI is part of this broader picture.

Some steps seem to be within both the control and reach of the HI to improve their services.

⁸ P4s12 - Brussels, 23.5.2018, COM(2018) 413 final – European Commission Council Recommendation on the 2018 National Reform Programme of Latvia

3. Some Overall remarks

3.1. Culture

The peer evaluation team starts this review with the principle that every inspectorate needs to work within its existing regulatory framework and legal mandate and in a traditional setting of culture and history. Sometimes there is a blurred boundary between whether processes and procedures are driven directly from legislation or the institutional interpretation given to it over the years.

In this broader context it is important to mention that each healthcare system and model has its own specific context and historic roots.

However, the EPSO experience shows that all supervisory systems have many aims goals and learning opportunities in common.

If we look at the Latvian system with a helicopter view we see that the system is operating in the model of a centralised control system. This system regulation is based on inspection and compliance and an implicit mistrust of public organisations, with a high focus on procedural checking and punishment for variation or infringements.

However, in the current environment we see a strong leadership of the inspectorate and willingness to change with a focus on improvement of the system. This is supported by the Minister of Health and the Ministry and potentially by a number of other stakeholders in Latvia (based on the cross-section interviewed), striving to introduce more of a quality improvement and learning culture.

Even if the policy settings or their interpretation by some staff at the inspectorate level is not yet completely aligned to this evolving culture, the basic setting of the inspectorate leadership appears solid. If enough support is provided, this is a positive start for a process to work cooperatively (in the same direction as other Inspectorates in Europe) towards improvement of quality and safety of healthcare and social care in Latvia.

3.2. Leadership

The leadership of the HI has changed four times in the last two years and the current head of the inspectorate has been in the role for eight months.

While there is strong vision at the leadership level, this is not yet reflected more broadly within the organisation and staff. The peer evaluation team observed strong leadership supported by staff members who experience a heavy workload and, although they approach their work with good will and enthusiasm, nevertheless the impression is that many of them see their role as reviewing documents and procedures and feel stretched and overworked in that setting.

3.3. Workload

The workload of the organisation balances public health, planned health inspection and complaint investigation and processing.

There are over 4500 health organisations that come within the remit of the HI. The current staffing levels and workload within the HI prevent an appropriate and systematic review of all facilities. Inspection methods: The work of the Latvian Health inspectorate can be separated in time spent to control (70%) and time spent to other activities in the office such as preparing control and evaluating documents (30%).

The various inspections are carried out by the Medical Institutions Control Division in Riga and by the four Regional Control Divisions. The inspectorate has a total of 18 inspectorate offices.

The methods used for inspection and control of Medical Institutions can be divided into the following type of control activities; the amount of time used for these activities is roughly indicated behind the various types of activities:

- Scheduled Control – scheduled in advance and carried out in 10 % of the cases in combination with received information or examination of applications

55% of the overall working time is spent to this type of work

- Thematic control regarding a selected policy theme (audits)

10% of the overall working time is spent to this type of work

- Examination of Applications regarding individual cases (work organisation, hygiene, recipes, medical certificates information etc.)

10% of the overall working time is spent to this type of work

- other type of Control such as follow up controls and examination of received information

25 % of the overall working time is spent to this type of work

There is a risk-based profiling methodology used by the HI to assist in prioritising which organisations to inspect. However, the criteria applied do not, in the peer evaluation team's opinion, consider sufficient nor relevant risk factors to be effective. Ideally these risk criteria should consider a mix of outcomes, reported harm events and patient feedback as indicators of risk.

3.4. Complaints and MRF cases

The Complaints and MRF cases as seen in the Latvian Health inspectorate are strongly interrelated by virtue of the process and expert staff – though should not be. The functioning of these two systems is, in the opinion of the peer evaluation team and most interviewees, suboptimal.

The examples of the complaints process and examples discussed with the inspectors and heads of department indicated that there is a strong reliance on experts, mostly from within the inspectorate though sometimes this role is outsourced. The experts review each case on its merits and determine the amount of the payment from the medical risk fund to the complainant.

This is a separate process from civil cases and, if the court is aware that there is a complaint pending under the medical insurance fund, they will not proceed with the civil case until the complaints process has been completed.

Feedback from the experts interviewed indicated approximately 1/3 of all complaint cases have subsequent appeals to their decisions. The process, as described, sounds highly bureaucratic and litigious and has started to drive a business line for some lawyers in Latvia. The procedure used in the complaints cases is comparable to a court procedure. However, complainants and defendants do not bring and pay for their own experts.

Those involved in the cases complain about the length of time that the cases take. Three-month timeframes and longer were mentioned. However, compared to court cases, this time frame is relatively short. The duration of court cases of this type in other countries can be measured in years rather than in months.

There is an open-ended question as to whether the experts are sufficiently skilled and up-to-date with all of the clinical practice and technology to be able to assess all of the cases they manage as an expert. There is also a question as to whether the experts, as medical experts, are the best role to decide both fault and the amount to be paid for damages.

The experts seem to be proceeding like independent judges in types of cases, however without the protection procedures of the defendant and complainant and the independence of judges.

Hospitals are unofficially aware - as Latvia is a small country- of the pending complaint cases against medical staff under their employment by evidence to investigate the case is requested at the relevant facility. However, the hospitals are not officially advised and there is no requirement on the part of the defendant to notify their employer and the facility that they have a case pending against them.

This process has (in addition to other questions it raises) the following effects for the healthcare system as a whole:

- a. There is no proper channel for mediation between the complainant and the hospital/ doctor/ nurse
- b. Each case is regarded as separate and there is no thematic analysis by the HI to identify common (systemic) issues in the health sector to help identify and influence any quality improvement at a systems level.
- c. Public review of the MRF claim cases, Research of the quality of the procedures for the parties involved (for the complainant, for the defendant and for the inspectorate) is not in place. Review of the outcome of the cases and review of the quality of the follow up is not possible.

There is a clear and very direct pathway from complaint to litigation and application for payment from the Medical Risk Fund. There are few gates in the process that could allow for an outcome that the patient/complainant may regard as justice having been served and an effective outcome reached - that do not relate to consideration of payment from the fund and a corresponding binary (yes-no) decision for payment. In many cases, the patient may not want compensation - they may just want an apology, remedy of a mistake or the assurance that steps have been taken to ensure the problem will not happen again to either themselves or another patient.

From the perspective of the peer evaluation team, the current process of the Medical Risk Fund has the unintended consequence of long-term litigation and work without taking steps earlier in the process to resolve the issue via other means (e.g. mediation) or, post the process, to address any systemic issues at source and address the cause rather than the symptom. While its function is clear, the process, workload it creates, and outcomes are sub-optimal.

4. Some current trends in Europe as observed by the team

4.1. Quality and patient safety as a priority

Nowadays quality and patient safety is a priority for healthcare systems and for most supervisory authorities and in many countries and regions. This has not always been the case. Traditionally, many countries have used an authoritarian, inspection or control approach to supervision of healthcare in the sense that inspection and supervision was based on a strictly formal legal framework of mainly organisational and timeframe related norms and standards

to be checked by the supervisory authority. This approach fitted in the more traditional hierarchy of social structure and was strong in many countries.

The EU 2016 report “Strategies across Europe to assess quality of care”⁹ deals with general issues of assessing quality and also has chapters about some European member state experiences in relation to the assessment of quality of care. While this report is not specifically focused on inspectorates, it is written from the EU perspective of comparing the approach for quality of care in Europe and compares and contrasts a number of different systems.

4.2. Quality improvement by measurement of outcome ¹⁰

Quality and patient safety has been investigated using both patient outcomes and measures of process.

4.2.1. Patient outcomes measures

Patient outcome measures include measures such as adverse events, complications, morbidity and mortality. These are the outcomes that healthcare systems aim to prevent through the implementation of patient safety practices.

4.2.2. Measures of process

In comparison to the patient outcome measures, measures of process allow for the identification of system and human errors, and near misses, which enable organizations to implement strategies on the assumption that improving these processes will lead to improvement of patient safety.

Since errors in process do not always lead to patient harm, near misses are also important measures of process.

Conversely, not all adverse events are caused by error and as such, therefore it is vital that patient outcomes are emphasized in any evaluation of quality and patient safety.

4.3. Integrated care

Healthcare has grown complex and needs a co-ordinated organisational approach of integrated care. Traditionally the task of ensuring safety and quality in healthcare has been in many countries¹¹ a component of professional duty, not only for medical doctors but also for other groups as healthcare professionals as well. However, a large proportion of patients need support from different types of professionals. This support needs to be coordinated to be regarded as sound practice. Therefore, not only each individual professional but also the organisation as such is responsible for delivering proper services. The complexity of the care - as it is today - is not limited to within one healthcare organization but extends to the pathway of the patient, sometimes even cross border. This requires an integrated care approach and for the inspectorates in Europe a co-operative approach to supervision with other stakeholders and caregivers.

4.4. Data driven and evidence-based approach

One of the trends with Supervisory organisations is to work toward a data driven and evidence-based approach while monitoring performance towards goals, using data for decision-making, and depending upon a regular follow-up in cooperation with the service providers and professionals involved.

⁹ https://ec.europa.eu/health/sites/health/files/systems_performance_assessment/docs/sowhat_en.pdf

¹⁰ Directorate of Health Norway (2005)and its going better ! national strategy for quality improvement

¹¹ for example in Norway - see Healthcare welfare and Law , Geir Sverre Braut, p136

4.5. A 'culture of safety' in a supportive environment

To achieve safe patient care, emphasis is placed on ensuring a 'culture of safety' that involves establishing a supportive environment where health professionals can identify errors or near misses and analyse why and how these may have occurred. There is a trend in a number of countries now implementing blame-free reporting in combination with a policy of reporting near misses by hospitals and healthcare professionals. Within this environment, patient safety practices, such as clinical supervision (CS), can be implemented to address the problems identified and reduce the likelihood of injuries.

A commitment to a supportive approach for quality improvement is seen in many countries. This supportive approach, where supervisor's health workers and health services work together to solve problems and improve performance of the system as well as work together to support individual health professionals is a challenge and aim for many inspectorates and regulators in Europe.

Supportive supervision is a process of helping staff to improve their own work performance continuously. It is carried out in a respectful and non-authoritarian way with a focus on using supervisory visits and the supervisory process as an opportunity to improve knowledge and skills of health staff, organisations and the health system.

Supportive supervision encourages open, two-way communication, and building team approaches that facilitate problem solving.

4.5.1. Instruments often used by inspectorates in a supportive approach:

4.5.1.1. Internal control as Clinical governance in social and health services

For this internal control an instrument that is often used is self- regulation, self-assessment, self-monitoring, or other internal quality control systems¹². Section 6.1.1 (more proactive using self-assessment) outlines some of these practices in more detail.

4.5.1.2. Training of Staff

On-the-job-training, internal and external coaching as well as international exchange programs - often combined with other types of international cooperation such as participation in working groups and international projects - are often used as improvement tools for inspectorates to implement new working methods in the organisation.

4.5.1.3. Engagement strategy

Most inspectorates in Europe are using specific instruments to set up an engagement strategy with their stakeholders. Finland has selected and practice a number of instruments such as¹³:

- interactive supervision
- regional events
- guidance
- assessment tools
- municipal initiatives

¹² For more information, refer also: Braut G.S. (2003) Public legislation and professional self- regulation : quality and safety efforts in Norwegian healthcare in B.J.Yongberg and M.J.Hatlie, The Patient safety handbook Boston : Jones and Barlett Publishers.

¹³ Refer Appendix 4 – Section 7.1 Engagement of Stakeholders - Finland

4.6. OECD Best practice principles for Regulatory Policy

In 2014, the OECD published a report with a set of principles to help guide regulatory enforcement and inspections¹⁴. This paper distilled a number of examples into a set of 11 principles. The main hypothesis is that an increasing number of OECD countries are coming to realise the importance of the enforcement phase in ensuring the quality and effectiveness of regulatory policy and delivery and for reducing the overall level of regulatory burdens imposed on businesses and citizens.

Increased attention is being given to the efficiency of the enforcement phase in the regulatory governance cycle and promoting proportionality in enforcement (proportionality being here understood both as allocation of resources proportional to the level of risk, and to enforcement actions proportional to the seriousness of the violation). Achieving efficiency improvements can follow from a review of the overall policies, the institutional framework and the tools used by regulatory agencies. It corresponds to a greater reliance on risk analysis and on a more targeted approach to the use of inspection and enforcement resources. Relatively little focus has been given to consistently improve the way regulatory enforcement and inspections are organised and delivered. There is thus considerable potential for reducing regulatory costs on businesses and citizens through improving the efficiency and effectiveness of inspection services.

Reform of inspections and regulatory delivery to make them more compliance-focused, supportive and risk-based can all lead to real and significant improvements for economic actors, even within the framework of existing regulations. Finally, the reform of enforcement and inspections is as much about changing methods and culture as it is about reforming institutions organisational mechanisms and legislation.

The 11 principles outlined in the OECD report include:

1. Evidence-based enforcement
2. Selectivity
3. Risk-focus and proportionality
4. Responsive regulation
5. Long-term vision
6. Co-ordination and consolidation
7. Transparent governance
8. Information integration
9. Clear and fair process
10. Compliance promotion
11. Professionalism

¹⁴ . <http://dx.doi.org/10.1787/9789264208117-en>

5. Medical Organisation Supervision Procurement Questions

5.1. Project I – Expert services in the area of medical institution supervision system

Analyse the current state of the inspectorate for the supervision system of the medical institutions in Latvia, to:

- Analyse the current state and procedures:
 - choice and application of supervision systems;
 - strong and weak points of supervision systems;
 - self-assessment methods;
 - indicators in supervision of medical institutions and provision of consulting support
- Reflect on development opportunities for development and improvement of the supervision system of medical institutions in Latvia
- Present suggestions for self-assessment for various institutions and practices. This includes the provision of at least three examples of foreign good practice by way of comparison while still being applicable to the Latvian context.

5.1.1. The current state and procedures of the inspectorate

The current state of the supervision system of the medical institutions in Latvia including its strengths and weaknesses is described in Appendix 3 - *Description of the Latvian Health Inspectorate using the Peer Evaluation Framework*.

This uses a framework of the following 13 areas to consider the current state of the inspectorate

1. Statutory basis clear and functions clearly defined
2. Independence, impartiality and integrity
3. Confidentiality and safeguarding of information
4. Organisation and management
5. Quality systems
6. Personnel (capacity and capability)
7. Facilities and equipment
8. Inspection methods and procedures
9. Engagement and communication with the organisation or individual subject to review
10. Openness and transparency
11. Disciplinary sanctions
12. Impact assessments
13. Co-operation and engagement with other stakeholders including other supervisory bodies.

While this appendix provides a detailed narrative, key highlights relating to the procurement questions as outlined above include some relevant areas for development and improvement of the supervision system of medical institutions in Latvia.

5.1.1.1. Independence

In its current state the HI is subordinated to the Ministry of Health reporting directly to the Minister of health. The functions are clearly defined by legislation and the Operation of the Inspectorate is regulated by Regulation No 76 of the Cabinet of Ministers "Regulations of the Health Inspectorate", dated 05.02.2008.

The purpose, task and functions are outlined in http://www.vi.gov.lv/en/start/_142/functions

Its purpose is at least internally within the inspectorate clearly known as to reduce the risk for society and consumer health by realizing state surveillance. The Health Inspectorate is to perform state administration functions in the field of supervision and control of the sector, in order to fulfil and implement requirements set by the laws and regulations valid in the said sphere.

Its task is to ensure legal, professional, consistent and competent state surveillance and control in health sector, taking part in such policy realization as public health, health care, pharmacy, drug and psychotropic substances legal circulation and consumer rights protection.

The external and internal perception is that it is for all its functions highly dependent on the Ministry of Health and therefore not operating independently. The external opinion is that there is reason for not trusting the opinions of the HI. Whether this image is correct or not is not a value judgement being made by the peer evaluation team. The team did not evidence any indication of unfair, incorrect or otherwise inappropriate functioning of the inspectorate. However, the perception of mistrust from stakeholders was quite clear.

As the team is of the opinion that the inspectorate is in need of and deserves empowerment of its function to make its work more worthwhile, effective and appreciated by the outside world in Latvia, some formal measures to make the inspectorate seen more as an independent institution could be useful. These formal measures could be legal settlement of the HI as an independent governmental organisation with direct reporting to the board of Ministers of Latvia, independent chairman appointed for instance for a fixed term.

Most countries have a more formal or informal independency set by the culture of the country, by formal or informal status of the chairman or by other legal measures ¹⁵ Some countries do not have formal independence of the regulator (e.g. the UK). In England this has led to politically driven decisions about the dismissal of the chairman or board members. From an outside view this does not seem to be helpful to improve the quality of the organisation and its effectiveness. The saying goes: ‘no progress without mistakes’. This, in our opinion, is also true for progress in supervision systems.

5.1.1.2. Choice and application of supervision systems

The choice and application of supervision systems including strong and weak points is described in Appendix 4, Section 8 (Methods of inspection/ supervision).

However, answering to the procurement questions more in detail the peer evaluation team comes to the following conclusions and comments on the choice and application of supervision system

5.1.1.2.1. Measurement and Risk based approach for inspection

In its current choice of systems, The Latvian Health Inspectorate has a high degree of regulation and procedure – from what was evidenced, this is well documented and followed.

Inspections by the HI place a heavy focus on procedural checking against legislative compliance and this is typically carried out by the checking of procedural documents in each site and the proof of compliance against these regulations.

¹⁵ For instance Norway's chair is appointed for a number of years and can only be dismissed by the crown (ministers and king); the Netherlands inspectorate does not have a formal independency of the organisation but has traditionally a chair with a high status; Portugal has an independent board with a broad political background which is appointed for a number of years without option to dismiss.

Quality of care is not measured by the Inspectorate in terms of process, nor outcomes. Measurement of the process of improvement of patient safety and quality of care is not an organisational concept of the Inspectorate.

Current measurements used by the HI are volume based (i.e. how many inspections were conducted, how many complaints were reviewed) and, within the inspections, many of the measurements relate to the volume of documents that were reviewed for compliance.

Most of the measurement is based on data regarding numbers and timescales and give no insight in quality of care and outcomes.

The so called “soft information” and the “qualitative information” is mainly still missing in most of the overview documents provided to the team. However, it seems that a great quantities data system is providing results in terms of number of reviews, numbers of staff, number of patients timetables etc. The objectives of the inspectorate itself are clear. These objectives of the inspections are for patient safety and quality of care, however, the outcomes in these field are not assessed and not measured. As a result, there is no knowledge on what the results have been achieved in terms of patient safety and quality of care based on the HI’s interventions.

To the opinion of the peer evaluation team, one of the important improvements for the Health inspectorate could be to move towards a more measurement (process and output) oriented approach and work towards risk-based inspections

The output measurement might be done in co-operation with The Centre for Disease Prevention and Control, which seems to work on some early stage developmental in this direction. Currently there does not appear to be a sharing of this reporting with the HI to assist them in identifying and prioritising inspection of organisations. An option is to share and work together.

Another option could be to develop some outcome indicators following for instance the Swedish model. Development of outcome indicators is complex and could easily get out of hand (too costly, too complex and too many indicators¹⁶) and bureaucratic with high costs as was evidenced in some of the EPSO countries and regions in the past.

On the topic of announced and unannounced inspections the peer evaluation team noted that both types of inspection are used in many EPSO member countries.

Both have a number of pros and cons. ¹⁷ Unannounced inspections do not really fit in a high trust partnership with health institutions. Furthermore, unannounced inspections have the disadvantage that wrong impressions can easily be set. However sometimes an unannounced inspection gives a clear perspective on how things work in a “normal” situation for a “normal patient”. If the unannounced inspection is combined with proper verification of the findings it can be a very useful and effective instrument.

5.1.1.2.2. Communication and engagement strategy

Specific results of inspections are shared with the institutions being reviewed and there is a right of reply from the institution.

¹⁶ England has a long term experience in developing indicators however after all the number of indicators grew enormously and was not useful anymore; new methods were introduced; France stopped the top-down development of indicators as it was getting too complex; Netherlands has been looking for a long time for predictive indicators but did not fully succeed and is now working with a mixed system of inspection input and some indicators; Sweden has a low profile , simple and seemingly useful risk based system based on its own inspection input; the EPSO Risk working group is led by Denmark working on a system for Risk based inspections with a mixed system, results are not yet available

¹⁷ see Appendix 4 (selected case studies), section 8.3 (other methods of inspection)

However, an organised open feedback system does not seem to be in place. Communication seems to be mainly top down from the Health Inspectorate to the healthcare professionals, patients and the public in general.

There is no public reporting of results including thematic analysis and reporting of themes of issues that the HI are discovering. Neither is this information shared with the medical society or hospitals, the Nurses association and other stakeholders.

The current risk-based assessment as to how structured inspections are prioritised is subjective and not based on a shared view of priorities with stakeholders including parliament and Ministry.

There is a template used for assessing the amount for claims – however, this is an internal document and is not visible to the public. Discussions with various stakeholders indicated variation and little team-based approach in the way in which claim amounts were calculated by the experts individually. Some inspections take place as unannounced inspections. This is different and separate from the complaint process.

The complaint process does not seem to be a main input for the risk analyses or other inspection targets (systematic quality based thematic inspections).

In all these fields of communication there is room for improvement.

However, the peer evaluation team wishes to emphasize that communication as such is not an option if the input is not used in an appropriate way and the communication is not based on an open 2-way system.

A combination of fear and punishment lead to a low trust communication or no communication at all. This will not lead to a culture of open 2-way communication nor support for quality improvement initiatives.

If an open trust community with stakeholders and other partners is going to be formed and aimed at meaningful communication and improvement of healthcare, it seems inevitable that the inspection must distance itself from:

- the top down compliance culture with a focus on non-compliance and punishment
- the strong partnership in the compensation claims against doctors and hospitals.

5.1.1.3. Strong and weak points of the supervision systems

From our assessment, the strong points of the current supervision systems include:

- A well-documented set of procedures
- Strong leadership
- The objectives of the inspectorate are clear
- The recognition of a need for risk-based profiling to determine prioritisation of inspections.
- Strong knowledge of the procedures and compliance requirements and legislation requirements for healthcare institutions, facilities and professionals
- Specific results of inspections are shared with the institutions being reviewed and there is a right of reply from the institution.

The weak points (and therefore opportunities for improvement) include:

- The current risk-based assessment as to how structured inspections are prioritised is subjective and not based on a shared view of priorities with stakeholders including parliament and Ministry.
- There is a template used for assessing the amount for claims – however, this is an internal document and is not visible to the public. Discussions with various stakeholders indicated

variation and little team approach in the way in which claim amounts were calculated by the experts individually.

- There is no thematic analysis undertaken to assess common themes and trends of issues across providers and therefore systemic issues to be addressed across the sector.
- The objectives of the inspectorate itself are clear. These objectives of the inspections are for patient safety and quality of care. However, the outcomes in these field are not assessed and not measured. As a result, there is no knowledge on what the results have been achieved in terms of patient safety and quality of care based on the HI's interventions.
- Quality of care is not measured by the Inspectorate in terms of process nor outcomes. Measurement of the process of improvement of patient safety and quality of care is not an organisational concept of the inspectorate.

Appendix 3 (Assessment of The Latvian HI using the EPSO peer evaluation questions) provides further detail and narrative on many of these points.

5.1.1.4. Self-assessment methods

While the HI has acknowledged the need to explore and develop self-assessment methods and tools, these are yet to be put in place. The Peer evaluation team regard this as a useful step to put in place to move to a more pro-active method of ensuring quality and patient safety.

Examples of self-assessment practices are described in Appendix 4, Section 6 (Self-assessment and Incident Reporting).

The European Commission, European Reference Networks (ERN), published the Self-Assessment Checklist for Healthcare Providers in 2016 which provides a useful set of criteria and corresponding questions for self-assessment.¹⁸

This list focuses on a number of topics related to various elements of the performance of healthcare institutions. However, the list has quite an instrumental and system-oriented approach and it is not clear for all of the topics if the outcome and the results of the healthcare institution is what the inspectorate is expecting from the institution as “good and safe care”

This ERN guide is a useful starting point for further internal discussion within the inspectorate and in cooperation with the stakeholders to assess what could and should be reviewed in the Latvian context and why.

The start of every self-assessment instrument should be: What is our aim as inspectorate and as healthcare community in Latvia and how do we inspire our health institutions, doctors nurses, etc. to work with us in the same direction; to do so you need the support of the institutions to look at quality items and improvement.

5.1.1.5. Indicators in supervision of medical institutions and provision of consulting support

In considering this topic, the peer evaluation team looked for evidence in the HI of a balance of indicators across organisation, process, system and outcomes that are typical of a highly functioning and mature Inspectorate to help assess:

1. The risk areas that are markers for risk profiling and corresponding prioritisation of organisations, facilities and/or professionals for review; and,

¹⁸ . http://ec.europa.eu/chafea/documents/health/8-self-assessment-for-hcp_en.pdf

2. An assessment of the impact that the inspectorate's activity is having on their stated mission (patient safety and quality).

What was found in Latvia was a focus by the HI on organisational measures including size, number of services, complexity of services and patient throughput/volumes. There are a number of procedural (as opposed to process) measurements that assess whether the organisation being reviewed complies with legislation and procedures.

Other examples of indicators that were provided to the peer evaluation team by the HI included statistics on the number of examinations conducted within what period across the various functions conducted by the HI.

There is a 'risk-based' profiling methodology used by the HI currently. This considers 5 areas:

1. Potential influence of society (GP- small, hospital-big)
2. Influence of the facility/organisation (GP, hospital); (i.e. the number and complexity of services)
3. How complicated is the legislation relating to the facility/organisation
4. How many patients under the relevant facility/organisation (i.e. volume)
5. Reputation based on
 - An internal score, checklist score based on last 3 years
 - A checklist filled by inspector
 - Complaints/claims.

The Peer evaluation team regard many of these either as subjective or not good indicators of risk.

The Peer evaluation team believes the Swedish system represents a useful risk-based approach as a low profile and relatively simple and low-cost system.

However other systems also contain useful lessons, this includes the systems in France and England which, although quite complicated and expensive, certainly have several interesting elements to consider.

Appendix 4, chapter 8 (Methods of inspection/supervision) outlines a number of practices regarding risk-based inspection including the Swedish system.

5.1.1.6. Reflection on development opportunities for the supervision system

The HI is an integrated team that serves a number of functions. Rather than reflect on just one aspect of the opportunities for development and improvement under this project, the peer evaluation team offers their overall reflection in section 6 of this document (Reflections and Recommendations of the Team). It is difficult to splice out those that relate solely to this element of the review (project 1) – as many of the recommendations are inter-related and (if followed through) should positively impact the various services and functions of the HI.

5.1.1.7. Self-assessment suggestions

If the goal is to focus the supervision from reactive measures to more proactive guidance and monitoring, then self-assessments can be used as one of the methods to supervise and evaluate the learning capability of health care providers, who are at the end responsible for the quality of care they deliver.

Presently there is no self-assessment system established in Latvia for supervisory purposes in HI work, however, it has been outlined as one area of focus in some of the HI documents provided to the peer evaluation team.

In Finland it is claimed that self-monitoring (self-assessment) carried out by service providers themselves is, and ought to be, the most effective form of supervision. They see the role of the supervisory authorities is to offer support and guidance to the social welfare and health care service providers as they undertake self-monitoring. National Supervisory Authority for Welfare and Health of Finland (hereafter – Valvira) has, for many years, placed great emphasis on providing support and guidance to service providers undertaking self-monitoring. Self-monitoring is now an integral part of all their supervisory activities. As a result, the quality of self-monitoring undertaken by the service providers has improved significantly in the past few years.¹⁹ .

Self-monitoring allows organisations to target their resources at higher risk areas and activities, to adopt a plan-led approach to their work and to develop a greater awareness of the quality of the services they provide. Any shortcomings must be prevented and addressed as close as possible to where the services are actually provided. This will also reduce the need for the supervisory authorities to address service providers' activities retrospectively and to avoid the additional work and costs that arise from such supervision activity.

Self-assessment should be designed to identify, prevent and address shortcomings in health care service provision.

Self-evaluation should always be able to answer following questions:

- Did we do what we promised?
- Did we make a change?
- Are we doing the right things?

Examples of self-assessment practices are described in Appendix 4, Section 6 entitled 'self-assessment and incident reporting' which sights examples from Denmark, The Netherlands, Sweden and Finland.

¹⁹ See Appendix 4, Section 6.4 (self-assessment and incident reporting – Finland)

5.2. Project II - Expert services in the area of patient complaint analyses

To improve healthcare quality and patient safety by assessing the normative acts of the Republic of Latvia and the EU regulation in the area of patient complaints in order to identify limitations and submit suggestions for:

- analyses methods for patient complaints and accident causes
- implementation of a patient complaint system to indicate events for improvement and development
- engagement of medical institutions in the process of complaint analyses
- prevention of patient complaints and accident causes engaging the medical institution.

5.2.1. Complaints and incident reporting; assessment of the Latvian Complaints system

In this section, the team reflects on improvement of healthcare quality and patient safety in patient complaints in the Latvian context.

The process for filing a complaint is clearly outlined, including an electronic/on-line form for lodgement of complaints. (<https://www.latvija.lv/Epakalpojumi/EP113/Instrukcija>)

Approximately 40% of the HI's workload relates to complaints.

The patient related organisations and individuals with whom the peer evaluation team met describe the application process as large, detailed, difficult and bureaucratic. It requires a high degree of technical detail.

The process involves case file review and the complainant/patient is interviewed as part of the complaint process.

Once the complaint is lodged, the patient is not consulted by the HI and there is no opportunity for the patient to meet with the HI or to engage their own expert to help present their case. There is no structural assistance to lodge a complaint

There is a lack of transparency on the claims process, its status and its outcome. Patients may apply for the full case notes but, as this fact is not widely publicised, the patients are not aware of this and therefore do not.

As there is a shortage of staff and capacity to deal with complaints the inspectorate finds it difficult to "promote" the complaints and to invite people to use the complaint process in order to make their experiences visible and part of a learning process.

Medical organisations involved in MRF cases and the relevant colleges may also apply to find out the outcome of complaints procedures but as there is no notification as to when the case has been completed, the organisations are not aware of when they can apply for the outcome and notes from specific cases. As cases may take quite a while it is not so easy to find out the status of the complaints

The outcomes of the complaints and results in terms of improvement of procedures are not openly published on a website or elsewhere visible for those involved in the process. It is not easy to use complaints for research and inspection purposes as they are not electronically filed and easily in detail approachable.

The idea of informing a person or an institution about a complaint or procedure that is launched against him or it is one of the fundamental rights on which any fair trial is based, namely the right to be heard and the right to give your view/opinion on the facts that are used in the procedure. More specifically, the principle of equality of arms is one of the basic rights which includes that both parties in any procedure always have to be in the same position in relation to information and available documents. In general, it is a fundamental tenet of article 6 ECHR (Convention for the Protection of

Human Rights and Fundamental Freedoms EVRM) which is not only applicable in criminal law but in all legal and comparable settings in which parties are launching complaints or claims. This principle originates from ancient Roman law: “Audi at alteram parte”.

Health care providers, in cases of complaints, have the right of third parties as stipulated by Art 28 of the Latvian administrative law <https://likumi.lv/ta/en/en/id/55567-administrative-procedure-law>.

The heads of the Health Inspectorate spoken to by the Peer evaluation team stated that there was a high workload and the staff are stretched. Complaints (and applications to the Medical Risk Fund) have increased 5 times over the last 15 years, however, staffing numbers have not grown correspondingly. The Patient complaints process and the Medical Risk Fund in Latvia are closely linked by virtue of the process and staff within the HI – a link which should be avoided.

Each complaint is considered by the head expert (doctor) and there is no triage process of cases whereby each case is considered by severity and impact, categorised (and therefore managed) accordingly. Each complaint involves a medical file review – which is a lengthy process.

Complaints are all following (in principle) an identical pathway. There is no difference between cases in which serious events or near misses in serious cases are handled and other more common complaints. For our advice on serious accident and incident reporting, refer section 6.1.8 (Project II Reflections of the team regarding complaints)

5.2.2. Analysis methods for Patient complaints and accident causes

Complaints, if registered in an appropriate and searchable way, can be helpful to support inspection on priority level and to support a risk-based approach to inspection (and profiling of cases to track trends and themes).

Each complaint results in either the patient being found not to have a case, or the healthcare provider being punished.

There are currently no gateways in this process for mediation or alternative dispute resolution.

The culture of blame, attribution and punishment leads to a potential underreporting of medical errors and serious event reporting which has a corresponding impact on quality improvement.

There is no thematic review of cases by the HI for subsequent analysis for quality improvement purposes.

An effective classification and indexing system is needed to register patient complaints, profile any trends (either by institution, professional or broader systemic issues across multiple providers) and record the process, actions and outcomes of the case for future research.

5.2.3. Engagement of medical institutions for analysis and future prevention of incidents

There is no evidence of this engagement taking place in a proactive way currently between the HI and the various medical institutions. There is an opportunity to move toward this using thematic analysis to find the systemic problems relating to a particular professional group or facility and use this as a learning opportunity for quality improvement. This requires a move away from the punishment regime to one of learning and improvement. It does require a level of trust and flexibility from the HI and, in return, a level of ownership and proof of effective change in behaviours and outcomes from the members of the relevant medical institution. This does not advocate for a relaxing of the need to ensure patient safety – rather it encourages the broader research of issues and adoption of professional standards to prevent harm in future (to err is human!).

5.3. Project III - Expert services in assessing the work of the Medical Risk Fund

The team performs assessment of the Medical Risk Fund and reflects on the option of receiving compensation for harm to life or health outside a court procedure as is set in the normative acts of the Republic of Latvia and the EU regulation and assessment of the proportionality of the amount of harm to patient as is set in the normative acts of the Republic of Latvia. In this chapter the team also submits suggestions for:

- a. principles for creating the budget for the Medical Risk Fund, management and administration
- b. methods and criteria of determining the amount of harm to patient life or health because of healthcare service provision
- c. methods and criteria which influence the amount of harm inflicted to the patient and which are applicable to the situation in Latvia.

5.3.1. Main characteristics and assessment of the Latvian Medical Risk Fund

Further to the adoption - on 9 March 2011 - of EU Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, several EU member states adopted various systems for regulation regarding systems for professional liability insurance, or a guarantee for similar arrangements.

The Directive did not oblige Member States to adopt a specific or new type of system different from their own regulation. However, according to article 21.1 of the Directive member states shall bring into force the laws, regulations and administrative provisions necessary to comply with Directive by 25 October 2013.

To comply with the Directive Member States, have to provide patients with an understandable complaint procedures and mechanisms enabling them to request remedies in accordance with the national law of the Member State of treatment if the health care provided is harmful. The European Commission shall according to the article 20 of the Directive conduct an assessment of the systems and practices put in place in the Member States by 25 October 2018.

In connection with this Directive and based on the example of mainly Denmark, the compensation system in Latvia was established by amending the Law on the Rights of Patients²⁰ (LRP). The main issues and means of compensation are dealt with in Articles 16²¹, 17²² and transitional provisions. The Medical Risk Fund became operational 25 October 2013.

²⁰ Pacientu tiesību likums. Text available at <https://likumi.lv/doc.php?id=203008> . Explanatory note with original draft presented to Seimas is available at <http://titania.saeima.lv/LIVS11/SaeimaLIVS11.nsf/0/3D79353E2F730131C2257BDE00426F87?OpenDocument> .

²¹ section 16 of the Law on the Rights of Patients includes a patients right to compensation for any harm including moral harm caused to life or health by a medical practitioner working in a medical treatment institution.

²² section 17 of the Law on the Rights of Patients includes the Medical Treatment Risk Fund funding as a state budget and health services contribution based organisation run by the National Health Service

The Main characteristics of the compensation system are as follows:

1. The patient has a right for compensation for any harm, including moral harm, in the amount of the harm caused, but not more than 142 290 euros that was caused to a patient after 23 October 2013 (LRP art 16.1 and 16.2.1; transitional provision 1).
2. The patient has a right for compensation of medical expenses incurred to him or her (for eliminating or reducing the consequences) - in the amount of the expenses incurred, but not more than 28 460 euros (LRP art 16.1 and 16.2.21).
3. Harm should have been caused by medical practitioner working in health care institution (LRP art 16.1). There is no difference if the service provider is public or private as well as if the services rendered were paid by public funds or by patient him/herself. Not only doctors, but all medical personnel with certificates are covered by the insurance.
4. Harm was caused by acts of such persons or because of failure to act (LRP art 16.1).
5. Treatments received within the framework of clinical trial are not covered by fund (regulation 1268 art 11).
6. Compensation for harm and expenses is paid by the Medical Risk Fund upon an application submitted to the National Health Service (LRP art 16.2 and 16.6). Format of the application is foreseen by regulation (regulation 1268 annex 1), documents proving the expenses must be added (regulation 1268 art 4). In case application and/or annexes are incomplete, the NHS gives deadline for producing proper documentation (regulation 1268 art 5).
7. In case of death of the patient, compensation can be claimed by heirs (regulation 1268 art 31).
8. Compensation is not paid in cases of late application as well as when compensation is paid during other proceedings (LRP art 16.5).
9. Proceedings should be concluded within 6 months, in exceptional circumstances it can be prolonged up to 1 year (LRP art 16.6).
10. Compensation should be transferred to the applicant within 90 working days from positive decision (regulation 1268 art 14).

The Main characteristics of the Medical Risk Fund are as follows:

1. The MRF is formed by contributions paid by the collective of health care providers in amounts determined by Cabinet (LRP art 17.1 and 17.3);
 2. The fund is run by the National Health Service (LRP art 17.2; Regulation 850 art 3.26) who also has a duty to collect the contributions and pay out compensations (Regulation 850 art 4.21). More concretely - The Health Inspectorate conducts an expert assessment, prepares an opinion and determines the extent of the damage as a percentage, as well as evaluates the assesses the need for health care expenses in order to reduce or prevent the consequences of harm to the patient (Regulation 1268 art 2.1; art 7).
- In the framework of evaluation of cases the Inspectorate has full access to all medical documentation, is able to ask for an expert opinion or to ask the establishment of a commission who will have to evaluate the case (Regulation 1268 art 8). The National Health Service administers the funds of the Medical Risk Fund and on the basis of the opinion of the Inspection, decides on payment of the compensation or refusal to pay it, as well as payments of remuneration from the Fund (Regulation 1268 art 2.2).

3. The amount of compensation is established by the Inspection according to annex 2 of the regulation 1268 taking into account 10 criteria (for example, a causal link, the patient participation in care process, the severity of damage, the contribution by the provider for remedying the situation etc.) (Regulation 1268 art 9). The Inspection's statement to the NHS contains its opinion about existence and extent of damage as well as circumstances that cause refusal to pay compensation (for example, missing causal link, no professional error, no damage etc.) (Regulation 1268 art 10 and 12).
4. The amount of the contributions by the health care providers to the fund are calculated by the NHS and invoiced once per year (Regulation 1268 art 18; method in art 23-26, 28) and it will not be changed during the year (regulation 1268 art 27). Payments are normally done on quarterly basis (Regulation 1268 art 20). A special formula is used to calculate the risk amount payable by each medical institution, based on the number of employees in the medical institution and the distribution of these healthcare professionals across the risk groups.
5. The National Health Service has a right to deduct insurance payments due from payments the service ought to pay to the health care providers for their services (Regulation 1529, art 276; Regulation 1268 art 21).
6. Both the National Health Service as well as the Health Inspectorate are obliged to share publicly information about Medical Risk Fund (Regulation 1529, art 10.2.5).
7. Proceedings of the Fund are based on administrative law (LRP art 17.2).
8. The fund is allowed to use its resources only for settling claims (LRP art 17.4).
9. The National Health Service has a right to recovery from the provider who has not paid the contribution but on whose behalf the Fund has made payment of compensation (LRP art 17.5; Regulation 1268 art 22).

A more detailed analysis is provided in the Appendix of this report. A summary of the key points includes:

This Latvian implementation of the EU Directive in national law seems to go further than necessary to comply with the Directive. The scope of the fund payments includes not only patients but also next of kin (heirs); the compensation of damage includes also moral harm.

5.3.2. Main problems of the current system of the Medical Risk Fund

During the evaluation process range of stakeholders as well as those who are responsible for the liability insurance system were interviewed. On the basis of data collected main problems of the current system seem to be:

1. Lack of human resources, professionalism – there are currently 3 persons in the NHS dealing with the MRF issues and additionally experts/other officials in the HI are mandated to perform different tasks for the fund. For the HI people this is in addition to their usual workload. At the beginning of the MRF expert division in HI was divided into 2 parts so 1 would be dealing only with MRF expertise. But as there were no additional funding for extra posts allocated, this settlement caused heavy workload for experts dealing with other matters than MRF and the unit was merged.

Therefore, processing the cases takes relatively long time.

Many stakeholders highlighted that as current permanent experts to the HI are not practising health care professionals who engage in continuous professional training, and therefore are not able to assess and evaluate activities concerning all disciplines. Also using modern tools, as e-solutions, seems to be rather low among the experts and overall in MRF processes.

There is very scarce outside expert/professional associations involvement in MRF proceedings to remedy the shortcomings with the expertise. Patients are not allowed to appoint (independent) experts themselves to provide the assessment in proceedings.

2. There is no such as thing as in other countries ²³an obligation to address the complaint to the provider first.²⁴ (streamlining the procedure mandatory or voluntary) In some countries the providers have the obligation to have a complaints commission and in some cases there is provided a limited amount of compensation for complainants by addressing the independent hospital complaints commission²⁵. Often insurance companies are involved in settling the claims with the complainants ²⁶ In Latvia there is no requirement to have a previous contact with the provider and streamlining of complaints is not regulated.
3. Mediation options are not standardised and not provided before dropping a complaint or claim. There is no mandatory pathway to follow for claims / complaints to the MRF except that apparently the court is not accepting complaints directly. However, the person can address directly the MRF without trying to settle the case beforehand with the provider or otherwise. The inspectorate has no task in mediation of complaints / claims. This lack of structure creates unnecessary burden to the fund. Furthermore, a number of cases could have been solved among provider and patient without outside engagement if a mandatory structure including information about this and mediation would have been in place This concerns issues of attitudes, communication but also legal structure to make the system work smoother. Having an opportunity to mediation including appropriate information about the outcomes of the system without mediation could have decreased the pressure to MRF.
4. Managing the data collected in categories and in such a way that the data are approachable for the inspectorate and useful to support the inspection policy (long term policy, short term policy, risk approach, certain categories based on national policy and priorities of the Health ministry.
5. MRF does collect and process data about (alleged) medical errors and events. Such a data is not used for learning purposes as well as for identifying general problems instead of dealing with single cases only.
6. Public awareness about MRF – public awareness about the fund is very low. Also, stakeholders involved, including HC providers and their unions, are not very sure about activities and frameworks of the fund.

There is a section about MRF on the webpage of the NHS²⁷, but it is not visible and easy to approach. Most patients – even highly educated ones – found it difficult to use the MRF without further professional assistance. It is not clearly evident from the webpage how MRF proceedings differ from court proceedings (e.g. faster, no fee, simpler burden of proof etc.)

²³ in Portugal hospitals have an online complaints book to file a complaint with a hospital.

²⁴ Sweden all complaints go the provider ; the inspectorate investigates serious complaints

²⁵ the Netherlands max 2500 euro by the independent

²⁶ Portugal, the Netherlands

²⁷ Available at <http://www.vmnvd.gov.lv/en/cross-border-healthcare-contact-point/treatment-risk-fund> .

and if they are more complainant-friendly. There does not seem to be an obligation for healthcare service providers to make information about methods of complaint, including MRF, publicly available and also to inform patients about such options.

7. Engagement with stakeholders – it seems that both prior to the establishment of the system as well as during its operations there has been no thorough and wide stakeholder consultation carried out. At the same time all major players on the field – state authorities, professional unions or providers and health care workers, patient organisations, insurance companies etc. – were very critical about modalities and framework of the existing system and its outcomes. Opinions and recommendations of stakeholders are not systematically analysed and discussed by policy makers. At the same time state plans to start reorganising the location of the MRF and this seems to happen again without consulting the stakeholders as well as comprehensively and holistically discussing this with institutions concerned.
8. Length of proceedings – proceedings in the MRF are excessively long according to all parties consulted. To the team however the mentioned length of procedure does not seem to be excessively long if being compared with a normal court procedure in the various European countries. If we look at the Danish system of the Risk fund an average term of 200 days seems to be an ambitious goal.²⁸ Nevertheless, if the idea of this MRF was that it should be an easy approachable and client friendly and quickly proceeding provision, this is not the result of the structure and its way of working.
There seems to be various factors influencing this, including a lack of efficient work methodology by experts as well as probably time for payments by NHS after making decision (90 days).
It was proposed to have quicker system of proceedings for “simpler” complaints – list of compensation sums or similar.
9. Transparency of the MRF proceedings – again common stance of the providers, associations and patients- was that during the proceedings – proactive- hardly any information if at all are shared with parties involved. HCPs who have to deliver their account on situations disputed do not get any information about outcome of such complaint/compensation proceedings. It seems that all parties involved might have right to enquire both final expert report as well as decision made in MRF proceedings, but as they are not informed about this option, it is not taken up.
Allegedly also basis and methods of deciding on the amount of compensation payable is not simple and understandable for parties. Proportionality with the sufferings or direct loss does not seem to have real impact on the final outcome in financial terms.
10. The system of reporting medical errors/incidents – there is currently no connection between out payments, insurance premiums, proceedings and cases of possible medical errors reported. A link between voluntary reporting, liability and compensation (as well as perhaps disciplinary proceedings) could make the system more efficient and less punitive.
11. Dissatisfaction with complaints – due to the combination of various reasons listed (lack of transparency, weak expertise, proportionality etc.) more than 30% of decisions made by NHS are applied to the Ministry of Health. Applications are mostly presented due to disagreement with the amount of compensation appointed.

²⁸ <https://pebl.dk/en/skader/sagsbehandlingen/sagsforl%C3%B8b>

5.3.3. Several options for (medical) claim²⁹ handling in the various countries

More in general speaking there are several options for (medical) claim handling in the various countries

- a. The health professional or service providers concerned
- b. Complaints officers and/or complaint committees (local, regional or national)
- c. (Patient) Ombudsman (local, regional or national)
- d. Health commissioner (national)
- e. Professional bodies or organisations including insurance organisations using professional experts (regional, national)
- f. Medical or disciplinary tribunals (regional, national or specialist)
- g. Inspectorates (first instance or appeal)

If we look at the Latvian system, some of these options seem to be more appropriate than others for the following reasons:

OPTION A

The health professional or service providers concerned

- the individual health professionals including GPs and service providers seem to dislike strongly the idea of not being involved in the decision-making regarding claims from patients. This being an understandable point of view in a landscape with more and more claims and more and more health professionals and services suffering from indictment, could lead to the idea of making them officially in first instance responsible for the claims handling.
- As mediation is a strong instrument to prevent litigation and elongated and lengthy complaints procedures³⁰ and many countries have successfully introduced comparable systems it seems a good point to consider for Latvia

Mediation is not officially organised in Latvia and is not given a proper place in the system of claims handling. Mediation as instrument is usually more successful at the start of a procedure as it seems that parties are in that stage more flexible and more open to settle a possible claim before it gets a fight.

Therefore, it seems it seems a good idea to think about complaints/ claim handling at hospital level in combination with a kind of mediation procedure.

Option B

Another option is complaints officers and/or complaint committees (local, regional or national).

This could be an option for the medical claims and the complaints handling in relation to claims. Looking at the situation in Latvia it has to be said that the officers or committees should be completely independent from the inspectorate and should have their own office and status. They should be able to attract sufficient experts from a sufficient quality level and should have a support office to support patients and a communication office to make sure that feedback to patients, hospitals and inspectorate as well as to the government levels is provided.

²⁹ we use the term claim handling instead of complaint handling as this paragraph and the cases discussed below are mainly focused on a solution for too many financial claims in the Latvian system and looking for alternatives in other countries in Europe.

³⁰ see Denmark ombudsman, Portugal mediation see England patient advice and liaison services PALS ; patient ombudsman in Norway as a conflict solving institute

If this must be organised by government, the costs would probably be prohibitive, and the outcome would probably be not much better than the results from the inspectorate experts. Therefore, this option is probably not the most favourite.

Option C

The patient ombudsman could be involved in complaints handling.

However, if we talk about medical expertise and expertise in conflict settling/mediation this is probably.

5.3.4. Suggestions for revising the medical liability insurance system in Latvia

Based on the information collected from various stakeholders the following suggestions for revising the medical liability insurance system in Latvia could be made:

1. The Ministry of Health (hereafter – MOH) should carry out a comprehensive analysis and about competences and resources needed for purposeful medical liability insurance system in short and long term:

- financial resources needed to run an independent state financed institute which runs the MRF (infrastructure and staff – no need for experts as the parties will bring the experts – no need for payments as the payments will come from insurance or from medical sector themselves if not insured.
- financial recourses to outsource this activity to insurance companies and keep it as a budget neutral institution
- possible domains considering state authorities, professional unions etc.); for the fund in present institutional structure and costs

Other topics for MOH to consider:

- method of deciding on compensation (expert-based or list-based)
- establishing a prior to MRF claims system of mediation proceeding system between parties (obligatory or mandatory)
- a streamlining system for complaint procedures (obligatory or mandatory streaming via the healthcare provider concerned)
- options for combining reporting and compensation systems etc.

2. Outcomes on analysis on policy level can be combined into report that should be comprehensively, constructively an openly discussed with stakeholders. This includes other state bodies, associations, academia (including economical sciences) etc. Consultations could be thematic i.e. by working groups maximising the input from parties. After hearing all stakeholders and carefully considering their input final report can be made providing the ground for decision of the model appropriate for Latvia.

Assistance for constructing the framework for stakeholder engagement could be enquired from other countries, as, for example, Estonia and Scotland, who have successfully performed such exercise within the framework of creating medical liability insurance.

3. Whatever model will be used for liability insurance in the future it should clearly address at least the following issues:
 - definition of complainant - only the patient or also others like partners and family

- the scope of the insurance for medical staff and health services – obligatory or voluntarily, state run or privately run
- cross border elements including the minimum standards from the transparent and efficient proceedings
- the insurance coverage and other details should at least be in accordance with the minimum stipulations in the EU Directive 2011/24
- methodologies for calculation of compensations; damages to be compensated - list of harm or individually
- information about the system publicly available – how to use the system what are the outcomes and who was to blame or not
- assistance available for settling the disputes prior to application and during the proceedings
- avenues of application after the decision
- and most important for improvement and research issues in all cases the inspectorate has to be informed and has to have access about all complaint and settlement information.

6. Reflections and Recommendations of the team

Overview of chapter 6

Summary of recommendations and advices

The following table provides a summary of the recommendations of the peer evaluation team:

1. Re-position the Health Inspectorate as more independent, transparent and accountable entity.
2. Move to more of a learning culture (including thematic review of common and systemic problems).
3. Empower the staff (including continuous education, training and fostering an integrated culture).
4. Improve the image of the inspectorate with the stakeholders and consider re-branding the organisation.
5. Focus on improving the quality and safety of healthcare.
6. Move from compliance to more co-operative methods of inspection to be a trusted partner for stakeholders).
7. Introduce self-assessment as part of the review framework.
8. Introduce better risk-based profiling for prioritisation of inspections and better use of indicators.
9. Redesign the complaints procedure e.g. consider introducing a triage process, categorisation and a mediation step into the process.
10. Improve engagement with health institutions and groups.
11. Externalise the Medical Risk Fund (MRF) function from the Inspectorate.
12. Separate the (expert) function of determining if a MRF case should receive a pay-out from the assessment of the amount to be paid-out. This could include creating a schedule of payment amounts, or ranges based on problem and severity (i.e. remove the subjectivity).
13. Separate the expertise functions of Pharmacy from the existing HI general Experts.

A more detailed narrative on each of these 13 points is provided in the following sections.

6.1. Project I – Reflections and Recommendations of the team regarding the evaluation of the Latvian Healthcare Inspection in the area of medical institution supervision.

The evaluation of the work of the Latvian Healthcare Inspectorate has been at the centre of this study, not only in this paragraph, but throughout the entire report.

The assessment of the Latvian medical institution supervision system by the peer evaluation team - as described in this study and in particular in Appendix 4 - has addressed essential elements of a quality improvement orientated supervision.

In this assessment the team found that, while the direction of travel for the HI is toward a philosophy of quality improvement, this is at an early stage and there are a number of actions that will help this become a reality.

If we reflect on the questions asked by the Procurement document in short:

- Analyse the current state and procedures:
 - choice and application of supervision systems
 - strong and weak points of supervision systems
 - self-assessment methods
 - indicators in supervision of medical institutions and provision of consulting support.
- Reflect on development opportunities for development and improvement of the supervision system of medical institutions in Latvia;
- Present suggestions for self-assessment for various institutions and practices.

The team comes to the following reflections and recommendations.

6.1.1. Independence and transparency

Independency and transparency is the Holy Grail for supervisory organisations. It will never be fully reached, however, it is important to strive towards it as it brings balance and the autonomy to do the right things. It stands at the basis of acting with integrity and impartiality.

One of the most important of the (so called) “EPSO standards” is standard 2³¹ about these founding norms of independency and transparency:

- Its independence is safeguarded to the extent that is required regarding the conditions under which it performs its services. As a supervisory body, its dependence or independence of the political system should be defined.
- It remains impartial to the influence of key stakeholders (umbrella organisations, press).
- Its personnel are clear and understand what is required of them to ensure that they act with integrity at all times; and personnel do not have a conflict of interest in relation to the area of work that they are required to perform. Procedures should be implemented to ensure that experts assisting the inspection body in specific cases declare a statement about conflicts of interest, for example political, commercial, financial pressure.

As previously stated in this report, the HI is subordinate to the government and to the Minister of Health and is not independent. The actual dependence on the Ministry and its policy seems to be accepted without any serious debate or comments from a professional and independently operating control and supervisory role from the HI.

³¹See Appendix 3 – EPSO Peer Evaluation Framework for a list of the considerations.

As there is no legislative nor current procedural protection to create an arms-length distance from the political system the inspectorate does not have formal instruments to provide independence from political steering and influence. This situation is not very different from some other inspectorates in Europe where the inspectorates are essentially functioning, not at arms-length, but in short reach of the Minister.

However, most of the inspectorates have at least some formal instruments in place to keep their opinions impartial, their decisions rule-based and fair and their implementation equal to all. Inspectorates should be able to keep defend their independence and integrity if necessary in order to defend good care for the public.

In Latvia (even if this is not the case) – the perception of many interviewed is that the inspectorate acts at the political instruction of the current government rather than acting independently and transparently.

Many of the stakeholders who were interviewed express (even without being asked explicitly) a fear and a lack of trust in the sense that they do not trust that the activities of the HI are impartial and fair. The general idea is that their priorities are mainly politically steered. Regardless of the truth, perception is very important and the lack of transparency in selecting which organisations or physicians to audit serves to compound this suspicion. Moreover, the process by which complaints are decided and, the corresponding payment methodology and the results/outcomes are not transparent which leads to suspicion by the public and other stakeholders regarding impartiality.

These observations lead the team to the opinion that something has to be done to make the inspectorate more robust and independent and that this has to be shown transparently to stakeholders and the public.

For options to work in this direction inspiration can be gained from systems such as:

- the Norwegian system where the independent inspector general is appointed as independent high officer by the crown which is comparable to the council of ministers for a long-term fixed period
- a construction as the Latvian Ombudsman in Latvia could be an option
- another option could be to make the inspectorate officially an organisation at arm's length as they call it in England of the government
- the Portuguese and Swedish model of an independent advisory board with links to a broad spectrum of stakeholders including patient organisations or representatives.

6.1.2. A learning culture as a priority

In the Description of Activities document the aim of the HI is described as follows: *to perform the functions of state administration in monitoring and control of the health sector in order to ensure compliance with the requirements and execution of normative acts that regulates this sector.*

This involves in daily practice a lot of practicing control and penalty activities. Although it is generally agreed that the basic safety and quality norms need to be ensured, the team is of the opinion that punishment should be a very last option, not only because this is what is seen in many other countries, but also because, in the long run, punishment as a practice is not shown to be an effective and workable instrument for improvement of healthcare.

As we see in the current environment of the HI a strong leadership of the inspectorate and willingness to improve, supported by the Minister of Health and Ministry and potentially supported by quite a

number of other stakeholders in Latvia, striving to introduce more of a quality improvement and learning culture should be a very high priority. The challenge for the HI is therefore to make the internal change from compliance to co-operation and from punishment to the internalisation of values and good practices.

The Peer evaluation team therefore points at a number of related policy aspects and priorities that seem to be important to make this change:

- **Empowerment of the staff** in order to create a ‘culture of safety’³² that involves establishing a supportive environment where health professionals can identify errors or near misses and analyse why and how these may have occurred. Within this environment, patient safety practices, such as clinical supervision (CS), can be implemented to address the problems identified and reduce the likelihood of injuries.
- **Improvement of the image of the inspectorate** – externally as well as internally – could be an important second goal to work on in cooperation with external stakeholders. A change of mindset (mentality) towards a more open stakeholder-oriented setting is not an easy path (as is seen in many other countries) but unavoidable if the inspectorate wants to be a trusted and open partner.
- **Re-brand the organisation** in such a way that it shows outside more clearly its credibility as supportive, co-operative, quality and patient orientated organisation. This “rebranding” should include the disappearance of the reputation as a punishment-oriented and police-like organization. A change of name as is done in Estonia and long ago in England could be a helpful option too. This change of brand should not be only optical but needs to be supported by behavioural and communication training among staff and those who need to perform the supervisory activities, communicate and co-operate with different stakeholders.
- **Become a learning organisation** to achieve improvement and to for improvement to become part of a sustainable culture of the organisation, there is need for support as so called “learning organisation”.

6.1.3. From checking compliance to collaborative methods of inspection

As is described in Section 4 of this report, the trend in supervision in Europe is shifting from compliance to more co-operative methods and the supervisory authority’s role is increasingly seen as supportive³³ and as ‘being part of the solution’ and improvement orientated instead of finding errors and measuring the effect by ‘how many bad apples are caught’.

- For instance, in Sweden³⁴ the supervision by Swedish Health and Social care Inspectorate (IVO) is carried out from a **user- and patient perspective** and must focus on matters that are important for individuals or groups. Unless laws or ordinances state otherwise, supervision should be **risk-based** and only review matters that are essential to ensure a health and social care service which is safe and of high quality. Supervision must be **effective** (IVO, 2015).

³² See section 4.5 ‘culture of safety’ in a supportive environment’ for further detail.

³³ Refer Section 4.5 culture of safety in a supportive environment and - 4.5.1.3 Engagement Strategy

³⁴ Refer Appendix 4 (selected case studies) for more details about the Swedish system

These elements (user perspective, risk based and effective) are the essential highlights and starting points for The Health and Social Care Inspectorate's (IVO) work. The Swedish system does not describe in full detail how to carry out risk-based supervision, however it is clear for all involved. It includes systematising and analysing IVO's own and other actors' findings at a national and regional level, as well as making use of the patients' and users' views and experiences to create an overall picture of our supervision area.

What is considered essential in a risk-based strategy can vary according to the purpose of supervision. The inspectorate focuses on what they think is really important when providing a good health and social care service for users and patients. This focus is not top down as well as bottom up discussed and influenced. One of the elements of this system is that IVO not only concentrates on documentation, guidelines and procedures but uses more information and but tries to ask the real questions of patient safety and quality of care.³⁵

- In **Scotland**³⁶ the social care and social work scrutiny is moving from compliance to an improvement-focused approach which provides assurance about care quality. There are two elements of change: a greater methodological emphasis on evaluating the quality of people's experiences and outcomes, and a new set of national care standards. This 'Scottish model' may help provide a theoretical framework to resolve past tensions between scrutiny and improvement. Modern scrutiny can become an important tool in the quality toolbox.³⁷
- In **Portugal**, users are central to the system. As the central figure of the health system, the user must be given the necessary conditions to make free and informed decisions. Taking into account the asymmetry of information existing in the health sector, in the context of the constant intervention of Portuguese Healthcare Regulatory Authority (hereafter – ERS) to guarantee the rights and interests of the user, along with the treatment of complaints are developed actions to strengthen literacy in the area of health and empowerment decision-making, and in particular in their direct contact with health care establishments and with the LRA.

To this end, ERS offers a designated area of "Information to Users", with useful and easy-to-understand information, based on interactive content and functionality such as answers to frequently asked questions, information leaflets, simulators and alerts that support the user in the effective exercise of their rights and duties. In this area, the online complaints book and the information request form allow you to quickly and comfortably submit a complaint to a health care establishment or a request for clarification from the ERS regarding matters within your competence. The use of the information and tools provided here will contribute to an increasingly effective regulation and supervision of the performance of health care establishments by ERS and to an increasingly user-oriented health system.

³⁵ *ibid*

³⁶ *ibid*

³⁷ Refer Appendix 4 (selected case studies), section 1.3 (Scotland) for further details

6.1.4.Improving quality of care and patient safety

- The goal should be improving quality and safety in health care
- To be able to improve the HI needs trust from the health care provider (so they listen to you), from the government (so you can act independent) and from the public (so you can defend the use of tax money)
- To be able to contribute to quality improvement and learning effectively, there has to be a certain level of trust between the supervisory agency and the supervised. The latter must trust that the agency's primary focus is learning and quality improvement. The supervisory agency must trust that the supervised want to develop and must act in a way that does not create fear
- The inspectorates have to prioritize the actions for instance by creating a risk analysis. In the risk analysis stakeholder information is important. The advice is to focus on outcomes, sometimes processes and very rarely structures such as numbers of beds, personal etc.)
- The risk analysis should also focus on what is important for the patients, which means that the inspectorate has to understand what is important and also creates a general knowledge about what the problems are in cooperation with health care providers, patients and other stakeholders
- There are several methods to inspect and different methods can be used considering what problem is faced. Inspections are basically about gathering information
- When choosing which tools to use, the basic rule is to start with the less radical measures and introduce stricter ones if necessary. This pyramid is also used for punishment and corrective measures
- Feedback and dialog after inspection and analyse is crucial to be able to be part of the solution to improve health care. Feedback also about the inspectorate, was the HI of any help or only trouble? This is of course not so easy to find out as usually respondents give the desired answer
- Follow up after a reasonable time after previous action is one of the normal inspection procedures; however, this follow up should not stop automatically and as standard with correction of the detected errors; system analyses and possibly find out if and why this error is made more often to change the
- Differentiate the inspectorate's actions. Be rather passive to a provider that have good processes regarding improvement and good control of outcomes. Be more active if the provider had little understanding or knowledge regarding improvement. Be assertive when there is direct danger to health -apply strict disciplinary actions if there is a high patient safety risk.

6.1.5.Tailor made system for Latvia

In order to make a relevant and practical comparison between approaches in different countries, the examples are highlighted³⁸ as a reference to use as inspiration and best practices to adapt suitable options considering the Latvian context and its cultural, political, legal and financial environment. Not every system that works in one country setting will necessarily works in other. Latvia needs its own tailor-made system, inspired and supported by the best practices from other

³⁸ see Appendix 4 (Selected case studies and international examples)

countries. Developing the best supervisory system is an ongoing process that needs to adapt and keep up with health care quality and improvement development.

Nevertheless, there are also some lessons to learn from other countries experiences. For instance, one of the lessons is that supervisory bodies should focus less on 'Big Data' and complex risk profiling. Instead, they should identify and find a smaller group of indicators that have the best correlation with on-site audit findings and focus on these indicators, thus 'finding the signal through all of the noise'.

6.1.6. More proactive using self-assessment

If the goal is to focus the supervision from reactive measures to more proactive guidance and monitoring, then self-assessments can be used as one of the methods to supervise and evaluate the learning capability of health care providers, who are at the end responsible for the quality of care they deliver.

Presently there is no self-assessment system established in Latvia for supervisory purposes in HI work, but it is brought out in the presented documents as one of the aims of inspectorate to implement.

In Finland is claimed that self-monitoring (self-assessment) carried out by service providers themselves is, and ought to be, the most effective form of supervision. They see the role of the supervisory authorities is to offer support and guidance to the social welfare and health care service providers as they undertake self-monitoring. Valvira has for many years placed great emphasis on providing support and guidance to service providers undertaking self-monitoring. Self-monitoring is now an integral part of all their supervisory activities. As a result, the quality of self-monitoring undertaken by the service providers has improved significantly in the past few years.³⁹ .

Self-monitoring allows organisations to target their resources at higher risk areas and activities, to adopt a plan-led approach to their work and to develop a greater awareness of the quality of the services they provide. Any shortcomings must be prevented and addressed as close as possible to where the services are actually provided. This will also reduce the need for the supervisory authorities to address service providers' activities retrospectively and to avoid the additional work and costs that arise from such supervision activity.

Self-assessment should be designed to identify, prevent and address shortcomings in health care service provision.

Self-evaluation should always be able to answer following questions:

- Did we do what we promised?
- Did we make a change?
- Are we doing the right things?

Additional information on the Finnish example, the Netherlands (serious adverse events example), the Swedish system, the Portuguese system, the Danish system are outlined in Appendix 4, section 6 (self-assessment and incident reporting).

³⁹ See Appendix 4 , section 6 (self assessment and incident reporting) for further details

6.1.7. Risk based supervision and the use of (organisation, process and outcome) indicators

While choosing indicators for risk-based supervision it is important to keep in mind that the aim and purpose of the indicators is the need to perform a risk-analysis. Therefore, important questions are if the indicators used to give general background information about the capability of care providers, benchmarking, to identify high safety risks or to choose inspection objects? In Denmark and Sweden, the inspectorates make a yearly plan based on their risk analyses. This helps them to make a selection of institutions to visit and what to ask.

As highlighted in section 4.4 (data driven and evidence based approach) of this report, the Latvian inspectorate is struggling - as inspectorates in many other countries worldwide are - to find a proper and effective way to introduce (cost) effective working method in inspection and supervision. This report provides examples from other countries are available on how a risk-based approach could be used⁴⁰

The Latvian HI has at the moment 5 risk themes:

1. Potential influence of society (GP- small, hospital-big)
2. Influence of the organisation/facility (GP, hospital) (range and complexity of services)
3. How complicated is the legislation relating to the organisation/facility (i.e. 10 different laws you need to check)
4. How many patients under the organisation/facility (i.e. volume)
5. Reputation based on:
 - an internal score, checklist score based on last 3 years;
 - a checklist filled by inspector;
 - complaints/ claims.

The risk-based criteria for prioritizing which organizations to audit - as being used or planned to use in Latvia do not consider statistical risk factors for helping determine who should be reviewed.

Furthermore, these criteria do not seem to select risky areas in the sense of “high risk for patient safety and quality of care”. The criteria are partly volume based which does not have a clear-cut relationship with health and social care risk, and the criteria seem to have a highly subjective character and are therefore difficult to defend and to use.

The peer evaluation team’s recommendation when choosing indicators is to consider what data you have available and to customise the intelligence from various sources (to move up the value chain from data to information to knowledge).

6.2. Project II – Reflections of the team regarding complaints

6.2.1. The Complaints procedure assessed

The Complaints procedure as assessed by the team in Chapter 3 lead to a number of ideas for improvement.

If we reflect on the questions asked by the Procurement document, in short:

- a. analyses methods for patient complaints and accident causes;
- b. implementation of a patient complaint system to indicate events for improvement of the complaint process;
- c. engagement of medical institutions in the process of complaint analyses;
- d. prevention of patient complaints and accident causes engaging the medical institution,

⁴⁰ see Appendix 4, Sections 6 (Self assessment and incident reporting) and 7 (Engagement of Stakeholders)

the team concludes that patient complaints is (as is shown in many best practices) one of the most powerful instruments for inspectorates to get in contact with the patients as well as with the health professionals and the health service providers.

Next to other methods of communication with the health field this is one of the easiest and best ways to find room for improvement of healthcare quality and patient safety.

6.2.2.Preconditions for open complaint management

- a. The **inspectorate has to be informed** about the complaints and preferably about its content in detail.
- b. The inspectorate should have the ability to **use the complaints for the purpose of Improvement of patient safety and quality of care**. This means that triage is necessary as not all complaints are useful for this purpose. If the inspectorate has to answer and investigate all the complaints this will take so much time and energy that the purpose of improvement get lost in the pile of correspondence and investigation⁴¹.

Triage means that complains are selected in for instance 3 categories:

- serious event which need more or less immediate action from the inspectorate;
- other events nevertheless serious but not acute which can be part of the regular inspection activity;
- low profile complaints which might be very important for the complainant but can be transferred to the caregiver to take care of in a considerate and thoughtful way.

Either way, all complaints should, in the first instance, be handled by the caregiver/facility that was the basis of the complaint.

- c. Registration of complaint should be done in such a way - preferably in a database with a **good search system to find the relevant elements of the complaints** - that research of the complaint system can support a risk-based approach of the supervisory activities of the inspectorate.
- d. Complaints should **not be handled as paperwork but as living feedback** with if possible options for the inspectorate to start a broader approach of the problem without focusing on the actual complaint.
- e. The complaints should be handled in a **culture of trust** Punishment is one of the possible follow up actions for complaints, but this should not be the main purpose.
- f. **Blame free reporting by hospital staff and voluntary or mandatory Incident reporting by staff and health providers** (reporting of serious events and near misses) is a useful supplement to and the specific information from the complaints.
- g. **Engagement with health institutions** on complaint handling and possibilities for **mediation** is one of the options for improvement in the Latvian system

The team highlights this option explicitly under the list of preconditions as this seems necessary to reduce the burden of complaint handling at the Latvian inspectorate and turn the wheel in in the direction of selection of priorities based on a clear inspection policy.

If the inspectorate wants to have a clear policy for improvement it seems unavoidable to include the health institutions and make them partners in (blame free) reporting on serious events as well as handling complaints in such a way that the focus is on solving the problem;

⁴¹ The Finnish system of complaint handling has been overloaded for years with too many complaints to answer in an almost legal way and within a pressing timeframe with no possibility to get in contact with the complainant.

mediation at local hospital level can be a good practice to use. In Denmark the Patient Ombudsman gives the regions - who are running the local hospitals – a 4-week deadline to undertake the mediation and after that term they ask to come back to the ombudsman with the results.

In The Netherlands the mediation procedure is officially organised in the procedure of launching a complaint via a complaints officer at a so called complaint commissions for care – “klachtencommissies zorg”⁴² These independent commissions are organised at hospital level for a number of special treatments (13 separate commission on special areas of care) The special mediation form is available at the website and can be used during the procedure if one or both parties want to settle the claim.

If these preconditions are fulfilled a system of complaints handling can be used as one of the communication systems that has to be in place to become a serious partner in the improvement of healthcare.

6.2.3. The position of the Medical Risk Fund in the complaints procedure

In the Latvian situation the complaint system seems heavily dominated by the complaints and claims regarding the Medical Risk Fund.

The team is of the opinion that, for many reasons⁴³, the Risk Fund should not be related to the inspectorate in the sense that the experts should not be part of the Inspection⁴⁴ and the Risk fund should not have another relation with the inspectorate than being a provider of information in such a way that the Inspectorate can make its own decisions on the selection of cases to use for learning and improvement⁴⁵. The inspectorate should not be the one to decide on the complaint. The Risk fund claims should be handled by an independent Risk Fund, possibly organised by insurers and other claims should in first instance be the responsibility of the care giver, service provider.

However, this does not mean that the inspectorate should not be informed about the complaints and furthermore this should not mean that the inspectorate will not be free to investigate and find ground for improvement of healthcare.

The team is aware that this opinion and advise may give some major discussions and is not so easy to implement. However, we as team really do not see another good solution for the problem of the Health inspectorate being dominated by the claims and being seen as the police aimed at punishing medical professionals. If the inspectorate wants to go for an openminded relationship with the professional to improve patient safety and quality of care this needs to be done from a different attitude. Complaints handling is useful as learning and improving instrument. The kind of claim handling in the context of the Risk fund as it is done now is in the way.

⁴² <https://www.degeschillencommissiezorg.nl/english/>

⁴³ As outlined in Section 5.3.2 of this report

⁴⁴ See Appendix 4, Section 5 (complaints handling)- Danish, Dutch, Portuguese , Swedish and Finnish system examples

⁴⁵ *ibid*, see triage in the Portuguese system and see also the Dutch system of complaints handling by the Dutch IGJ (Health and Youth inspectorate)

6.2.4.Complaints handling in other countries

If we look at the practises and experiences with complaints handling in other countries such as the Swedish, Danish, English, Finnish , Portuguese, and the Netherlands systems ⁴⁶, there are a number of common characteristics of the experiences, views and research findings.

The characteristics of all these systems are not all the same but with a helicopter view the team has found a number of characteristics from these systems that might be good to keep in mind when looking at changes in the Latvian system.

6.2.5.Complaints: keep in mind what the patient might want to receive!

From various research studies⁴⁷ we know that patients have various goals such as:

- explanation, recognition, being taken serious, apology
- feeling that 'justice is done'
- to prevent the situation from happening again
- get compensation for damages
- 'punishment' in one way or another of the responsible ones

From the Swedish investigation in complaints handling we know from patient surveys that more than half (55%) of the patients who launched a complaint did so because they wanted to prevent others from what happened to them. Almost as many, 52 percent, stated that the purpose of their complaint was to solve their own problem. From this group 20% stated explicitly that they wanted an excuse or apology for what has happened.

If we look at these the team finds an important message that it is not always money and it is not always punishment that are the remedies sought by patients in a grievance case.

Often the complainant can be satisfied by listening to their problems or another type of personal approach From the Danish model⁴⁸ can be learned that after a dialogue with the patient, 43 percent of patients chose not to proceed with their complaint. Patients were generally more satisfied with their complaint if the complaint was terminated after a dialogue.

6.2.6.Look for a simple system of complaint handling

Look for a simple system in the sense that the patient is guided through the system⁴⁹; the information about the complaint system should be clear, available an easy to find; comparing other countries and systems and various foreign experiences there is enough ground for the advice to keep it simple.

One of the findings from the Danish system⁵⁰ as a whole was for instance that despite improvements made the complaint system has not been easier for the patient but rather more complicated as the patient has more opportunities to complain. The evaluation showed that the five regions handle complaints in different ways.

⁴⁶ See Appendix 4, Section 5 (complaints handling)- the Swedish investigation in the complaint system including references to other countries systems see English google translation at EPSO website

⁴⁷ source Johan Legemaate at EPSO

http://www.epsonet.eu/mediapool/72/723588/data/tallinn/Handling_complaints_Legemaate_Tallinn.ppt

⁴⁸ Refer Appendix 4, Section 5.2 (complaints handling – Swedish report on the Danish model) see English google translation at EPSO website

⁴⁹ A good example is the Danish Patienterstatningen <https://pebl.dk/en>

⁵⁰ Refer Appendix 4, Section 5.2 (complaints handling – Swedish report on the Danish model)

6.2.6.1. A pathway to file a complaint

The peer evaluation team found the Portuguese system to contain good practice for complaint handling in the sense that complaints are always referred to the local level first i.e. it is mandatory to send the complaints to the healthcare provider in first instance. This is done by writing the complaint in the Official Complaints File Book⁵¹ which must be made available by private and public health care providers. The Portuguese Health Supervisory Organisation (ERS) is informed when a complaint is launched and always receives a copy of the complaint and the outcome. The ERS, at first, just tracks the complaint and the outcome.

6.2.6.2. Refer complaints back to the provider

The complaint systems for patients should be referred back to health care provider⁵², whose responsibility should be to start the dialogue with the patient and/or the relatives. Intelligent registration and availability of complaints, complaints handling including claims and including reporting of serious adverse events seems to be a must for improvement of healthcare by using all data about possibilities to improve the health system, the patient safety and the quality of care.

6.2.6.3. Complaints as a source of information

Again, Portugal is a useful example of good practice based on the fact that they use a database with all complaints filed in such a way that it can be a useful source for (risk) analyses, inspection and recommendations for quality improvement. In addition to the registration of complaints in the database, a descriptive report (publicly available) is published twice per year. In Portugal all the complaints are in the ERS database including the outcomes.

If the complaints are solved at a local level, they are used as a source for later analysis.

If the complaints are not (yet) solved the complaints go into a process of data analysis and triage. The complaints that ERS finds useful to work on are being elaborated by the Portuguese inspectorate ERS, and always involve an inspector and caregiver. The ERS asks for further information from the parties and from the medical association, nurse association, etc., to gather their expertise and views. The ultimate decision rests with the Portuguese inspectorate ERS. If not accepted, the complainant can go to court.

To ensure healthcare quality improvement it is important that the complaints are handled only as a source of information and to receive patients feedback (views and experiences) and not handled as financial claims with aim to prove the guilt and/or determine the compensation.

6.2.6.4. The Inspectorate as a trusted partner in complaints handling

It is imperative that the Health Inspectorate becomes a trusted partner in improvement of healthcare. Therefore, the activities of the inspectorate should not primarily be to blame health professionals about the medical faults they make in their work. On the contrary the Health inspectorate should be the one to support medical professionals staff, patients and health institutions to find (blame free) medical failures or near misses, to find out what went wrong and how to improve. This does not mean that individuals cannot be blamed, and payments should not be processed. Nor does this mean that the inspectorate must first ensure that practice is safe.

⁵¹ see www.ers.pt <https://www.ers.pt/pages/167>.

⁵² The Dutch complaint commission can only look into cases which have been referred to the hospital first see for general info in English about these commissions <https://www.degeschillencommissiezorg.nl/english/>

However, the work the Medical Risk Fund should be strictly separated from and the inspectorate should not be used for the corresponding purposes. The complaints handling purpose and process as now in Latvian Health Inspectorate does not fit in an inspectorate whose main purpose is to work towards improvement of patient safety and quality of care;

If the inspectorate is not any longer the individual complaint handler within the legal framework of the MRF a big bureaucratic burden will be removed from its back. They will be free to improve the quality of the care and to detect structural quality problems in health care.

The HI can select and division of complaints according to HI monitoring priorities how to use individual complaints (feedback) if they do not have to answer and react any longer to every received complaint and do not have to decide on guilty or not in all these cases.

The Patient views and experiences from healthcare givers are not any longer be hidden for the inspectorate as a result of their “police” function

The HI will be part of an open communication with the health professional’s institutions and patients. Complaints can be used as a valuable information source.

Blame free reporting of serious adverse incidents and near misses as well as other voluntary and mandatory reporting systems are next to received ‘signals’ (seen in the existing system as potential complaints) an extremely important source of information. The public relations strategy for the Inspectorate can be a serious method to deal and communicate with the public in Latvia via press and media.

6.2.6.5. More effective complaints handling

Complaints can be used as a source of information for improvement. Therefore, in most countries, initiating a complaint is free of charge. However, the costs of complaint handling at hospital level can be reduced by asking a fee for launching a complaint. This should of course not be prohibitive but can be a method to make people aware of the costs of complaints handling. In The Netherlands the fee varies per amount of the claim⁵³. The fee is returned if the commission agreed with the complaint or if was not admissible. The result for 2017 of this procedure was that 110 complaints were received not more than 5 complainants received compensation and the highest compensation was 2500 euro.

For further information and examples on complaint handling, refer to Appendix 4 “Selected case studies”, Section 5 “Complaints handling”.

6.3. Project III – Reflections of the team regarding the setting of the Medical Risk Fund

Budget, fund management and administration criteria for the amount of harm and examples of good practice

The Medical Risk Fund as assessed by the Peer evaluation team (refer Section 5.3) is creating a great number of fundamental questions that indicate a need for change.

If we reflect on the questions asked by the Procurement document in short:

- principles for creating the budget, fund management and administration of the Risk Fund
- setting methods and criteria for the amount of harm
- examples of good practice

⁵³ complaints without financial claim costs 52,50 euro , with a claim from 5000 -15000 euro – 77,50 and for claims from 15.000-25.000 euro – 127,50 ; higher claims have to go to court.

The Peer evaluation team has the following recommendations regarding the Medical Risk Fund setting:

- a. The budget for the Latvian healthcare is relatively speaking one of the smallest in Europe ⁵⁴ , therefore improvement of health outcomes and investment in the quality and safety care should not be combined with a too costly and too generous compensation system for harm
- b. The actual Risk fund is not as it should be (see above). Restructuring the Fund seems a logical step forward
- c. If the idea is that the actual budget for the Risk Fund should be limited - at least not expanding further - the Peer evaluation team suggests using the following infrastructure as a starting point. The Risk fund could be a basic provision with a simple and straight forward approach to the problem with at least the following characteristics:
 - a simple limited function for instance not including moral harm and not including not dependant relatives (not included cases use the court procedure - civil or other court procedure)
 - easy to use
 - transparent
 - independent
 - low cost
 - quick
 - experts if necessary are paid by the party that wants to bring the expert
- d. As the civil court procedure is always available as back up for the system it is not necessary to imitate a court procedure within the Risk Fund. Therefore:
 - the Risk Fund could for instance use the WHO list or a comparable fixed list as basic compensation system⁵⁵
 - compensation could be limited to for instance an amount of money and to the patient themselves (or only in case of death the relatives)
 - compensation for moral harm which is difficult to set could be excluded
- e. The Risk fund should not be too attractive for lawyers and third parties representing patients for the purpose of getting money out of the system; to prevent this the insurance companies could be a good partner to make the Risk fund work and organise a system to provide an answer to the question whether the doctor / nurse hospital is guilty or not and should pay or not; if this system is combined with a mandatory insurance for health practitioners and health services (liability insurance) this system⁵⁶ could possibly work out budget neutral in a competitive setting between insurers.
- f. Another option could be – if the insurance parties are not interested enough - that the government is paying for the independent setting of a kind of Risk Fund structure (housing, staffing and infrastructure) but not for the experts, lawyers and provides a kind of independent

⁵⁴ See Section 2.3 (Financial Context)

⁵⁵ World report on disability 2011., 1.Disabled persons - statistics and numerical data. 2.Disabled persons - rehabilitation. 3.Delivery of health care. 4.Disabled children. 5.Education, Special. 6.Employment, Supported. 7.Health policy. I.World Health Organization, ISBN 978 92 4 068521 5 (PDF)

⁵⁶ compare the Finnish system – refer Appendix 5

special administrative court for medical failures⁵⁷. Parties bring their own specialists and lawyers (in case of insolvency paid by government) and the judges decide about the case. Financial settlement is afterwards made in civil court. An example of this kind of system can be found in the Dutch system of administrative disciplinary courts⁵⁸. These courts have doctors in the court and parties bring their own experts. If the court decides that the care provider has not acted carefully, the disciplinary court declares the complaint to be well-founded and can impose the following measures on the accused care provider: warning, reprimand; fine (maximum € 4500); (conditional) suspension of the registration of the care provider in the register (maximum one year); partial denial to exercise the profession; cancellation of the registration of the care provider in the register. All imposed measures are made public. If the disciplinary court finds that the care provider has not acted carelessly, it rejects the complaint. In that case, the Court does not impose a measure.

If the doctor has not acted carefully the patient can use this decision for financial compensation and go to a civil court to claim compensation in the individual case between him/her and the caregiver.

- g. A third option could be to make the Health providers in first instance responsible for their failures and provide an independent complaint commission for hospitals with a limited amount of compensation⁵⁹.
- h. In all those options there is no place for inspection experts or experts from a separate training school in University. The team is of the opinion that the inspection experts are being placed in an impossible or at least very difficult position and cannot without great difficulty be transformed in such a way that the system will work smoothly. In fact, an inspectorate as an organisation set directly under the minister with a task to improve healthcare in Latvia is not the right instance to decide on compensation and set on its own the medical standard for the broad spectrum of medical procedures in Latvia. Even if the medical association of doctors and the university are included with a number of highly qualified experts this system will not be positioned in the right place. Other countries do have experts in this field but usually not in a comparable setting.⁶⁰
- i. There should be a clear link with the inspectorate to make sure that the inspectorate can use the information to inspect and to make the system learn by using complaints and claims as input for their inspection policy. However, this link should not have any relation with decisions on the amount of harm and compensation payments.
- j. Compensation payments and the amount of harm could be set by a simple list with a maximum payment. Also, other options are possible. In a system such as that in Latvia with a very limited

⁵⁷ compare the Dutch healthcare complaint system:

<https://www.landelijkmeldpuntzorg.nl/burger/english> and

<https://www.landelijkmeldpuntzorg.nl/files/2018-07/20180320%20IGJ%20LMZ-engels-3e.pdf>

⁵⁸ compare the Dutch healthcare complaint system:

<https://www.landelijkmeldpuntzorg.nl/burger/english> and

<https://www.landelijkmeldpuntzorg.nl/files/2018-07/20180320%20IGJ%20LMZ-engels-3e.pdf>

⁵⁹ *ibid*

⁶⁰ The Danish system also uses experts but is completely separated from the inspectorate does not have a link with the compensation payments (www.patienterstatningen.dk)

health budget a system such as the one in Denmark with a high standard for compensation payments is not recommended. An insurance-based system of payments with a link to a legal limit for the claim should be considered.

6.4. Reflections of the team regarding the Latvian legal context

6.4.1.EU- National legal framework

The legal context for a framework for supervision of medical treatment in Latvia is greatly nationally determined. The European Union has no specific obligations for Member States to have a specific setting for health inspections or regulators organised by government (national or regional). From the perspective of the European Union there is a great amount of freedom - almost no restrictions - to organise healthcare inspection, supervision, regulation or monitoring in a national preferred way. The various European member states differ greatly in their organisational structure for supervision of health services (see for instance Germany, Poland, Spain and some other countries having no inspection of any significance at the national level). There is not such a thing as an EU obligation to have or realise a specific legal framework for supervisory activities in Latvia or anywhere else in Europe.

However, this does not mean that there is no legal framework at all. The European Treaty including the regulations regarding the three freedoms (free movement of goods services and persons) , and the more general -however not less important – human rights and freedoms are a solid context for the jurisprudence of the European Court and a fundamental base under the Luxemburg healthcare jurisprudence and the European Cross border healthcare Directive.

In many European countries we see more and more frequently citizens claiming that their individual health treatment in the context of healthcare services and institutions has to be compliance with patient safety and quality norms including European standards and Human rights. It is to be expected that also Latvian citizens will find their way more and more to ask for treatment in healthcare services in accordance with human rights standards in accordance to their individual needs. To be proactive towards those claims the legal context in Latvia could be patient centred and flexible and towards individual needs of patients and citizens.

The tendency seen in other EU countries towards more complaints orientation, a more structured focus on individual cases and more attention for the real needs of patients should to the opinion of the team also have consequences for the structure, setting and styling of the legal context in Latvia.

A change of attitude by the inspectorate as advised by the Peer evaluation team to the health inspectorate and described here, will certainly have to have effect in the legislation. These changes in attitude cannot stay without impact on the styling of the laws and regulations in Latvia in the field of healthcare and healthcare supervision.

This means that to the opinion of the Peer Evaluation team it is advisable to change the regulation (laws and subordinate legislation) in such a way that the inspectorate can focus its attention in the field of healthcare more towards rules that stimulate patient oriented good practice and less in the direction of strict rule based compliance (check and control of formal procedural compliance and output in accordance with strict procedural descriptions). Instead, more open norms based on good practice and improvement of outcome should be included In this regulatory context. Punishment, fees, and other corrective measures should be a last resort instrument. Other alternative measures, such as

a give warning or a give the opportunity to show improvement, should be in place to make the inspectorate more flexible in stimulating improvement of healthcare practices and prevent of substandard behaviour. This all should be done in close co-operation with the healthcare stakeholders (including doctors, nurses, health services and third parties in healthcare) in such a way that the measures are effective in the eyes of the healthcare professionals and to take patients into account.

Furthermore the legal context should provide enough security and protection for healthcare professionals and institutions to become transparent so that there is an open culture in which medical staff and institutions feel free to discuss options for improvement in healthcare with the healthcare inspectorate. This culture should include being open about their own failures. A legal setting with - for instance - “protected blame free reporting” might be necessary to reach these goals.

The legal instruments and context for the health inspectorate should be regulated in such a way that the inspectorate has sufficient options for alternative measures to avoid punishment and fees. Sanctions should in healthcare context legally be reserved for exceptional cases with a criminal character. The inspectorate should be able to gives the right incentives for improvement and change where necessary to safeguard and promote quality and safety of care and prevent fear for being open and transparent about unintended failures by individuals or system failures in institutions and even about system failures in the broader setting of the organization of society.

6.4.2. Legal base for frequency of inspections and for how and what to inspect

The frequency of inspection and the description of what and how to inspect is in many countries a topic described by law. In many other countries the inspectorate is to plan and decide on what , how and when to inspect. Usually in one way or another this is decided in co-operation with the political steering bodies and with input from the public.

The Peer evaluation team does not think that it is wise to mention an obligatory number of inspections or a frequency in the law or in the legal context. In some countries - for instance Denmark - this was the case; as it was not a success for a number of reasons the very restrictive numbers have been changed again.

The law is, and should not be, a flexible instrument in the sense that it has to be changed all the time if new healthcare or social developments or priorities are coming up. The law should be a stable and trusted factor. However planning and priorities should be open for change in accordance with developments in society. Therefore these do not fit in a law.

The team advises therefore to have less restrictions on what and how and when to inspect. However the team advised to use a risk approach for the inspection in Latvia which means that inspection has to be done only or mainly in selected institutions and only or mainly on selected topics. For this risk approach it is not necessary to have a specific legal base or regulating procedures in the legislation. However it does certainly mean that it is not advisable to set a frequency or a way of inspection by law.

6.4.3. Complaints handling – not necessary to regulate by law

The procedure of complaints handling is not necessarily a topic for which it is advisable to regulate this in detail by law apart from:

- a centralized streamlining procedure for returning complaints to the initial source of the complaint (hospital or healthcare provider) with the obligation to answer or react otherwise - mediation;

- obligatory information to the inspectorate without the obligation to answer.

Regulation by law can easily lead to bureaucracy without practical solutions for the patient and without possibilities to explain and discuss instead of claim and sue between parties involved.

However the Peer evaluation team has looked into the Portuguese system which is quite in detail regulated by law. This system seems to provide nevertheless workable solutions for complaint handling with a positioning of the inspectorate in the second row of handling complaints.

The idea that complaints are a source of information and can be used for learning by the parties involved does indeed have consequences for type of legislation regarding complaints handling in Latvia. If all complaints have to be registered, investigated and answered within a time limit there will be no possibility to use complaints as a source of information, no mediation and no open debate on what went wrong. Even if the number of complaints decreases drastically and the number of inspectorate employees increases drastically the setting of all complaints handling at the inspectorate is not inviting for an open and non-defensive attitude to the incident.

6.4.4. Protection of vulnerable and weak groups and human rights by law

In many countries the law is an important instrument for protection of vulnerable and weak groups and more in general to protect basic human rights including the right the right to proper health care. Inspectorates are often used to monitor at least the bottom line of the quality and safety of health care and prevent vulnerable and weak groups from sinking through the bottom.

In the Latvian health context the law could be used – more than in the actual Latvian legislation is done - to make sure that the inspectorate and government are using its competences to protect and monitor at least the bottom line of quality and safety of health care .

6.4.5. Legal base for the inspectorate to be regulated by law

Furthermore it seems important that the inspectorate is being seen as trusted partner by doctors, nurses, patients, medical institutions, medical third parties and citizens.

In the Latvian context of the Health inspectorate it might therefore a good option to regulate the inspectorate by law and include legal standards for openness and transparency.

Legislation on transparency and openness about rights and obligations in the context of medical procedures, health standards, risks and also about sub-standard medical behaviour is an important aspect of an appropriate legal context for the health inspectorate in Latvia.

6.4.6. No necessity for a Legal base for self-assessment

As self-assessment is highly dependent on a high level of co-operation and trust between the inspectorate and the health care providers it does not seem necessary to provide a legal base for self-assessment in the law. Self-assessment should be based on a voluntary cooperation between providers of healthcare and the health inspectorate.

The Peer evaluation team is of the opinion that it is not recommended to start on a too large a scale. It seems advisable to start with small scale pilot projects in specific areas of healthcare such as patients relations , communication and information exchange between health institutions, professionals and patients.

At EU level, recent initiatives have led to an interesting study on opportunities for self-assessment. The Peer evaluation team provides in Appendix 6 to this report a copy of the document which contains a

Self-Assessment Checklist for Healthcare Providers which can be used as inspiration and example of good practice. This document is also provided in an active pdf link to this report. The document is part of a series of nine documents from the European Reference Network including: “8. Self-Assessment Checklist for Healthcare Providers in Active PDF”⁶¹.

6.5. Reflections of and evaluation by the team regarding “Strong and Weak points” of the supervisory methods as advised in chapter 6

6.5.1. Summary of strong and weak points of the advised methods and changes of setting

The following table provides a summary of strong and weak points of the supervisory methods and the suggestions for change of settings recommended by the Peer evaluation team to the Latvian Healthcare Inspection

The below mentioned methods and suggestions for change presented by the Peer evaluation team are strongly recommended by the team to use by the Latvian Inspectorate in the area of medical institution supervision. However - as said before- the various models from other countries are presented as useful inspiration and not as a copy paste model for Latvia.

A more detailed narrative on each of these points is provided in the following section.

⁶¹ http://ec.europa.eu/chafea/documents/health/8-self-assessment-for-hcp_en.pdf

Table 1. Summary of strong and weak points of the advised methods and changes of setting

	Advised method or setting	Extremely Strong point ***** Strong point *** Important to include in setting and methods discussions *	Risky aspects to avoid	Weak aspects to avoid
1.	Independence and transparency	*****	Risky if a solid public relations strategy is missing	Weak, if no training and education of staff is implemented
2.	A learning Culture	***	Punishment and sanctions should be avoided as much as possible	Weak if public expectations are not handled properly. Weak if no attention is paid to <ul style="list-style-type: none"> • empowerment of staff • Improvement of the image • communication about changes ahead • rebranding the organisation

3.	From compliance to collaborative methods	*****	Punishment and sanctions should be avoided as much as possible	<p>Weak if public expectations are not handled properly;</p> <p>Weak if it is not carried out in combination with a number of supporting measures such as training and education of staff, a strong public relations policy, contact with media and social media and stakeholders including health professionals and patients</p>
4.	Improving quality of care and patient safety	***	Priorities should be set in a collaborative way with the health professionals and the patients	<p>Weak if public expectations are not handled properly</p> <p>Weak if it is not carried out in combination with a number of supporting measures such as training and education of staff, a strong public relations policy, contact with media and social media and stakeholders including health professionals and patients</p>
5.	Tailor made system for Latvia	***	It is very risky if a foreign system is copy- pasted for use in Latvia; Methods of inspection should fit in Latvians cultural social legal and financial environment	<p>A tailor made system starts with analysing and setting priorities and goals in the local context ; for what problem do we need a solution?;</p> <p>If this is not done a new system and new methods of inspection can only be a weak solution</p>
6.	More proactive using self-assessment	*	In a setting like the Latvian setting of the HI it seems risky to set all cards on self- assessment as self-assessment has a high risk of failing if there is not enough “spirit of collaboration “in the system.	<p>A weak point of self-assessment is that it might be time consuming for those involved.</p> <p>To avoid this it could be started at a small scale as pilot projects.</p>

			Self-assessment seems in the Latvian setting a good instrument (less risky) to start with at a small scale, to evaluate specific areas of healthcare such as patients relations and information	
7.	Risk based supervision and the use of (organisation, process and outcome) indicators	*****	<p>Introduction of a Risk system in Latvia could be very risky if the chosen system would be too complicated and too much big data driven like the French or English systems</p> <p>The risk would be that too much time and money is spent and the results could be too much detailed.</p> <p>If the results of the data driven Risk system are uncontrollable and unworkable for a relatively small inspection staff it might be less risky to start in a more straight forward way as is done in the Swedish risk model.</p>	<p>A weak point of every risk system is always that good practices are not being seen and the information from these good examples is not disseminated between health providers and other partners in the system.</p> <p>This weak point could be avoided by paying explicitly attention to the so called “winners in the system”.</p> <p>A good risk based approach requests good communication between those analysing the system and the inspectors.</p> <p>Training and</p> <p>If this weakness is not recognized and training of inspectors is omitted, the system can become unnecessarily complicated and weak</p>

- Independence and transparency

Strong:

Independence and transparency is a very important and strong point for a supervisory organisations to strive towards. It will never be fully reached. However it stands at the basis of acting with integrity and impartiality. Acting with Integrity and impartiality is a necessary to build trust. Trust from patients, stakeholders such as doctors, nurses, health institutions and other third parties in healthcare is a basic value for cooperation with and support from the outside world.

Furthermore, trust is a necessary to get informed about the functioning of the system and to be able to find indicators for improvement of the health system.

Weak:

Independency means also more that the Health inspectorate takes more responsibility and its staff has to act and think as independent individuals. It is not enough to follow the rules and check the pre-set standards. Not everyone likes this responsibility and not everyone is well trained to do so if the setting of independence and responsibility is new for an organisation. More transparency means also for the organisation and for the individual organisation members that there is more openness about the mistakes and miscalculation and failures. This is not always perceived by all as positive. Individual members of the organisation can feel unprotected. Furthermore, transparency about failures of the organisation and its individual members is a weakness if there is no professional education in place to train the staff and individual members how to handle this openness and transparency.

If a professional information strategy and a public relations policy is missing openness and transparency can cause unrest and trouble.

- A learning culture as a priority

Strong:

A learning culture is a strong and effective instrument which can be used by the Latvian inspectorate for improvement of healthcare practices. A learning culture enhances improvement. This method however is necessarily related to an open and communicative relationship with stakeholders, patients and society. This This kind of relationship is a powerful instrument for finding possibilities for change and preventing risk.

Weak:

A learning culture is an instrument to change the direction of healthcare for instance towards more safety and quality of care. Therefore, this instrument is not the best if the organisation is not focused on change in any direction.

A learning culture is not always as predictable as an organisation which is focused on preservation of the existing culture to stay without unpredictable changes.

A learning culture does not combine well with a strong focus on strict rule based compliance and punishment. However after serious events expectations from citizens politics and press are often that the inspectorate should turn its working methods more in the direction of punishment, sanctions and blaming the "one who has done it". As in the long run, punishment as a practice is not shown to be

an effective and workable instrument for inspectorates this is not advised by the team. However handling social expectations is in these cases not always easy.

- From compliance to collaborative methods of inspection

Strong:

If the inspectorate moves its main focus from strict rule based compliance towards more collaborative methods of inspection, this opens possibilities to find – in collaboration with stakeholders in healthcare - successful methods for improvement and ways to avoid failures in healthcare practice. This is a very strong point if the inspectorate wants to find a way to make its work more appreciated and respected for the broader society in Latvia. This method is strong if the inspectorate wants to advice on methods which have a good chance to be carried out successfully with support of the healthcare workers and the health institutions in Latvia.

This method can make that the inspectorate will be focused more on what is really important for providing good health and social care service for users and patients.

This method is also a way of supporting good relations with the service providers and use their willingness to be helpful in finding ways to improve patient care and prevent substandard behaviour in healthcare.

Weak:

However, as this collaborative method will be - in the eyes of society – perceived as weak and as a major change in culture of inspection methods, this method is indeed weak if it is not carried out in combination with a number of supporting measures such as training and education of staff, a strong public relations policy, contact with media and stakeholders

The idea that the inspectorate is not anymore in the first place to blame and punish and is primarily focused on co-operation with healthcare workers and institutions and improvement without using in case of structural problems, unintentional errors, system failures etc., the available instruments such as financial and other sanctions.

- Improving quality of care and patient safety

Strong:

If the inspectorate proves to be one of the factors in the country to improve quality and safety of health and social care in a substantive way, this will be a great success not only for the inspectorate itself but also for the Ministry of Health and will significantly strengthen the status of the inspection in the country.

This instrument is only strong if it is successfully done, if the inspectorate is seen as a trusted partner for improvement and maybe even more important if the effects are “publicly seen”. This means that it can only be successful in a collaborative way with healthcare professionals, patients and other relevant stakeholders. This method places a lot of importance on trust and relationships with those who are doing the work in healthcare, trust between the supervisory agency and the supervised. The

goal of the inspectorate (improving quality and safety in health care) should be easily understandable for all the stakeholders and therefore clear priorities within this goal have to be set and communicated.

Weak:

If the inspectorate is losing trust from stakeholders and the public as not being a successful partner in improving the quality and safety of care, this instrument will become a weak, even if healthcare is better than before and patient safety is improved. The inspectorate will only get the profits from their work if public expectations are handled properly and priorities are set in accordance with public expectations.

This instrument is also weak if it is not carried out in combination with a number of supporting measures such as training and education of staff, a strong public relations policy, contact with media and social media and stakeholders including health professionals and patients

- Tailor made system for Latvia

Strong:

A tailor made system of inspection for Latvia makes it possible to use the best examples of other countries and avoid mistakes already made elsewhere. However it is very risky to use a foreign system as “copy- paste” in Latvia; Methods of inspection should fit in Latvians cultural social legal and financial environment. A good tailor made system starts with analysing and setting priorities and goals in the local context ; for what problem do we need a solution?

A tailor made system for Latvia can be a very strong and useful instrument if it is introduced as an ongoing process, which needs evaluation and adaption to new developments in Latvia. A good introduction of new inspection systems include that the system is necessarily accompanied by ex-ante evaluation based on good knowledge of local context. New systems cannot be simply be copied from any other country even not so when it looks from the outside comparable.

Weak:

If a system is simply copied from another country without proper analyses and evaluation this new system and the new methods of inspection will most probably end as a failure. It is most likely that this kind of change will lead to a weak solution for problems that in the first place were not identified properly before and might not solving the relevant problems for Latvia.

A good example of this copy- paste failure is the use of the so called Danish system for the Medical Risk Fund. This system works completely different in Denmark and does in Latvia not solve effectively the Latvian problems with compensation for medical mistakes and failures.

- More proactive using self-assessment

Strong:

Self-monitoring allows organisations to target their resources at higher risk areas and activities, to adopt a plan-led approach to their work and to develop a greater awareness of the quality of the services they provide. This system is supporting trust between providers and the inspectorate and is used in a culture of improvement. It supports furthermore a reporting culture among health care providers.

Self-assessment seems for the Latvian Health inspectorate a very strong instrument in the context of active collaboration with stakeholders in healthcare and working towards improvement of quality and safety of care.

However as self-assessment has a high risk of failing if there is not enough “spirit of collaboration” in the system, in a setting like the Latvian HI it seems risky to set all cards on self- assessment.

Self-assessment at a small scale seems -to start with- in the Latvian setting a good instrument (less risky) .It might be good to evaluate specific areas of healthcare such as patients relations and communication an information exchange

Weak:

A weak point of self-assessment is that it might be time consuming for those involved.

Self-assessment furthermore requests a high level of co-operation; this approach needs good relationships with health care providers as it puts trust on the health care provider who is in the end responsible for the quality of care delivered. This is a risky and weak point in the Latvian context.

As self-assessment requires a good self-assessment system in place and as self -assessment is a relatively new approach which needs some more time to develop in Latvia, it is not recommended to start on a too large a scale. It seems advisable to start with small scale pilot projects in specific areas of healthcare such as patients relations, communication and information exchange between health institutions, professionals and patients.

- Risk based supervision and the use of (organisation, process and outcome) indicators

Strong: In the Latvian setting a relatively simple Risk based system seems very helpful as a start for finding priorities for the inspection and to support risk based inspections by the staff of the inspectorate.

Such a system is a strong point as it helps to target and prioritize the use of the limited resources of the inspectorate effectively.

Weak: Introduction of a risk system in Latvia could be very risky if the chosen system would be too complicated and too much big data driven like the French or English systems. The risk would be that too much time and money is spent and the results could be too detailed.

As the results of a big data driven Risk system can become uncontrollable and unworkable for a relatively small inspection staff as the Latvian, it might be better and less risky to start in a more straight forward way as is done in the Swedish Risk model.

A weak point of every risk system is always that good practices are not being seen and the information from these good examples is not disseminated between health providers and other partners in the system.

However, his weak point could be avoided by paying explicitly attention to the so called “winners in the system”.

A good risk based approach requests always good communication between those analysing the system and the inspectors. If this weakness is not recognized and training of inspectors is omitted, the system can become unnecessarily complicated and weak.

6.6. Reflections of and evaluation by the team regarding “Strong and Weak points” of the supervisory methods as advised in Appendix 4 – Other methods of inspection

6.6.1. Other methods of inspection

▪ Other methods of inspection-Scheduled organisational supervision

Strong: Scheduled organisational supervision can easily be combined with other supervisory methods and gives a good overview of the entire organisation. This type of supervision can be planned ahead and those inspected have time to prepare for all necessary paperwork and can ensure that all necessary staff are present. This method works out well for benchmarking and for testing of selected indicators.

Weak: A weak point of scheduled organisational supervision is that it is in general time consuming, usually a multidisciplinary team is sent and often external experts with specific competence (including organisational leadership) are asked to join the scheduled supervision. Facilities are usually selected based on a sample. Therefore this method is not the best if the inspectorate wants to concentrate on catching the ‘bad apples in the basket’.

▪ Other methods of inspection -Reactive organisational supervision

Strong: Reactive organisational supervision gives reason to get involved with the relevant stakeholders and start a dialogue with them on what went wrong. This method also gives an opportunity to see the shortcomings in the organisation based on real events.

Weak: Reactive organisational supervision is mostly based on complaints and therefore it is not predictable which organisation will be selected. This type of supervision does not contribute systematically to the prevention of serious adverse events. In a risk analyses it can only be used in afterwards, not in advance.

▪ Other methods of inspection -Administrative supervision

Strong: Administrative supervision is simply to plan and simply to execute. This method is strong for strictly rule based compliance as it is easy to see if paperwork and documents are in place. It is used to check the availability of patient safety standards. This method doesn’t need costly experts or highly trained inspectors.

Weak: The administrative supervision concentrates on compliance documents and checklists which does not necessary show that the patient safety standards are actually followed in practice. This method is too weak to be used as the sole supervisory instrument.

▪ Other methods of inspection- Individual supervision

Strong: Individual supervision of authorised healthcare professionals can become subject to supervision based on a concrete concern for patient safety, e.g. based on complaints or other sources of information. The strong part of this method of supervision is that the target is clear. This method is specifically useful if there are expectations for a possible threat and a need to punish with disciplinary sanctions. This method is aimed to eliminate the ‘bad apple’ and can if communicated externally have immediate visible results.

Weak: Individual supervision as such does not support a learning culture if it is not used in a wider and more structural context. A weak point of individual supervision, can be that punishment and disciplinary sanctions can create fear and if not communicated well can lead to hampering the open communication needed in a “learning culture”. Healthcare professionals will not be open about mistakes and near misses if they have the feeling that unreasonable punishment and disciplinary sanctions could be used against them. This attitude of the staff does not help to detect or improve structural problems.

- **Other methods of inspection -Un-announced inspections**

Strong: Unannounced inspection is often used in combination with announced inspection. It is a strong method to use in addition to other inspection methods. The aim of this method is sometimes not to ask too much paperwork and organisational hassle in advance and ask afterwards only the necessary documents. Another reason for this type of inspection is that it can give an realistic view of the daily practice. This method is sometimes supposed to be suitable for detecting serious matters, to capture the possible serious wrongdoings which otherwise could stay hidden from the inspectors. The method has an element of surprise which can be good and bad.

Weak: The Unannounced inspection method does not necessarily support trust and co-operation. When the timing of the inspection is wrongly selected the inspection can cause hindrance to the inspection process (the right people not being present, materials not prepared etc.). It can disturb the organisations daily routines and planning, which might also affect the patients.

6.7. Reflections of and evaluation by the team regarding Examples from various countries as mentioned in Appendix 4 and in Appendix 5

Reflections of the team on the examples from various countries mentioned in Appendix 4 and 5

In Appendix 4 and Appendix 5 the team provide a broad overview of divergent practices from various countries.

As mentioned in the introduction to the report (1.5 structure of the report) these options are to be used as good practices for inspiration; the examples provided should not be adopted or copied without consideration of the local context and are not meant to be rated as good, better or best and also not as good, better or best for Latvia; All systems have their own characteristics. Most of them have positive and less positive aspects and all of them are strongly based in their own national culture.

In order to make a meaningful and practical comparison between approaches in various countries the report chooses where and when relevant – to give a concrete reference to alternative options in various countries. This is explicitly done without giving a full description of those systems and a full description of the health systems in the countries concerned.

However, it is understandable that the reader of this report will ask what system is best? What is most advisable for Latvia? Which system is to be copied in the Latvian practice? and comparable questions.

The answer to this question is as follows:

None of the systems mentioned in appendix 4 and 5 are to be copied or advised as such in the Latvian system or context. All or at least most of them have interesting and good aspects. All or at least most of them have lesser or not so good aspects.

The team has therefore in the report provided a great number of recommendations and advised system changes. Most of the recommended methods of inspection and mentioned changes can be found in a number of countries.

It is not the intention of the team to make a shortlist of most advised or less advised systems for Latvia.

However, as this is quite obvious we make here some exceptions to this principle:

1. To introduce a risk based supervision approach in Latvia it seems most advisable to look as a starter at the Swedish system which could be very helpful for Latvia with its simplicity and its low profile approach
2. For qualitative Patient information look at the Dutch so called "TripAdvisor for healthcare" (www.ZorgkaartNederland.nl)
3. For patient involvement the Scottish system gives interesting options
4. For a pathway for patients and "second row complaints handling by inspectorates" the Portuguese inspectorate is a good option to look at for Latvia
5. For MRF no specific system is advisable in the sense that it could be copied although the Finnish system has quite some interesting aspects to use as inspiration
6. The Danish system DPSA has an interesting approach for engagement of stakeholders in the development of indicators and the focus for the supervisory activities

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- 4.** Appendix 4: Selected case studies, international examples and best practices
- 5.** Appendix 5: Risk Fund research for this project (Expert services in assessing the work of the Medical Risk Fund)
- 6.** Appendix 6: Self-Assessment Checklist for Healthcare Providers in Active PDF- EU - ERN Assessment Manual for Applicants

Appendix 1 The Latvian Peer Evaluation team ⁶²

Based on the contract with the National Health Service of Latvia Stichting Eurinspect has invited the members of the Latvian Peer evaluation team” to join the team and take part in the planned activities. The members of the team were selected by Foundation Eurinspect based on their knowledge of various fields of health and social care inspection activities in various countries worldwide, their positions and former positions in the context of inspection and peer evaluation of inspectorates and their relationship with EPSO.

Despite tight timeframes and prescriptive scope, Eurinspect were able to assemble a team of experts who have worked hard to ensure the best quality of review within the time constraints.

The expert team comprised a mix of medical doctors who have senior/director level experience in national supervision, experts who have had hands-on experience in inspectorates in different countries, an international legal expert to assist in the analysis of the Risk Fund and the Executive and project office of EPSO/EURinSPECT. All of the team have had previous experience in Peer Evaluations or Coaching inspectorate organisations.

Overview of the team members of the Latvian Peer Evaluation team 2018 (brief summary including current and past positions and background of the team members and translators):

Prof. Álvaro **Moreira da Silva** (PhD, MD)

Chief Medical doctor at Hospital Geral de Santo António do Porto, EPE , Porto , Portugal and Professor and former Director of the medicine course at the Abel Salazar Biomedical Sciences Institute (Instituto de Ciências Abel Salazar) and a. o. former Board member of the Portuguese Health Board, Porto, Portugal

Andrew **Terris** (trained information and health systems expert)

Senior associate at the International Foundation for Integrated Care (IFIC), former Consultant to the Ministry of Health New Zealand and the New Zealand Health Quality and Safety Commission, New-Zealand

Anette Lykke **Petri** (Phd MD MPG)

Head of Department of Supervision at the Danish Patient and Safety Authority, (Styrelsen for Patientsikkerhed) Copenhagen, Denmark, EPSO board member and former medical officer of public health

Jooske Marijke **Vos** (Master in Law)

director at Eurinspect and a.o former director at the Dutch Academy of Legislation (Academie voor Wetgeving) (Ministry of Justice), The Hague, The Netherlands

Klas **Öberg** (Phd in Economic History)

Deputy University Director at Örebro University, Örebro Sweden and a.o. former Head of Department at the Health and Social Care Inspectorate (IVO) , Stockholm, Sweden, chair EPSO advisory Board

⁶² arranged in alphabetical order of first names

Mari **Amos**, (Master in Law and MPH Master in Public Health and MA Master of European Affairs), Independent expert (UN Subcommittee on the prevention of torture), Geneva (Switzerland) and former Advisor to the Estonian Presidency of the EU Council (Estonian Ministry of Social Affairs)

Mari **Murel** (Master in Science)

Senior Research and Policy officer for EPSO at Eurinspect and former research assistant at the RIVM (the Dutch National Institute for Public Health and Environment) former Senior inspector at the Estonian Health Board (Terviseamet), Tallinn, Estonia

Translators for the Latvian Peer Evaluation team Latvian – English – vice versa

- Kalvis **Logins** - Law Student and part time translator - Riga, Latvia
- Katrīna **Bičevska** - Law student and part time translator - Riga Latvia

Appendix 2: List of organisations included in the interviews;

List of Organisations included in the interviews of the Latvian Peer evaluation team
Inspectorate from 2-5 July 2018 in Riga

- Health Inspectorate (HI)

Government

- the Latvian Parliament
- The Latvian Minister of Health
- the Latvian Ministry of Health
- National Health Service

Independent

- Ombudsman of the Republic of Latvia

Medical Representative organisations

- Latvian Medical Association
- Latvian Hospital Association
- the Latvian Surgeons Association
- Latvian Nurses Association
- the Latvian Rural Family Doctors Association

Academic organisations

- Riga Stradins' University

Hospitals

- The Children' Clinical University Hospital
- Quality Department in the Children' Clinical University Hospital

Patient Representative organisations

- Latvian Alliance of Rare Diseases
- the Latvian Association for Cystic Fibrosis
- Patients' Information and Rights Protection Centre of The Latvian Umbrella Body For Disability Organizations SUSTENTO
- the Pulmonary Hypertension Association

Appendix 3: Description of the Latvian Health Inspectorate using the EPSO Peer Evaluation Framework

This uses a best practice set of guiding questions as used for similar EPSO peer evaluations. These questions including those set by the International Society for Quality in Healthcare (ISQua) and ISO/IEC standard 17020:19987.

EPSO identified 13 key areas that were to be considered as standard of good practice for questions regarding supervisory organisations in Europe. These so called EPSO standards are based on the ISO standards, on good practice from EPSO Peer evaluations and cover the areas of:

14. statutory basis clear and functions clearly defined;
15. independence, impartiality and integrity;
16. confidentiality and safeguarding of information;
17. organisation and management;
18. quality systems;
19. personnel (capacity and capability)
20. facilities and equipment;
21. inspection methods and procedures;
22. engagement and communication with the organisation or individual subject to review;
23. openness and transparency;
24. disciplinary sanctions;
25. impact assessments; and
26. co-operation and engagement with other stakeholders including other supervisory bodies.

It has been used to structure a first general assessment of the Latvian medical institution supervision system (Technical Description 2.1). For this assessment questions are answered based on the available information provided to the team, the interviews with the stakeholders (see list) and staff and leadership of the inspectorate.

1.1. Statutory basis clear and functions clearly defined

The supervisory body or the organisation of which it forms part should:

- be legally identifiable;
- have a documented function defined by legislation and its area of competence shall be clearly defined; and
- have documentation describing the goals and responsibility of the inspection body.

The HI is legally identified as a body directly steered by the Ministry of health reporting directly to the Minister of health.

The functions are clearly defined by legislation and the Operation of the Inspectorate is regulated by Regulation No 76 of the Cabinet of Ministers “Regulations of the Health Inspectorate”, dated 05.02.2008.

The purpose, task and functions are outlined in http://www.vi.gov.lv/en/start/_142/functions

Purpose

To reduce the risk for society and consumer health by realizing state surveillance. The Health Inspectorate is to perform state administration functions in the field of supervision and control of the sector, in order to fulfil and implement requirements set by the laws and regulations valid in the said sphere.

Task

To ensure legal, professional, consistent and competent state surveillance and control in health sector, taking part in such policy realization as public health, health care, pharmacy, drug and psychotropic substances legal circulation and consumer rights protection.

Within this, there are (as stated within HI documentation) 9 scopes of activity which are:

1. Control of medical treatment institutions.
2. Supervision and control of availability of health care services and application of the public funding.
3. Control of quality of health care and capacity checks.
4. Maintenance of the Register of Medical Institutions and the Register of Medical Persons and Medical Support Persons.
5. Control of pharmaceutical companies and circulation of drugs.
6. Control of heightened risk objects.
7. Supervision of factors potentially affecting the health of the population.
8. Control of trade of chemical substances, chemical compounds and safety of cosmetics.
9. Control of distribution and application (operation) of medical devices.

The MRF task is not mentioned separately, although this task takes up an important part of their time. Possibly the experts are not officially part of the inspectorate but otherwise working in their jurisdiction.

1.2. Independence, impartiality and integrity

The supervisory body should have processes and systems in place that ensure that:

- its independence is safeguarded to the extent that is required with regard to the conditions under which it performs its services. As a supervisory body, its dependence or independence of the political system should be defined;
- it remains impartial to the influence of key stakeholders (umbrella organisations, press);
- its personnel are clear and understand what is required of them to ensure that they act with integrity at all times; and
- personnel do not have a conflict of interest in relation to the area of work that they are required to perform. Procedures should be implemented to ensure that experts assisting the inspection body in specific cases declare a statement about conflicts of interest, for example political, commercial, financial pressure.

The HI is subordinate to the government and to the Minister of Health. There is neither legislative nor current procedural protection to create an arms-length distance from the HI and the political system. The HI is, like many other inspectorates in Europe, not independent of political influence and reports to the Minister. Although there are annual areas of focus these are not summarised and reported back and while the workload is governed by the internal inspectorate management team, the priorities are largely set by the Minister. The actual influence of the Inspectorate on targets and goals seems relatively minimal. The legal framework looks comparable to some other countries in which the inspectorate is in fact functioning, not at arms-length, but in short reach of the Minister. However, in this setting the actual dependence on the Ministry and its policy seems to be accepted without any

serious debate or comments from a professional and independently operating control and supervisory role from the HI.

The perception from many interviewed is that there is little independence in the HI and that they operate at the political instruction of the current government and minister. Regardless of the truth, perception is very important and the lack of transparency in selecting which organisations or physicians to audit serves to compound this suspicion.

The perception of most of the stakeholders who have spoken the team is that the HI is subject to political interference and is not impartial. Many of the stakeholders express – even without being asked explicitly- a fear and a lack of trust in the sense that they do not trust that the activities of the HI are impartial and fair. The general idea is that their priorities are mainly politically steered.

Beside this, the perception of some interviewees is that it is better not to co-operate with the HI as the impression is that their first goal is to perform a non-compliance check and control with the final aim of punishment.

The personnel interviewed have the highest integrity in following process and direction. However, this direction is to their own opinion mainly set and highly influenced at more senior levels and by the Ministry.

The (internally employed) HI experts are spending more and more of their time to investigate claims towards the health system (mainly MRF 63c claims). Their workload is, in their own opinion, very high. However, they do not complain about the quality of their work and - in their own opinion - do not appear to have any conflicts of interest. They are well trained and have sufficient knowledge to do their work properly.

However, the process by which complaints are decided and, the corresponding payment methodology and the results/outcomes are not transparent which leads to suspicion by the public and other stakeholders regarding impartiality.

The use of outsourced experts and their corresponding impartiality is less clear. Latvia is a small country with few experts, most of whom, by virtue of their professional bodies and collegial relationships, may find it difficult to prove impartiality. These experts are sometimes used in addition to the internally employed HI experts to solve the workload and availability problem of the internally employed experts.

Another way of solving this problem is apparently the start of a new university expert training course for students in Latvia. These young experts seem to have little experience. The team is not really convinced that these newly trained ‘experts’ are to solve the problems of workload and availability in an independent authoritative and undisputed way.

1.3. Confidentiality and safeguarding of information

The supervisory body should:

- ensure the confidentiality of information according to national legislation;
- have policy and procedures in place to safeguard its data and information; and
- ensure that personnel can only access sensitive data that is relevant to their job function.

This area was not observed first hand by the team, however, review of procedural documentation and corresponding interviews indicates that there is no doubt that the information is treated as and

⁶³ The Medical Risk Fund (further mentioned MF)

remains confidential. The complaints cases are managed by the relevant Experts and the inspection team retain separation of duties that means that the team has the impression that probably sensitive data is not being shared

The recent advent of the General Data Protection Regulation (GDPR) legislation should act as a catalyst for reviewing of privacy procedures within the HI. This does not appear to have been reviewed by the HI yet.

1.4. Organisation and management

The supervisory body should:

- have well defined relationships with the Department of Health, umbrella organisations, patient organisations;
- have well defined relationships with the regional offices of the inspection body;
- have a well described and documented organisational and management structure;
- define and document the responsibilities of its personnel and the reporting structure of the organisation;
- have procedures in place to prioritise its activities and is transparent about that prioritisation;
- ensure its inspection activities are carried out in accordance with legislation and the defined standards;
- ensure the effective supervision of all personnel; and
- have procedures in place that ensure the coordination of the various supervisory activities.

The HI is subordinated to the Ministry of health. The leadership has started working on closer relationships and meetings with umbrella organisations. There do not appear to be strong relationships to establish an effective patient voice into the HI's planning and processes.

There is no strategy for stakeholder involvement and dialogue which has led to the actual situation that all relations with outside stakeholders are not well developed or, in some cases non-existent. The HI seems overall not very active in co-operating.

The main offices are situated in Riga, with satellite and outlying offices in the regions. Intra-departmental relationships with regular meetings together and exchange of ideas and learning does not appear to feature strongly in the HI.

The organisational structure is defined and there are heads for each division. While there is strong strategic vision at the leader level of the organisation, the next level down does show a high degree of loyalty to the leadership and supports openly backing the new ideas and a desire to be in line with the management of the organization. However, they do not appear to share this strategic vision strongly from inner conviction and seem to work top-down, policy and protocol driven. The new ideas which are openly advocated by the leadership seem to come from an outside source, which is logical as the organisation has been through several leadership changes and has not been given much time to absorb and process these new ideas after the appointment of their new director.

The organisation splits its functions generally into public health, regulatory inspections and medical registration.

It is not clear how prioritisation of annual focus areas is chosen, and the HI staff interviewed indicated that this was highly influenced by the Minister. The Minister however did not seem to feel the same way and gave the impression she supports the HI becoming a semi-autonomous - organisation setting

its own goals – in cooperation with its stakeholders - toward improvement of healthcare and social care in Latvia.

As in inspectorates in many other European and other countries worldwide, the Latvian inspectorate is struggling to find a proper and effective way to introduce a (cost) effective working method in inspection and supervision. Many practices from other countries are available on how a risk-based approach could be used.⁶⁴

The risk-based criteria for prioritising which organisations to inspect or audit - as being used or planned to use in Latvia do not consider statistical risk factors for helping determine who should be reviewed. Furthermore, the current criteria do not seem to select key risk areas as the criteria are partly volume based (which does not have a clear-cut relationship with health and social care risk) and the criteria seem to have a highly subjective character and are therefore difficult to defend and to use.

The current risk criteria applied by the HI are:

- Influence on society – the number of specialties covered by the institution
- Previous claims history
- Complexity of legislation that is relevant to the institution
- Patient volumes
- Results of prior inspections and sanctions

There appears to be little transparency of the prioritisation processes.

Inspections appear to be carried out using protocols that relate to the current legislation. However, when asked for proof of the impact of this on the health and safety of the population, there do not appear to be much of an evidence-based to support this.

Effective supervision of personnel is difficult to gauge with the leadership having changed so frequently and the current leader only having been in-post for a relatively short period (8 months). The leadership talked about the need for cultural change and that this was a journey of at least 2 years – which they are at the early stages of.

The Experts are a resource shared across different functions and appear to be stretched and overworked. It was described that each expert was supported by an administrative team, however, many did not use this team environment and, therefore, put more workload on themselves. There are a wide range of duties of the Experts which include review of complaints, preparation and defending of appeals of the outcome of complaints (1/3 of outcomes/findings are appealed) and determining the settlement amount for each claim they review.

The nature of the complaints in relation to the Medical Risk Fund process creates high administrative and litigation burden that adds distraction and high costs to the system and does not seem to have direct and positive influence on the health and safety outcomes for the population.

⁶⁴ see Selected case-studies international examples and good practices

1.5. Quality systems

The supervisory body should:

- define and document its policy and objectives for, and commitment to quality, and shall ensure that this policy is understood, implemented and maintained at all levels of the organisation;
- operate a defined quality system which is fully documented. The system should consist of feedback procedures;
- have a quality system in place that is up to date and accessible to the relevant personnel;
- maintain a system for the control of all documentation relating to its activities. It should ensure that the appropriate documentation is available at all relevant locations and to relevant staff;
- ensure that all actions (documentation and legal actions) are conducted according to national law;
- have documented procedures in place for dealing with feedback and corrective action when discrepancies are detected in the quality system and/or in the performance of inspections; and
- review the quality system at appropriate intervals to ensure its continuing suitability and effectiveness. The results of such reviews should be recorded.

Procedurally, the process is well documented. Whether the process is the most efficient and effective is a separate question. Usually a quality system is one that provides strong procedures with feedback loops to review, reflect and improve processes.⁶⁵ The feedback and review mechanisms in the HI processes are unclear to the EPSO team.

Controls for registration of documentation and corresponding access appear to be in place- though this was not evidenced directly by the EPSO team.

The processes and procedures are reconciled back to national law. Follow-up on actions is less clear. Currently there does not appear to be thematic analysis of systemic issues and a systemic quality improvement culture to help organisations address these issues.

The results of reviews are summarised mainly in the form of summary statistics—including the volume of inspections, volume of and financial amount of claims and penalties. The system seems to have room for improvement of soft skills and improvement of qualitative information exchange.

1.6. Personnel (capacity and capability)

The supervisory body should:

- have procedures in place that define an appropriate skill mix of personnel to be able to conduct supervisory activities;
- ensure that all staff have the appropriate qualifications, training, experience and a satisfactory knowledge of the requirements of the functions to be carried out. They should have the ability to make professional judgements as to the conformity with general requirements using inspection results and to report thereon; and

⁶⁵ see Selected Case Studies International examples and Practices App 4- 8.4.8 (see also the link to the presentation: definition of a well defined good practice for a quality reporting system –by Iceland Leifur for EPSO 17 april 2018 Reporting model for Landlaeknir Iceland.pptx [Download](#))

- have in place a documented training system to ensure the relevant training of its personnel, especially the personnel involved in inspection or disciplinary cases. The programme should include introduction, initial training, supervision and continuous education.

The HI team operates over 6 divisions across 14 locations with two main focus areas of inspection and public health. (50/50 split). This includes 5 regulating and controlling and 1 Registration. There are 214 staff, 140 of which are involved in inspections which includes 10 senior experts (doctors). The staff include 20 with a medical background (from a range of specialties). The current HI is a consolidation of 9 different institutions brought together in 2009 and there is a split of 9 main activities.

The leadership reflected that the separate areas of the HI still often operate as separate cultures. There does not appear to be a common mission/goal that gives the team a common identity and purpose.

There is no dedicated training programme for inspectors. Training in quality improvement practices does not exist. However as one of the goals of this peer evaluation mission is to use the results of the review for training purposes, there must be a supportive atmosphere for training of staff as improvement instrument.

There are limited numbers of staff available to undertake inspections.

The procedures used by the internal experts are largely self-determined and there is no culture of a team-based approach.

It is unclear as to how the (internal/employed) experts keep up-to-date with their professions to ensure the inspections and complaint reviews include the latest evidence and best-practice of the specialties that are involved.

1.7. Facilities and equipment

The supervisory body should:

- have access to suitable and adequate facilities and equipment that support the delivery of its function. This includes IT systems, databases and relevant documentation.

From our interviews, we understand that there are central systems for the recording and tracking of inspections, results, follow-up and for complaints. Except for shortage of staff there has not been much mentioning to the team of issues regarding shortage of facilities or qualitative or other shortage of the relevant IT and database systems.

However, given the relatively new and relatively poor approach regarding a risk-based system of inspection and apparent lack of systematic analysis 'of inspection data such as complaints, outcome of health service's etc., it would be surprising if adequate facilities to support a more data driven, and evidence-based approach would be available without extra financial input.

One advantage of being a late adopter is that an organisation can take advantage of the learning and examples from other countries to ensure the introduction of any new system is customised to their own environment and context.

The situation of a new starting point (new leadership, strong support from the ministry, a positive mindset within the inspectorate towards improvement and change) gives a great opportunity to start with a risk-based approach based on the local circumstances such as political priorities etc., build a sound set of goals and build and adopt the necessary systems afterwards.

In some other countries, the focus has been on implementing an electronic system first then trying to work out how to make it function for the local context – which has resulted in expensive and sub-optimal results.

1.8. Inspection methods and procedures

The supervisory body should:

- ensure that the methods and procedures it uses for its planned inspections are those that are defined in legislation or documented in its policies and procedures;
- ensure that the methods and procedures it uses for incident inspections, are those that are defined in legislation or documented in its policies and procedures;
- set out in a way that is transparent and clear the methods and types of inspections in case of supervision of individual health personnel (disciplinary cases);
- have sound inspection planning arrangements in place. Planning and prioritisation processes should be documented;
- set clear terms of reference and objectives for its inspection activities;
- have quality assurance procedure in place that assure the consistency of judgments across teams;
- set standards for the delivery of its supervisory functions. The standards should include standards for the documentation of observations, the results of testing, information and data obtained during the course of inspections to ensure that they are recorded in a timely, consistent and professional manner to prevent the loss of relevant information. All documentation should be appropriately referenced, signed off and cross-referenced;
- use standardised techniques for sampling and inspection. These should be documented in circumstances where the absence of such instructions could jeopardize the efficiency or outcome of the inspection;
- describe in detail the use of unannounced inspections and the legal framework for such visits; and
- have arrangements in place for the follow up of its inspection findings.

The Latvian Health Inspectorate has a high degree of regulation and procedure – from what was evidenced, this is well documented and followed. Inspections by the HI place a heavy focus on procedural checking against legislative compliance and this is typically carried out by the checking of procedural documents in each site and the proof of compliance against these regulations.

Quality of care is not measured by the Inspectorate in terms of process nor health outcomes. Measurement of the process of improvement of patient safety and quality of care is not a concept held within the inspectorate. There is some early developmental stage work being undertaken in Latvia within a branch of the Ministry – The Centre for Disease Prevention and Control in the development of some outcome indicators. Currently there does not appear to be a sharing of this reporting with the HI to assist them in identifying and prioritising inspection of organisations.

The objectives of the inspectorate itself are clear. The objectives of the inspections are for safety however, the outcomes are not assessed.

Current measurements used by the HI are volume based (i.e. how many inspections were conducted, how many complaints were reviewed) and, within the inspections, many of the measurements relate to the volume of documents that were reviewed for compliance.

Most of the measurement is based on numbers and timescales

The so called “soft information” and the “qualitative information” is mainly still missing in most of the overview documents provided to the team. However, it seems that a great quantities data system is providing results in terms of number of reviews, numbers of staff, number of patients timetables etc. Specific results of inspections are shared with the institution being reviewed and there is a right of reply from the institution.

A feedback system does not seem to be in place and communication seems to be more one-way top down towards the Health institutions and Health professionals and Health Patients, and public.

There is no public reporting of results including thematic analysis and reporting of themes of issues that the HI are discovering. Nether is this information shared with the medical society or hospitals, the Nurses association and other stakeholders.

The current risk-based assessment as to how structured inspections are prioritised is mainly subjective and not complemented with objective factors.

There is a template used by the internal experts for assessing the amount to pay for successful MRF claims, however, this is not published. This leads to the impression in the sector from a number of stakeholders that this is a highly subjective process and subject to wide variation based on the interpretation of individual experts.

Some inspections take place as unannounced inspections. This is different and separated from the complaint process. The complaint process does not seem to be a main input for the risk analyses or other inspection targets (systematic quality based thematic inspections). There is opportunity for improvement in this area.

There is no clear procedure that the EPSO review group sighted that outlined the criteria for an unannounced inspection.

The EPSO review team did not see evidence of procedures for inspection of new institutions and facilities.

1.9. Engagement and communication with the organisation or individual subject to review

The supervisory body should:

- clearly communicate the objectives and purpose of its inspections to those subject to inspection.
- clearly set out the consequences of non-compliance with supervisory measurements and requirements and its expectations in terms of response to its recommendations.
- give those subject to inspection the opportunity to comment on the findings, conclusions and recommendations set out in the inspection report.

The purpose of inspections regarding review of compliance with national regulation is clearly outlined in the documentation for the HI. The EPSO review team interviewed a number of stakeholders including some of the hospitals and clinicians (‘customers’ of the HI) regarding the working relationship between the HI and the institutions. There is a clear recognition by these stakeholders that the HI is reviewing legislative compliance – the term ‘Policeman’ was used during several interviews to describe the HI role.

The HI provide a report and there are sanctions for non-compliance including fines being charged.

The institution subject to the inspection is provided with the report and findings and has an opportunity to comment/provide feedback.

It is not completely clear what follow-up process the HI applies to check what remedial action has been undertaken by the institution.

As the initial actions are mainly compliance checks, the follow up actions seem to be of the same character. As far as the team noticed, there is no broader view based on support for improvement (being part of the solution) and search for deeper (systemic) causes of non-compliance with rules or procedures. An example of how this could be effective is for the HI to take a broader view of where there are similar trends across other comparable institutions to find out if and for what reason the same or comparable non-compliance is found.

The team found the communication of the focus of the inspectorate is strong in on compliance and with clear objectives. In case of non-compliance the role of the inspectorate is completely clear and focused on forced compliance actions and sanctions (including fines).

Furthermore, the inspection role is dominated by policing-activities and therefore does not invite to open two- sided communication with improvement as main objective.

In comparison to other inspectorates in Europe this picture is recognisable. However, for good reasons many other inspectorates in Europe are on moving to change this (mainly) compliance approach and make it more pro- active, friendlier, two sided and improvement oriented. These inspectorates usually choose to ask for feedback and invite partners to come forward with solutions. This does not mean that safety is compromised or that sanctions never happen. However, the focus is on improvement not on compliance.

Furthermore, a more Public Relations oriented / minded approach could be a helpful change for the future and to show to the stakeholders as well as to the broader public: what are the goals what is being done and what the challenges are.

1.10. Openness and transparency

The supervisory body should:

- make details of its processes and the findings of its inspections and activities available to the public and other stakeholders; in so doing it should ensure that its reports are written and published in formats that are user friendly and accessible.
- have a policy and guidelines in place setting out its approach for the publication of the results of its inspections.

There is little transparency of results of inspections or cases of complaint to the public. There is no public transparency of the HI's inspections and findings. This is not current policy within the HI and engagement with patients and community is not in place.

From the perspective of the review team, this is an area for improvement and to help change the perception of the HI in the sector.

1.11. Disciplinary sanctions

The supervisory body should:

- have appropriate processes in place for the issuing and management of disciplinary sanctions.

Disciplinary sanctions at the institution level appear to mainly be in the form of fines for non-compliance. The processes are well-documented. It is not clear from the documents sighted as to how corrective action (to ensure the same issue does not arise again) are measured and enforced.

The management of disciplinary sanctions can take a number of forms in Latvia in addition to fines, including:

- the possibility to take or suspend the individual licences (conditionally or unconditionally and entirely or partially) for doctors regulated by the Medical doctor's association;
- the possibility to take or suspend individual licences for nurses and other support staff is regulated by the Nurses association;
- the possibility to take or suspend licences for health institutions is regulated by HI;
- financial claims by patients or others (mainly relatives) as follow up to complaints regarding harm or medical failures;
- claims regarding professionals;
- publicly assessable and independent reviews of doctors' hospitals and other health services by patients HI etc. can be a strong instrument if used appropriately; and
- press and media coverage can be a very helpful instrument for transparency.

The team did find a number of opportunities to move more in the direction of other levers rather than the traditionally-used sanctions in Latvia.

One of the weak points of the inspectorate / government is that these options are not yet sufficiently used and supported.

If the government and the inspectorate of Latvia could use other parties to help 'police' the system, the inspectorate could focus more in the direction of co-operation and improvement of healthcare system and individuals.

Possible options for change are discussed in the chapter entitled 'Reflections of the team'. In summary this provides ideas about involvement of others in this police role so that the HI can focus on its central HI tasks. If we think about others this could include different parties such as: the doctors association, the nurse's association, the health services themselves with distanced supervision of the health inspectorate, the insurance organisations using the rights to claim and possibly other options. Possible good practices are shown in chapter 6 of the main report.

1.12. Impact assessments

The supervisory body should:

- have a policy and process in place for measuring the impact of its work
- regularly consider and assess how its inspection activity may contribute to the improvement of quality of care and patient safety.

The EPSO review team did not see any evidence of measures in place to enable the HI to assess the impact of its work. Metrics are volumetric and not linked to risk analysis or outcome indicators (e.g. reduction in falls, reduction in sepsis or other conditions to assess risk and impact).

There is some developmental work on quality indicators being undertaken within the Ministry's Centre for Disease Prevention and Control - which may prove useful for the HI to plan risk-based audits and reviews, over time, improved outcomes that can be traced back to the HI's interventions.

1.13. Cooperation and engagement with other stakeholders, patients and other supervisory bodies

The Supervisory body should:

- ensure that in taking forward its role it engages with patients, the public and other stakeholders; seeking their views and experiences.
- work in collaboration with other review bodies to share experiences and identify noteworthy practice.
- share its knowledge in relation to patient safety issues with health organisations.

The HI prioritises its planned activity for each year based on a combination of Ministerial priority areas and (the HI's existing) risk-based scheduled inspections. Currently there does not appear to be consultation with community and patient groups or professional bodies.

Appendix 4 Selected case- studies, international examples and good practice

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Introduction

This Appendix to the Report of the Report Regarding Expert services in the area of healthcare quality and patient safety provides a selection of international examples and best practices.

The examples and best practises are chosen for their value as inspiration to the Latvian Health inspectorate for their future work by the Peer evaluation team which carried out this project

The Examples and best practices are divided per category; the following categories are distinguished:

1. The aim of supervision with key issues in most countries (Quality and patient safety and involvement of the User perspective)
2. User and patient centred supervision
3. Effectiveness of Supervision
4. Prioritising and Differentiating the supervisory activities
5. Complaints Handling
6. Self-assessment and Incident reporting
7. Engagement of Stakeholders
 - 7.1. Advisory Bodies
8. Methods of inspection
 - 8.1. Risk based supervision – general
 - 8.2. Use of indicators in Risk based supervision
 - 8.3. Other Methods of inspection
 - 8.4. Feedback Reporting and Follow up activities

The input in this Appendix is based on several sources:

- a. input from team members and contacts of team members
- b. input from EPSO members in EPSO working groups and presentations at EPSO conferences
- c. other sources such as open sources like relevant websites in the various countries sometimes translated by the team or checked by the team.

EPSO is ready to facilitate contacts between Latvia (Ministry of health, Health Inspectorate etc.) and officials in the countries mentioned in this Appendix

1. The aim of supervision

Key issues in most countries are quality and safety and the user perspective

1.14. Sweden

<https://www.ivo.se/om-ivo/other-languages/english/about-ivo/>

The Swedish Health and Social Care Inspectorate (IVO)

The aim of IVO's supervision policy is that Supervision shall contribute towards ensuring that health and social care is both safe and of high quality, and works to serve best to its recipients. Sweden, The supervision's focus of IVO is supervision carried out from a user- and patient perspective, and must focus on matters that are important for individuals or groups. Unless laws or ordinances state otherwise, supervision should be risk-based and only review matters that are essential to ensure a health and social care service which is safe and of high quality. Supervision must be effective.

(<https://www.ivo.se/globalassets/dokument/om-ivo/andra-sprak/swedish-health-and-social-care-inspectorate-supervision-policy.pdf>)

1.15. England

The Care Quality Commissions (CQC) purpose is to make sure that health and social care services provide people with safe, effective, compassionate, high-quality care, and to encourage care services to improve. CQC's challenge is how they measure that they are achieving their purpose and how they measure the impact that they are having on quality and improvement.

https://www.cqc.org.uk/sites/default/files/20170425_Impact-report.pdf

CQC's corporate strategy ambition for the next five years is the more targeted, responsive and collaborative approach to regulation, so more people get high-quality care:

1. Encourage improvement, innovation and sustainability in care
2. Deliver an intelligence-driven approach to regulation
3. Promote a single shared view of quality
4. Improve our efficiency and effectiveness.

1.16. Scotland

The Care inspectorate Scotland for social care and social work scrutiny in Scotland is moving its aim from compliance to an improvement-focused approach which aims to provide assurance about the quality of care.

Recently there are two elements of change in the Care inspectorates approach: a greater methodological emphasis on evaluating the quality of people's experiences and outcomes, and a new set of national care standards. This 'Scottish model' may help provide a theoretical framework to resolve past tensions between scrutiny and improvement. Modern scrutiny can become an important tool in the quality toolbox.

<http://www.careinspectorate.com/index.php/papers-in-scrutiny-and-improvement-practice>

<http://www.careinspectorate.com/images/documents/3809/If%20inspection%20is%20the%20enemy%20of%20improvement.pdf>

Fig 1. The Scottish model of social care scrutiny

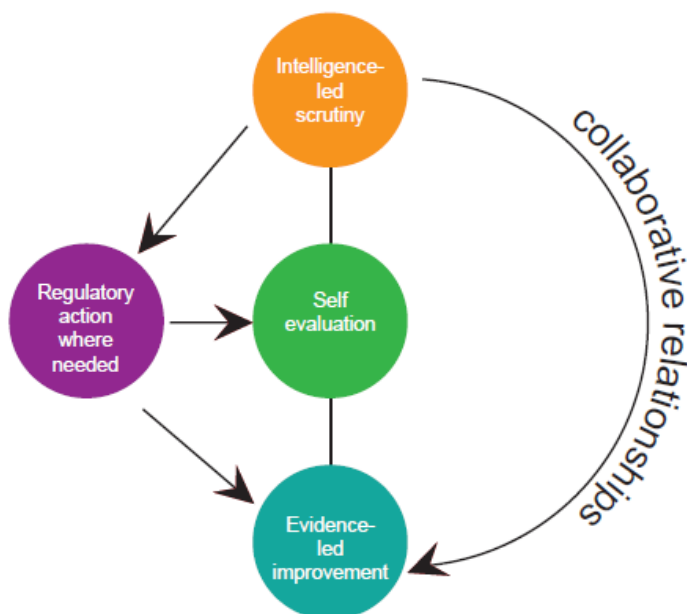


Fig 2.The shift from compliance to improvement support (CI, Scotland).



1.17. Denmark

1.17.1. the NBSS (The National Board of Social Services)

In Denmark The NBSS has a number of guiding principles:

- Proactive supervision:
 - a minimum one annual inspection (announced & unannounced)
 - Ongoing monitoring and dialogue
 - Approvement of all major changes
 - Intensity of the supervisory process according to the conditions
- Supervision based on risk assessment (differentiated supervision)
- Data triangulation (e.g. document studies, interviews and observation)
- Involving the users perspective is a must in the legal framework.

1.17.2. The DPSA (The Danish Patient Safety Authority)

In Denmark the goal the DPSA is to ensure that it is safe to be a patient and to support learning in the healthcare sector. The aim is to allocate resources to areas associated with the highest risks for patients based on a continuous risk analysis and thereby achieve the highest possible level of patient safety. In 2017, the DPSA introduced a new risk-based model for supervisory activities. It is expected that the DPSA will be able to identify high-risk situations and help ensure correct handling of these in the healthcare sector. Furthermore, learning should be integral to supervisory activities of the DPSA. It is the aim that both healthcare facilities that are subject to supervisory activities and those that are not will be drawing on the DPSA as a source of knowledge and learning to improve patient safety.

2. User and patient centred supervision

The user perspective is in most of the EPSO member countries an important issue. This has not always had such an important priority as it has nowadays. The main cause and reason for this seems to be the fact that patient views often differs from the views of the medical professionals and differs from the inspectorates views. Many countries have seen changes for the good by using the patient perspective.

2.1. Sweden

Ivo highlights the user and patient perspective as the essential starting points for IVO's work. <https://www.ivo.se/globalassets/dokument/om-ivo/andra-sprak/swedish-health-and-social-care-inspectorate-supervision-policy.pdf>

2.2. Scotland

An important element of the Scottish patient centred system is that the improvement of patient safety and quality of care is enhanced by the individual patient experience.

What they found in Scotland in the past, is when they made recommendations for improvement, providers were improving to satisfy the regulator (supervisors) rather than having the patients perspective in mind for improvement. It is good to think about how the assessment of improvement looks like. It is not about compliance with their (supervisors) expectations and agreeing with them, but to really take patient-centred approach.

http://www.epsonet.eu/mediapool/72/723588/data/2018/171103_EPSO_Working_group_Effective_ness_Meeting_report_Iceland_Sept_2017_M.Murel.pdf

2.3. England

The Care Quality Commission's (CQC) Public engagement strategy: a more targeted, responsive, and collaborative approach to public engagement which harnesses the power of people's voices throughout our regulatory work and empowers people to expect and choose good care.

Public engagement objectives:

1. Work in partnership with organisations that represent people who use services to strengthen our collective voices and influence improvements to care – including closer working with the Healthwatch network;
2. Continuously encourage and enable the voices of people who use services, their families and carers to drive our understanding of the quality of care, making better use of their information and improving our reporting on the action we take in response;
3. Provide and promote public information which helps people understand what good care looks like and make decisions about services;
4. Develop and improve what we do through public participation and insight.

People's self-reported experiences of care are core to CQC identifying where quality of care may have changed to the extent that regulatory action may be required.

CQC understands the efficacy/accuracy of people's self-reported experiences of poor care as a risk indicator (across different population groups, care themes and service types).

CQC Policy Teams, Chief Inspectors and CQC Board report increased confidence that they have heard from enough members of the public to make informed decisions about CQC strategy, policy and methods.

www.epsonet.eu/mediapool/72/723588/data/2017/Chris_Day_London_2017.ppt

2.4. Denmark

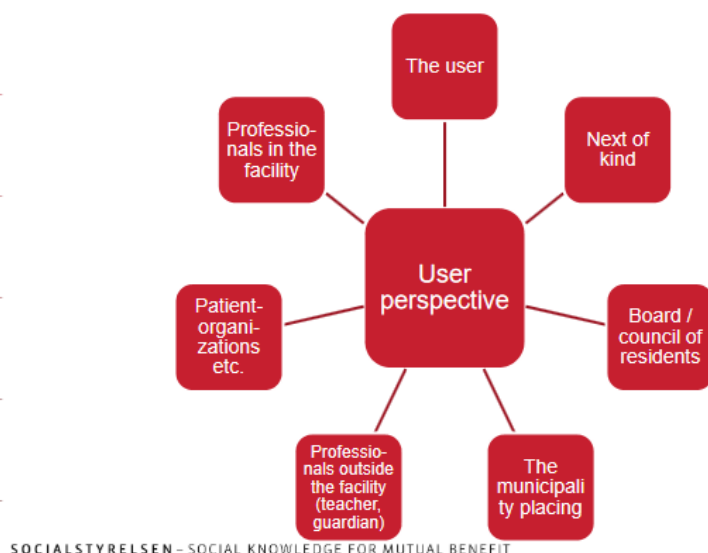
2.4.1. The National Board of Social Services

The NBSS has a policy to strengthen the user perspective in several ways:

1. Transparency regarding aim, process and methods promote trust
2. Use daily activities and the natural setting as a starting point
3. Create safe spaces for communication and supervision (not the managements office)
4. Methods and products of communication aimed at relevant target group –e.g. children and disabilities

5. Professional analysis and reporting counters fears/actions of repercussion.
http://www.epsonet.eu/mediapool/72/723588/data/2017/EPSON_-_WG_patient_and_user._Henrik_Frostholtm_-_London_-_April_2017.pdf

Figure 3. NBSS: A wider Understanding of the “user”:



2.4.2. The DPSA (Danish Patient Safety Authority)

One of the aims for the supervisory activities of the DPSA is to “follow in the patient’s footsteps” to ensure safe care across the healthcare sector.

The DPSA has involved patient organisations in the stakeholder engagement regarding the supervisory activities aimed at healthcare institutions. These organisations have been invited to contribute to the development of indicators and to follow the progress of the DPSA’s supervisory activities. However, so far patients/users have not been actively involved in supervisory activities.

In 2018, the DPSA is introducing supervisory activities specifically aimed at elderly care with a strong focus on the user and patient perspectives. These will most likely include interviews with residents/patients and relatives/next of kin as well as staff and management but as they are still in development it is too early to say anything about the outcomes and effect of this approach.

2.5. The Netherlands

Patient involvement in Dutch supervision:

- Incident-based supervision: calamities reported by citizens
- Risk-based supervision: patient rating site Zorgkaart Nederland
- National Reporting Centre for Health care Complaints (LMZ)
- Inspection practice: SOFI-method for elderly clients with dementia, mystery guests, layman inspectors (pilot)
- Interview with clients or family during visit, especially in care sector

Patiënt rating site Zorgkaart Nederland:

- Ratings and reviews
- 800,000 visitors per month
- 9,000 new reviews per month, more than 300,000 reviews in total
- Editorial office
- Check on IP-addresses, names
- Only explanatory, constructive reviews
- Subject of studies

Exploratory interview study of the potential contribution of Zorgkaart Nederland to daily hospital supervision showed by IGZ (Dutch Health Inspectorate) identifies the same hospitals at risk as the patients rate as underperformers.

http://www.epsonet.eu/mediapool/72/723588/data/2016/5_IGZPatient_Involvement_EPSO.pptx

Also patient rating sites may contribute to the risk-based supervision of hospital care of a health care inspectorate. Health care inspectors do have several objections against the use of patient rating sites for daily supervision. However, when they are presented with texts of negative reviews from a hospital under their supervision, it appears that most inspectors consider it as an additional source of information from the patient's perspective to detect poor quality of care. Still, it should always be accompanied and verified by other quality and safety indicators. Preferably, it should also be accompanied by other methods to reveal patient's experiences, to broaden the patient's perspective on quality and safety of care.

http://www.epsonet.eu/mediapool/72/723588/data/2016/Kleefstra_et_al._2016_Investigating_the_potential_contribution_of_patient_rating_.pdf

3. Effectiveness of supervision

In most European countries the topic of effectiveness of supervision came higher on the agenda in the years of austerity and the financial crises which has had severe effects on healthcare funds in some countries. The results of this focus can be seen in this paragraph

3.1. Sweden

The effectiveness of the supervision must be seen in relation to the extensive demands and expectations which are placed on the organisation, in combination with its limited resources. This allows a lot of room for manoeuvre when selecting the emphasis of the supervision. As such, the emphasis becomes a prioritisation matter based on what elements will contribute the most toward a health and social care service that is safe and of good quality. It involves weighing the required efforts against the achieved results of the supervision.

<https://www.ivo.se/globalassets/dokument/om-ivo/andra-sprak/swedish-health-and-social-care-inspectorate-supervision-policy.pdf>

3.2. Scotland

Scotland is looking for measurement questions regarding effectiveness of the inspection and regulation activities. Evidence based added value is not easy to prove. However, the Inspectorate is working on these questions.

http://www.epsonet.eu/mediapool/72/723588/data/2018/171103_EPSO_Working_group_Effectiveness_Meeting_report_Iceland_Sept_2017_M.Murel.pdf

3.3. The Netherlands

In the Netherlands the Inspectorate (IGJ) is working on a model in which hospitals are doing the investigation in their own serious adverse events cases. Thanks to evidence based research it was shown that this method has an effective improvement element. This positive result could be shown to the politicians afterwards as a result of the availability of data.

http://www.epsonet.eu/mediapool/72/723588/data/2018/171103_EPSO_Working_group_Effective_ness_Meeting_report_Iceland_Sept_2017_M.Murel.pdf

3.4. Denmark DPSA

In Denmark there is so far no conclusive evidence on the effect of the supervisory activities of the DPSA. However, there are indications that in certain types of healthcare facilities, compliance levels are higher in the second year of the current supervisory set-up, suggesting that supervision is a driving force for improvements across facilities. Also, feedback from both healthcare institutions and supervisors indicate that supervisory activities can facilitate learning both before, during and after a supervisory visit, which in turn can lead to improvements and higher levels of patient safety. Follow-up interviews with management in residential care facilities suggest that learning and knowledge sharing following a supervisory visit can spread to other facilities, e.g. in the same municipality. This is in line with the DPSA's aim that learning should be integral to supervisory activities and that both healthcare institutions that are subject to supervisory activities and those that are not can draw on the DPSA as a source of knowledge and learning to improve patient safety throughout the healthcare sector. However, these findings are preliminary and will need to be supported by more data to conclude with certainty what the effects of the DPSA's supervisory activities are.

4. Prioritising and differentiating the supervisory activities

4.1. Sweden

In Sweden prioritising may differ from case to case and is depending on the purpose of supervision as seen by IVO. The aim is to focus on the important elements in order to provide a good and safe health and social care service for its users and patients. The inspectorate uses its procedures to concentrate on outcome for patients and tries to prevent to look only at documentation, guidelines and procedures.

<https://www.ivo.se/globalassets/dokument/om-ivo/andra-sprak/swedish-health-and-social-care-inspectorate-supervision-policy.pdf>

4.2. England

CQC is in line with its five-year strategy, has also consulted on moving towards a more targeted and responsive inspection model, which will see services rated 'good' or 'outstanding' inspected less frequently along with the introduction of a new 'Insights' model to support its ambition to become more intelligence-driven. The CQC's proposals represent an important step forward towards a more streamlined approach.

<http://nhsproviders.org/the-changing-nature-of-regulation-in-the-nhs/care-quality-commission>

4.3. Denmark DPSA

The aim for the DPSA is to allocate resources to areas associated with the highest risks for patients based on a continuous risk analysis and thereby achieve the highest possible level of patient safety. In 2017, the DPSA introduced a new risk-based model for supervisory activities which is being

implemented over a three year period. During this period, all types of healthcare institutions and facilities should be subject to supervision, and the aim is that 10 percent of facilities should receive a visit from the DPSA supervisors. This should establish the baseline risk profile for each type of facility which, alongside others sources such as reported patient safety incidents and patient complaints, should help identify high-risk areas for future supervisory activities.

At this point, institutions are selected for supervision based on samples, not individual risk analyses. The DPSA is working to develop an algorithm that will allow for risk assessment of individual institutions. So far, however, risk analysis is solely used to identify risk areas, such as medication and patient transfers, and types of facilities, such as residential care, where many data sources point to high risks.

The risk-based model entails that in the future, alongside selection of healthcare facilities based on risk analysis, there should be some level of sample-based supervision to ensure that all healthcare institutions could potentially be subject to supervision. However, the bulk of activities should be aimed at types of facilities involving the highest risk for patient safety.

5. Complaints Handling

5.1. Denmark DPSA

See below – under 5.2 Sweden

5.2. Sweden

All complaints should first be handled by the caregiver who has to investigate all complaints. There is a "patients ombudsman" (patientnämnd) who can help in the communication between the patient and the caregiver. The patient ombudsman doesn't investigate self any complaints.

Prior to the new law IVO had to investigate all the complaints. As of January 1, 2018, IVO has the obligation only to investigate all events that have resulted in permanent injury, a significantly increased need for care or death. IVO will also investigate complaints relating to compulsion or isolation and events that seriously and negatively affect self-determination, integrity or legal status.

IVO has no obligation to investigate all that is notified as complaint. IVO has the right to decide independently if there is reason to use their supervisory powers in case of a complaint. The assessment is based, inter alia, on what individuals report, but also on other tasks that IVO may have. A supervision can be initiated immediately, or may happen later, depending on how the IVO assesses the data available. All data are to be submitted to IVO if activities are registered as complaint and can be used when IVO plans which controls to be implemented.

If something is reported to IVO it will be notified and the person involved is informed on how IVO will handle the information.

Anyone can provide information about deficiencies or misconduct, or comment otherwise. This applies regardless of whether you are concerned, whether you are related or if you are otherwise aware of the shortcomings in an activity.

This change in the Swedish complaint system was made based on a government ordered investigation, of which the aim was to provide suggestions on how to handle healthcare complaints more effectively based on patient needs, contributing to improvement of patient safety and resource-effectiveness. The Swedish report is called Fråga patienten Nya perspektiv i klagomål och tillsyn. Statens Offentliga Utredningar 2015(Ask the patient New Perspectives in Complaints and Supervision. The Governments Official Investigations). This investigation concluded that the previous complaints handling system was

taking too much of IVO's resources, which reduced the authorities ability to conduct a patient-centred risk-based supervision.

The Swedish investigation commission also compared the complaint systems in four other countries: Denmark, England, Norway and Finland.

In all these four countries, there is also the possibility of submitting notifications and complaints directly to the healthcare provider. In Finland and England, it is encouraged to first and foremost conduct a dialogue between patients and caregivers.

In Denmark patients are given the opportunity to have a dialogue with the healthcare provider before the complaint is handled by the supervisory authority. An evaluation has shown that in almost half of the complaints sent by the Danish supervisory authority to the care provider for dialogue with the patient, patients chose not to proceed with their complaint to the supervisory authority. Patients were generally more satisfied with the treatment of their complaint if the complaint was terminated following a dialogue with the caregivers.

In all countries there is also the opportunity to report a complaint to a supervisory authority- in England and Denmark at national level and in Finland and Norway at both regional and national level. Other similarities between the systems are that in all countries there is a supportive function for patients.

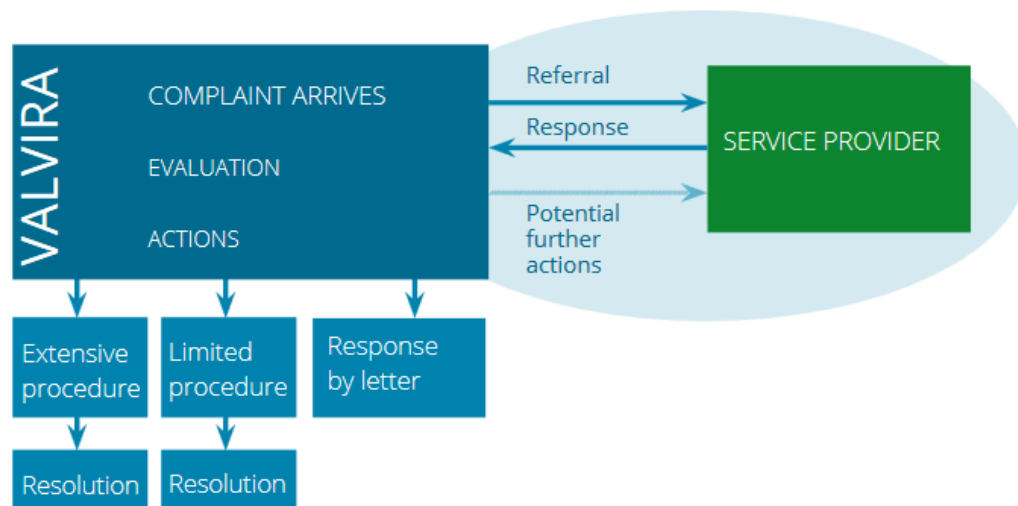
In England the Care Quality Commission has worked actively to develop patient-centred supervision. The Authority has developed different strategies for collecting patients' experiences as a basis for supervision, for example in the selection of supervisory objects. People are always interviewed during inspections and their reports are available to the public. In Finland, the goal is to refocus supervision from retroactive measures to proactive guidance and supervision. Although there has been no systematic follow-up of the conversion, the supervisory authority has a clear perception that the planned oversight of specific areas has been effective and that the number of complaints has decreased as a result.

5.3. Finland

The Finnish Health supervisory organisation (Valvira)⁶⁶ has revised its approach in health care supervision matters. The overhaul has allowed them to gain greater efficiencies, to respond to the challenge of diminishing resources and to apply self-monitoring as the primary regulatory approach. The health care complaints procedure was revised in 2015. A proportion of the complaints will now be referred to the service providers as grievances, some will be responded to by letter and copies of the patient records will be requested for the remainder to allow Valvira to address the matter. A part of these complaints will be resolved on the basis of the patient records or another more limited procedure. Only some of the complaints will be called in for a more extensive investigation. In order to speed up and improve the processing of complaints and feedback submitted by clients and patients, they would amend current procedures and legislation to create a requirement for all expressions of dissatisfaction to be initially dealt with by the service provider in question.

⁶⁶ This information is presented to EPSO in the past and is not recently checked for this report with the Finnish Valvira

Fig.5 complaint system in Finland:



5.4. Portugal

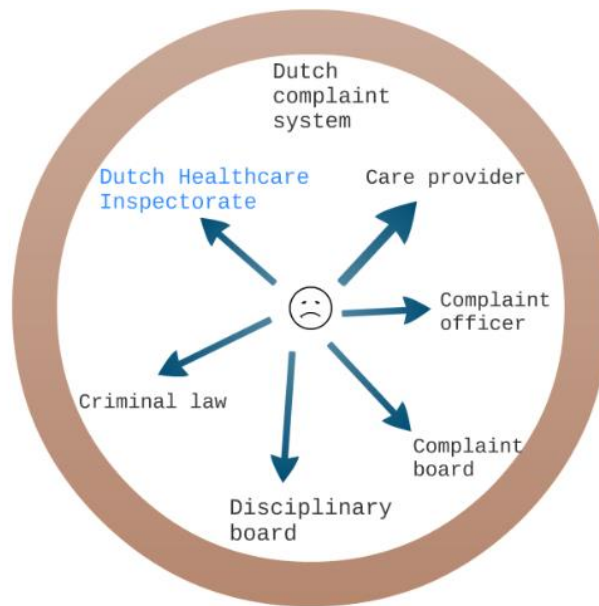
In Portugal, if patients /users believe that a health care provider violated their (or someone else's) rights, they may file a complaint through asking the provider for the official Complaints Books, which must be made available by the public, private and social health care providers, submitting a complaint at the Online Complaints Book that is available at www.ers.pt, <https://www.ers.pt/pages/167>, addressing a written complaint to Portuguese Regulatory Authority (ERS), by post or by email.

All complaints are first handled at a local level, but a copy of the complaint must be sent to ERS, as well as information on its outcome. ERS, initially just traces the complaint and the outcome. All the complaints and outcomes are in the ERS database. If they were solved at a local level, they are used as a source for risk analysis, for inspection or recommendations on quality improvement. Nevertheless, twice a year a global descriptive report is published. The complaints which are not solved enter in a data analysis triage, elaborated by ERS, involving an inspector and an independent caregiver. ERS asks for further information, from the parties, and from the medical association, nurse association, etc. to gather their expertise. The final decision is from ERS. If the decision is not accepted the case goes to the courts, but ERS may suggest mediation or other alternative dispute resolution process. Only situations involving serious or permanent injury to the patient occasionally go to court.

5.5. The Netherlands

The Dutch Healthcare Inspectorate (IGJ)

- Receives 1500 complaints citizens annually
- Not meant to be an individual complaint handler
- They are eligible for further investigation when complaints point to structural or very severe problems
- Was however criticized for not taking patients seriously.



They divide complaints:

- Clinical domain
- Relationship domain
- Management domain

http://www.epsonet.eu/mediapool/72/723588/data/2016/4_R_2_.Bouwmann_epso_prezi.pdf

5.6. Belgium

Belgium ⁶⁷(Flanders' Care Inspectorate) was in the past used to divided the complaints in three categories:

- Information
- Notifications
- Complaints.

Notification is done in case of:

- Anonymous complaints (without the residents' safety being threatened)
- An inspection has already been instructed, i.e., for another complaint or as part of the recognition process
- In case of a recent regular inspection having resulted in a positive report. For instance: complainant states occupational therapy is lacking, but inspection report states occupational therapy is sufficient, and there is no staff shortage
- Complaints which can only be determined with great difficulty or not at all
- Subjective complaints: i.e. food contains too much pepper, unpleasant smell in cafeteria
- Complainant wants to wait before officially lodging a complaint, i.e. wants to talk to management first. Notification then seeks to establish whether anything has been resolved.

⁶⁷ This information from Belgium is a best practice of complaint handling as presented to EPSO in the past; the actual developments in complaints handling are not checked for this report.

- Complaints that can no longer be redressed but imply no direct danger to residents
- Complaint can be resolved by RIF (i.e. wrong monthly invoice, written contract not according to legislation.) Inspectorate is notified in order to establish whether the problem has really been solved as agreed between RIF and care provider. (i.e. has the written contract been adapted and been presented to all residents.

http://www.epsonet.eu/mediapool/72/723588/data/brussel/Presentatie_brussel_complaints_wg_rusthuisinfofoon_rif_eng_2.pptx

6. Self-assessment and Incident reporting

6.1. Denmark (Danish Patient Safety Authority - DPSA)

In Denmark, reporting patient safety incidents is mandatory for healthcare professionals and optional for patients and relatives/next of kin. In 2017, a total of 211.873 patient safety incidents were reported to the Danish Safety Database (DPSD). This is a slight increase compared to previous years.

Individual reports are analysed and used for learning locally before they are submitted to the DPSA. The overall aim of reporting patient safety incidents is to improve patient safety and support a safety culture in the health services where learning from mistakes is integral to the daily routines in the healthcare sector.

The reporting system is confidential and sanction-free. This means, among other things, that details about the reporter may only be disclosed to a few specific persons working with patient safety in the region, municipality or similar institution where the incident was reported and that incidents are depersonalised before being concluded and submitted to the DPSA. The intention is to build confidence in the system and encourage the reporting of incidents so we may learn from preventable errors.

Therefore, individual reports cannot lead to supervisory activities aimed at the facility or professional(s) involved in the incident. The DPSA can only use reports to identify high-risk areas and gain a deeper understanding of high-risk situations. This knowledge can in turn be used to develop indicators for supervisory activities in general.

The DPSA encourages healthcare facilities to perform self-assessment using the indicators used in the DPSA's supervisory activities. However, there is no requirement for institutions to do so, and it would seem that there are very different approaches to this type of self-assessment across the healthcare sector, with certain types of organisations being very mature in terms of having routines for self-assessment, while others have no such routines.

6.2. The Netherlands (Health and Youth Care Inspectorate – IGJ)

The Dutch Healthcare Inspectorate aims at improvement of the earning capability of hospitals. Hospitals are responsible for their quality of care. The inspectorate aims at prevention of the risk a hospital experiences an adverse event and does not take adequate improvement measures, thus sustaining the safety issues that made this event possible. The inspectorate expects hospitals to execute a proper adverse event investigation (self-assessment), leading to improvement measures. Afterwards the inspectorate will evaluate the report. The Inspectorate's goal is that each Dutch hospital can execute a proper investigation (e.g. Root Cause Analysis). The IGJ measures the quality of the investigation reports, gives specific feedback on relevant items and tracks the quality of these

reports over time. The Dutch questionnaire for scoring used by the IGJ: <https://qualitysafety.bmj.com/content/26/3/252>

6.3. Sweden

Healthcare providers must conduct self-control with a frequency and to an extent such as that it ensures the quality of care provided. A satisfactory self-check is one necessary part of a caregiver's work to get to know her business better and identify improvement areas. Systematic patient safety consists of among other self-monitoring there one of the parts they willing to identify risks and deficiencies in activities, for example through collection and analysis of complaints and data from different quality records. By analysing risks and deviations at the aggregate level the underlying causes can then be identified after which action can taken right place. Furthermore, self-control deals with the care provider systematically follows up introduced measures or new ways of working have resulted in desirable effects.

It is important that experience from self-control in terms of collaboration is spread in part their own activities, and partly to other healthcare providers who can learn lessons. Through such work, caregivers can work long-term towards increased patient safety. It is a continuous work that is ongoing and therefore cannot be said to have any final goal. When all aspects of patient safety work and happen with regularity and systematics care providers have a satisfactory self-control that complies with the requirements for control of the activities set out in the third chapter of the Patient Safety Act.

<https://www.ivo.se/globalassets/dokument/publicerat/rapporter/rapporter-2018/samverkan-for-multisjuka-alldres-valbefinnande.pdf>

There is no well-defined self-assessment model in Sweden. In one project the idea of IVO was to let the health care providers make their self assessment. The inspectorates role was to create an arena for the providers to discuss their outcome of the self assessment, both method and outcome.

6.4. Finland

National Supervisory Authority for Welfare and health (Valvira) and regional administration work out nationwide on-screen programs that provide common guidelines for supervision and asset management. The goal is to focus the supervision from retroactive measures to proactive guidance and monitoring. The supervisory programs have been prepared in such a way that they also serve as basic documents for self-control. Valvira has placed particular emphasis on promoting effective, proactive and interactive supervision based on risk assessment. They state that self-monitoring carried out by service providers themselves is, and ought to be, the most effective form of supervision. The role of the supervisory authorities is to offer support and guidance to the social welfare and health care service providers as they undertake self-monitoring. Evidence suggests that their work has been effective, and the quality of self-monitoring has improved significantly and they also perceive a greater culture of openness among the service providers.

http://www.valvira.fi/documents/18508/101799/Valvira_effective_supervision_2016_web.pdf/335007a4-6c27-45df-bc2d-9c754ea06dee

Social welfare and health care service providers in Finland are committed to:

- Continuous service improvement
- Drawing up, updating and reviewing a self-monitoring plan and making it publicly available
- Implementing the self-monitoring plan
- Ongoing monitoring, assessment and improvement of their service

- Reflecting the views of staff, patients, clients and next of kin as they further develop their self-monitoring practices

Valvira, the Finnish Health care inspectorate:

- Provides support and guidance on self-monitoring
- Ensures that self-monitoring arrangements are fit for purpose
- Is responsible for creating a national knowledge base, self-monitoring quality indicators and self-monitoring models in collaboration with the Ministry of Social Affairs and Health (STM) and the National Institute for Health and Welfare (THL).

The Aim of Valvira is to ensure that systematic self-monitoring arrangements are in place at all social welfare and health care settings that will prevent inappropriate conduct, identify shortcomings and allow service providers to address these without delay. This ensures the availability of safe and high-quality services for clients and patients. Self-monitoring will always be the primary supervisory method in the social welfare and health care sector in Finland. The employer is primarily responsible for monitoring their own operations and staff. It is also the sole entity with the capacity to provide guidance, undertake monitoring and evaluate the services for which they are responsible in real time and to take action without delay to address any shortcomings identified. Leadership plays a key role in the self-monitoring of service quality and compliance.

Training and research into self-monitoring is now being undertaken as part of the initiative, resulting in new information and free online training resources. The free online training module provides a wealth of useful information on how to create and implement a self-monitoring plan. (<http://www.lapinkorkeakoulukonserni.fi/Sociopolis/Opetus/Omaalvontakoulutus#>)

7. Engagement of Stakeholders

7.1. Finland

National Supervisory Authority for Welfare and Health (Valvira) sees that their operating environment is changing. Instead of a normative approach, they need new practices based on dialogue and interaction. They have taken action to eliminate some of the earlier policies, statements and guidance. They have reduced red tape to ease the administrative burden for municipalities, service providers, businesses and other public bodies without compromising on client and patient safety. They engage different stakeholders via so called interaction supervision

Interaction supervision:

- The supervisory authorities and service providers/commissioners work together to generate long-term solutions.
- Through interactive supervision, cumbersome, retrospective supervision can be avoided.

Interactive supervision methods:

Regional events and guidance and assessment visits

- Meetings between the authorities and service providers as well as other key stakeholders such as clients, patient and client experience experts and patient representative bodies
- Opportunities to discuss broad, pre-agreed topics at regional events and more detailed, specialist topics during guidance and assessment visits
- Consistent approach nationally retrospective analysis and communications
- Information sharing and feedback between the sector and supervisory authorities essential

Guidance

- Multi-platform delivery, incl. at stakeholder meetings, by telephone and letter and via the Valvira website
- communications are also a form of supervision: communicate openly across a number of channels to all our stakeholder groups

Municipal initiatives

- Supervision to become indicator-based
- Action to be in good practice
- Focus on developing self-monitoring and interactive supervision

7.2. Denmark (Danish Patient Safety Authority – DPSA)

The DPSA has a strategy for involvement of representatives from the healthcare sector as well as citizens/patients. The aim is to ensure the relevance and legitimacy of the DPSA's activities. A steering committee with representatives from a range of organisations, institutions and professional societies has been set up to support and oversee the DPSA's supervisory set-up.

The steering committee consists of representatives from the following types of organisations and institutions:

- Professional societies/organisations representing a wide range of healthcare professionals, e.g. physicians, nurses and dentists
- Regions and municipalities
- Private healthcare providers
- Patient organisations
- Authorities, e.g. The Danish Medicines Agency and The National Board of Social Services
- The Ministry of Health.

Stakeholders are invited to participate in the development of indicators and to provide suggestions for the focus of the DPSA's activities.

7.3. Advisory Bodies

7.3.1. Sweden (Swedish Health and Social Care Inspectorate - IVO) Advisory Body

IVO is an arms-length body reporting directly to the Ministry of Health and protected by legislation. The government appoints the advisory council: The task for the council is to have insight and to advise the Director General. The council has no right to take any decisions. The government has appointed 9 persons from the following organisations to advise the Director General (these can be amended over time)

- Private healthcare providers organization
- Stockholm city council
- SALAR (Swedish Association of Local Authorities and Regions)
- Member of Parliament (Government party)
- Member of Parliament (opposition party)
- Nurses organization
- Patient organization (Social and mental health)
- Physicians organization
- Patients Board, (e.g. Ombudsman for patients)

7.3.2. Portugal

The Portuguese Health Regulation Authority (ERS) reports directly to the parliament, and the head of the ministers (Presidência do conselho de ministros) as prescribed by legislation. It has its own budget, coming from the fees of all the caregivers.

The ERS Advisory Board is the channel for consultation and participation in the definition of the general lines of action of the ERS and in the decisions of the Board of Directors.

The Advisory Board's role includes the requirement to issue a prior and non-binding opinion on all matters relating to the regulatory functions of the LRA that are submitted to it by the Board of Directors and, unless there are duly justified emergency situations, on the generic regulations and recommendations of external effectiveness.

It is also incumbent upon **the Advisory Board to decide on:**

- The budget, the annual and multiannual plans of activities, the balance sheet and accounts, and the activity report
- Other matters referred to it by the Board of Directors.

The Advisory Board may submit suggestions or proposals to the Board of Directors to improve the activities of the ERS. It meets ordinarily at least twice a year and extraordinarily whenever called by its chairman, at the request of a third of its members or at the request of the Board of Directors. The rules on the organization and mode of operation of the Advisory Board are established by ERS regulation: ERS Advisory Board Regulations

The Advisory Board of the ERS is made up as follows:

- A representative of the Government member responsible for health: Member of the Directing Council of the Regional Health Administration of the North, I.P.
- Five representatives of the various categories of establishments referred to in Article 4 (2) of the ERS Statute:
 - A representative of the providers of public nature, with hospitalization: Local Health Unit of the Northeast, E.P.E, represented by the Chairman of its Board of Directors.
 - A representative of the providers of public nature, without hospitalization: Association of Health Centers of the Eastern Port, represented by its Executive Director.
 - A representative of the providers of private nature, with internment: APHP - Portuguese Association of Private Hospitalization, represented by the President of the Direction.
 - A representative of the providers of private nature, without hospitalization: ANEAE - National Association of Specialized Support Companies, represented by the President of the General Assembly.
 - A representative of the social sector providers (private institutions of social solidarity - IPSS and others of this nature): Pulmonale - Portuguese Association for the Fight against Lung Cancer.
- Five users' representatives through specific associations of health care users and consumer associations of a general nature:
 - APIR - Portuguese Association of Renal Insufficients
 - DECO - Portuguese Association for Consumer Protection.
- Five representatives of professional public associations and other professional associations in the health sector:

- Two permanent members:
 - Order of Dentists
 - Order of Physicians
- Three rotating members (two mandates). First two-year term (2015-2017):
 - APEGSAUDE - Portuguese Association of Engineering and Health Management, represented by the President
 - APLO - Association of Licensed Optometric Professionals
 - FNAM - National Federation of Physicians
- Second two-year term (2017-2019):
 - SPMA - Sociedade Portuguesa Médica de Acupunctura
 - UPOOP- Professional Union of Portuguese Opticians and Optometrists
 - Union of Nurses
- Two representatives from other public bodies linked to the health sector:
 - Directorate-General for Consumer Affairs
 - Council of Rectors of Portuguese Universities
- Two independent personalities with knowledge and / or experience in the health sector.

8. Methods of inspection/ supervision

8.1. Risk based supervision

8.1.1. Risk based supervision – general

8.1.1.1. Sweden

The policy of the Swedish Board of Health (IVO) does not describe in further detail how to carry out risk-based supervision,

Ivo provides with the aim to create an overall picture of the Swedish area regularly a systematic analyses of findings from different sources:

- IVO's own sources such as visits , other information etc.
- sources from other actors')
- sources at national level
- sources at regional level
- the patients' and users' views and experiences.

8.1.1.2. England

As the science and evidence of risk profiling comes under the microscope, <http://qualitysafety.bmj.com/content/early/2016/04/15/bmjqs-2015-004687> more countries are looking at their measurement frameworks to see where the best measures and highest correlation to risk actually are. Supervisory organisation are often confronted with budgets and also in England the Care Quality Commission(CQC) with only limited resources for conducting on-site inspections, has used statistical surveillance tools to help it identify which providers it should prioritise for inspection. 'CQC has tested and uses statistical surveillance tools to assess risks to quality and prioritise inspections accordingly

8.1.1.3. The Netherlands

The Dutch Health Care Inspectorate (IGZ) is the official regulatory body charged with safeguarding the quality of care services, prevention activities and medical products. The Inspectorate will take action against any care provider or manufacturer who fails to comply with current legislation. Its approach is 'risk-based', i.e. the Inspectorate focuses on those sectors, health care providers and manufacturers whose activities are seen to represent a high (or higher than average) level of risk to patient safety. The potential risks are identified by a framework of risk indicators.

The Dutch framework of risk indicators consists of five main categories:

- Incident reports and indicators based on the quality of treatment of incidents;
- Inspection findings (The Dutch health Inspectorate's own observations);
- Patient experiences, such as reviews on the public website www.ZorgkaartNederland.nl
- Healthcare related indicators (quality and safety) such as patient outcomes;
- Organisational information, such as financial position and personnel turnover of the hospital or care institute;

http://www.epsonet.eu/mediapool/72/723588/data/2017/20170314_input_Dutch_Health_Care_Inspectorate_IGZ_for_EPSO_risk_working_group.pdf

8.1.1.4. Denmark DPSA

In 2017, the DPSA introduced a new risk-based model for supervisory activities which is being implemented over a three year period. During this period, the DPSA aims to establish a baseline risk profile for each type of healthcare facility which should help identify high-risk areas for future supervisory activities, alongside other sources for risk analysis. These sources include reports on patient safety incidents, patient complaints, input from advisory bodies, clinicians and other stakeholders.

At this point, institutions are selected for supervision based on samples, not individual risk analyses. The DPSA is working to develop a method for risk assessment of individual institutions. However, at the moment risk analysis is solely used to identify risk areas, such as medication and patient transfers, and high-risk types of facilities, such as residential care, where many data sources point to high risks. The risk-based model entails that in the future, alongside selection of healthcare facilities based on risk analysis, there should be some level of sample-based supervision to ensure that all healthcare institutions could potentially be subject to supervision. However, the bulk of activities should be aimed at types of facilities involving the highest risk for patient safety.

8.2. Use of indicators in risk-based supervision

8.2.1. Denmark (DPSA)

In the current model for supervision, the DPSA selects indicators based on risk analysis to ensure that supervisory activities support the highest possible level of patient safety. This includes looking at patient safety incidents, complaints, input from advisory bodies and other sources. External stakeholders are invited to participate in the development of indicators to ensure clinical relevance and legitimacy. However, it has been a governing principle that all indicators should be based on relevant legislation to ensure compliance. This means that for all indicators, there must be a clear method for determining whether or not requirements are met since non-compliance could lead to sanctions for the healthcare facility. This in turn has proven to impose limitations in terms of addressing

known and serious risks for patient safety since it is not always possible to define a clear method for measuring compliance or to point to legislation directly tied to the relevant risk.

Therefore, the DPSA is considering introducing a new type of indicator for use in organisational supervision where the supervisor can introduce one or more topics regarding known and serious risks to ensure that staff and management are aware of these risks and know how to deal with them, without any reporting of the outcome of the conversations about these topics. The aim is to increase the relevance of supervisory visits and strengthen the role of learning and knowledge sharing as opposed to sanctions in relation to supervisory activities.

8.2.2.The EPSO Risk working group (including lessons from the UK, The Netherlands, Sweden and France)

One of the lessons from working group is that supervisory bodies should focus less on 'Big Data' and complex risk profiling. Instead they should identify and find a smaller number / group of indicators which have the best correlation with on-site audit findings of the inspectors

The advice is to focus more on these indicators, and try to work in the direction of 'finding the signal through all of the noise'.

One of the learnings is also one indicator or a small group are not covering all, but can be useful as a start for investigation more in deep.

The EPSO Risk working group is already engaged in this simplification project of identifying the 'best indicators'. Perhaps unsurprisingly, some of the best data sources for the 'state of health' of an organisation are found within patient and staff surveys and cover patient engagement and leadership. This sets the tone for the culture of care and quality.

8.2.3.England.

During previous years CQC has performed large inspections almost in all regulated services and in other regulated sectors. All have received a rating. The CQC ratings have four point rating scale:

- Outstanding
- Good
- Requires improvement
- Inadequate.

Because of those ratings of the providers, CQC is able to look at the relationship between their indicators and those ratings. That has abled them to identify which of their indicators have the best statistical relationship with the ratings. Those are listed out in that document: http://www.epsonet.eu/mediapool/72/723588/data/2017/170314_CQC_SWE_Best_performing_RISK_indicators_overview.docx . Strongest relationships are for hospitals (where they have the best data) and you can see that there are 10-12 indicators for hospitals which are their best performing predictive indicators. Quite a few of them are related to leadership. They are looking quality by using 5 questions:

- Is it safe?
- Is it effective?
- Is it caring?
- Is it responsive?
- Is it well led?

What they see in their analyses is that the quality of the leadership (well led) make really big difference to the rest of the ratings. Therefore quite a lot of their best performing predictive indicators are about leadership. Example- The health worker flew vaccination-quite a strange

indicator on first appearances, but what it tells is that if the hospital is good at getting their workers vaccinated for the flu to make sure they don't have staff absent or have flew in the hospital, that's a sign that they are well performing organisation. And they are getting their people to do what they want them to do.

The last three indicators (from the staff survey from NHS):

- Good staff communication
- Open reporting culture
- Support from managers

Those tell them a lot about what the quality of leadership is, which also has a high correlation to what their quality of care overall is like. There are probably some more familiar ones, like waiting time in A&E (how long ambulance waits outside the hospital before person is inside) and infectious diseases.

For GP's they have less data and their statistical relationships are less strong. The best one are all from GP patient survey, where people tell about their relationship with the GP. For the Adult social care they have relatively little data. They have three indicators they have to look:

- Residential Safeguarding
- Concerns and complaints received by the CQC in the previous 12 months
- Whistleblowing.

They are useful, but they are all relating to something negative what has already happened, so they are not very good early warning for the problem happening at the first place, but often they are indicator that there is a wider problem.

Some of the leadership indicators often are also best performing indicators, but not always. As seen, none of the ASC (Adult Social Care) well led indicators appear in the best performing predictive indicators and none of the GP (General Practitioners) ones either (they do not have any). They keep learning about it and running the analyses, and the patterns they see gives them thoughts where to pay most attention to.

There is a lot of information about their methodology at their website in the handbooks they publish for the providers, so they know what the CQC going to look at when they come. At the website there is also information about how they construct the indicators and where the data comes from. <https://www.cqc.org.uk/>

8.2.4.The Netherlands.

The Dutch Health Care inspectorate uses dashboard (see the presented Dutch input document http://epsonet.eu/mediapool/72/723588/data/2017/20170314_input_Dutch_Health_Care_Inspectorate_IGZ_for_EPSO_risk_working_group.pdf), they make for the inspectors and it is for all health care providers (hospitals, GP's, nursing homes etc.) the same way.

They get part of the information from their own inspectorate i.e. from the incidents reports or previous inspections and then there is information they get from outside (patient experiences, care-related indicators and company information). Separate indicators are listed in the input document. From all the indicators they have chosen together with the inspectors, what are for them the main indicators. They did not measured it really in the statistical way, but they talked with the inspectors and the indicators they thought were very important, they gave a risk score (0-100 where 100 is maximum risk) and together they got overall risk score for each group of indicators and of then they got the end risk score. It is not really the average as the inspectors give a weight to every group score and to every

indicator within the group. They are going to also measure the end score after the inspection, that how risky the inspector found the health provider and then they compare it that with the dashboard end score. They also trust the 'feelings' of the inspector. Sometimes the dashboard says it is all right in that hospital, but when inspector visits it, he/she might not feel that well about it. All together gives them an end score and if the inspectors score differs a lot from the dashboard score, that gives an input for the discussion with the inspector.

8.2.5.Sweden.

For IVO indicators are a very important goal. The indicators are meant to make the risk analyses. Based on that analyses the inspectorate has a focus point. This point indicates where change should be most important. They look at what they have used and what do they like to use. As they have not used many, they really had discussions what they think about different indicators. In that sense if they are good or bad and not really if they are working. They thought that the outcome indicators are important and the process indicators could be interesting and the indicators that show you the structure, they won't definitely not use. If you do not have outcome indicators, you could use the process indicators to show that this is the process you want to change. So their input to best performing indicators is a brief overview what they think might work, not what they are using (see the CQC_SWE Best performing RISK indicators overview) http://www.epsonet.eu/mediapool/72/723588/data/2017/170314_CQC_SWE_Best_performing_RISK_indicators_overview.docx.)

They also had another idea, that if it is reported by the patient side it has much more value in it. When they started the inspectorate years ago there were opinion that incidents reports are really interesting and not the complaints as the patients does not know what they are talking about and now it is all about changing that thought and that patients are the most important. Yes, some are not really informative, but still the information from the patients is important. And also how they use the information they get from the incidents reports.

8.3. Other Methods of inspection

8.3.1.Denmark (DPSA)

The DPSA performs a range of different supervisory activities:

- **Scheduled organisational supervision:** Healthcare facilities receive announced visits, where supervisors perform reviews of documentation and interview staff and management on topics related to the indicators for the relevant type of facility. Indicators are selected based on a risk analysis, while facilities are selected based on a sample.
- **Reactive organisational supervision:** Healthcare facilities receive announced visits based on a concrete concern for patient safety, e.g. based on a complaint or other source of information.
- **Administrative supervision:** Healthcare facilities can be required to hand over relevant documents, e.g. guidelines and patient journals, for scrutiny to ensure that they are compliant and live up to established patient safety standards.
- **Individual supervision:** An authorised healthcare professional can become subject to supervision based on a concrete concern for patient safety, e.g. based on complaints or other sources of information. This can entail interviews and/or monitoring of the healthcare professional over a period of time.

8.3.2.Sweden:

There are different methods for carrying out supervision, such as announced and unannounced inspections, desk supervision, collegial supervision, self-evaluation and system supervision. While performing these different types of supervision, various techniques can be used, for example, document reviews, focus groups, observations, conversations with users and patients, private interviews and questionnaires. When choosing which tools to use, the basic rule is to start with the less radical measures, and introduce stricter ones if necessary.

<https://www.ivo.se/globalassets/dokument/om-ivo/andra-sprak/swedish-health-and-social-care-inspectorate-supervision-policy.pdf>

IVO was established in 2013 with the objective to strengthen the supervision.

Deregulation with many private service providers, in combination with already existing devolution of power, has left the state with few means to govern. There are increasing expectations that the national supervisory agencies shall assure quality and safety in the services provided. That requires a more strategic supervision that contributes to learning and quality improvement.

To be able to contribute to quality improvement and learning effectively, there must be a certain level of trust between the supervisory agency and the supervised. The latter must trust that the agency's primary focus is learning and quality improvement. The supervisory agency must trust that the supervised want to develop and must act in a way that does not create fear. The opposite to trust – mistrust and also fear of making mistakes and the consequences that can follow – is an obstacle for learning and development. At IVO they find that respectful dialogue the most successful method, next to a credible analysis of the problem and addressing the right organisational level.

8.3.3.England

CQC main aim is to make sure health and social care services provide people with safe, effective, compassionate, high-quality care and that they encourage care services to improve.

To achieve that, CQC 'journey' starts with:

- Working with providers and the public to understand what we (CQC) should do and how we should work Responding to a changing market;
- Using the public insight effectively to improve on how we approach organisation's change

The 5 key questions of CQCs are

- Is it safe?
- Is it effective?
- Is it caring?
- Is it responsive?
- Is it well led?

- KLOEs and consultation

Patient centred and involvement:

- Voice before inspection
 - Pre-inspection
- Voice on inspection
 - Experts by Experience (ExE)
- Voice after inspection
 - Thematic inspections
 - State of Care (public report)

8.3.4. Portugal

ERS, The Portuguese Inspectorate/ regulator operates along three distinct lines:

- Investigation, rather than inspection;
- The main aims are to guarantee access to health care and to guarantee quality and safety of healthcare
- Conducting studies and research on specific topics (thematic inspection) resulting in recommendations and advice with a time limit and a follow-up approach .

http://www.epsonet.eu/mediapool/72/723588/data/2018/171103_EPSO_Working_group_Effective_ness_Meeting_report_Iceland_Sept_2017_M.Murel.pdf

The particular characteristics of the Portuguese Health System inspection (ERS) are based on the coexistence of the National Health Service with public and private financing subsystems and voluntary insurance, in which health services the public, private and social sectors are the first objectives of the activity of the Health Regulatory Agency (ERS) to guarantee:

- Compliance with the requirements for the exercise of the activity and functioning of regulated establishments that are part of the Portuguese Health System, including licensing;
- The rights relating to access to health care, the provision of quality health care, as well as other rights of users;
- The legality and transparency of economic relations between the various operators, financing entities and users. In this framework of permanent supervision of the regular operation of the market, it is also of particular importance that ERS assumes its role as Licensing Entity, which is responsible for verifying the minimum technical requirements for the operation of the law and decides to issue licenses to private operators. This is a condition of openness and functioning. In the face of the described, the activity of the ERS in this domain rests, essentially, in two great vectors of performance and three operational models.

The vectors are those of predictability and momentum. Indeed, ERS assumes its commitment to regular market monitoring annually, based on an annual plan of programmed and targeted inspections based on a strategic intervention, which defines the target universe (s) and the factors that determine its selection. This is the monitoring model on the initiative of ERS, with predictability and proactivity in the area of inspection. However, ERS is also involved, on the impulse of operators wishing to access the health market and requiring the obtaining of an operating license, and whenever there are circumstances which indicate a disturbance in the sector of activity and which justify immediate intervention. Here ERS assumes an eminently reactive attitude, in the framework of the flexibility of performance that is required. Regarding the operational models of intervention, we can affirm that they are trailing, to three: - Periodic evaluations / monitoring: Actions to verify compliance with legal and regulatory requirements, quality and safety, applicable to health care establishments, including minimum technical requirements for Users, Documentation in Archive, Organization and Operation, Electrical installations, medical gases, mechanical equipment, areas and circuits and procedures, among others. As a rule they fall into the programmed monitoring. - Inspections: precede the decision on license applications and condition access to the market and are characterized by the evaluation of the minimum requirements for operation, quality and safety. These actions depend on the impulse of the interested party. - Dedicated inspections: These may arise from monitoring or confirmation needs in ongoing processes in the ERS, from external requests, complaints, complaints from users or requests for inter-institutional cooperation, and will consist of an ad hoc visit with specific objectives and scopes. Supervisory teams are multidisciplinary and tend to be composed of at least one elements of

law, health and engineering, which can be reinforced by experts of the specialty and strengthened in some of the areas depending on the size of the health unit and the number and complexity of the services to be evaluated. In view of the mission and duties of the ERS, the oversight activity carried out under the authority powers legally recognized to the personnel of the ERS and carried out by carrying out the necessary actions on the ground, is a necessary instrument to guarantee the regularity and legality of the functioning of the health market which, serving the first purpose of defending users' interests and rights, ensures the on-site verification of the degree of compliance of the operators with the established obligations, allows the identification of risk situations and the more regulatory needs.

8.3.5.The Netherlands

The Dutch Care Inspectorate⁶⁸ has conducted some field research by comparing the results of unannounced inspections with the results of announced inspections. This research was undertaken in a nursing home environment.

In practice the Dutch Health Care Inspectorate usually announces the inspections of nursing homes in advance. The announcing of inspections is derived from the relationship between the inspector and the institutions. This relationship is based on consultation, co-operation and trust in the efforts of the institutions to deliver quality care. Unannounced inspections seem, at first glance, not to fit in with this trust. Instead, it suggests an inspectorate whose aim is simply to expose the deficiencies of the institution in complying with the regulators.

Another reason for the announcement of an inspection is purely practical: the files and protocols are waiting, people have time for an interview and departments are ready for an inspection.

http://epsonet.eu/mediapool/72/723588/data/2015/_un_announced_inspections_HEAP.pdf

8.4. Feedback Reporting and Follow up activities

8.4.1.Denmark (DPSA)

At the end of a supervisory visit the DPSA, the supervisor, immediately provides feedback to the management, summarizing the visit and pointing to any requirements that have not been met. After the visit, the facility receives a written report with a summary and comments on each requirement that have not been met. The facility can be asked to provide an action plan for improvements, and if there are serious patient safety risks, the DPSA can issue an injunction regarding specific requirements. In cases with serious risks, the DPSA will typically perform a follow-up visit and issue a new report to reflect any improvements in the facility.

Before, during and after a supervisory visit, many healthcare facilities ask questions regarding the visit and specific requirements, and supervisors spend a significant amount of time answering questions and explaining legislature associated with the different requirements.

The DPSA aims to publish annual reports summarizing the findings from each type of healthcare facility that has received supervisory visits. These reports are based on qualitative data on compliance as well as qualitative data based on interviews with supervisors. The reports provide an overview of patient safety issues across healthcare facilities as well as suggestions for topics that could form the basis of learning activities both at a local, a regional and a national level.

⁶⁸ at this moment merged to IGJ- Healthcare and Youth inspectorate

8.4.2.Sweden

IVO considers feedback as a crucial element in their activities. It is possible to make a change if they sit down and discuss with different parties, who has the power to make a change. They find it necessary to develop this framework point – feedback- even further to learn and to make a change.

8.4.3.Portugal

After inspection by ERS there is follow up to see what is missing. Sometimes hospitals are not to blame as politics are short of measures and support. A common answer from hospitals is : –‘We do not have human resources and/or financial resources to do that’. In Portugal the ERS can recommend to the health minister and ask to take responsibility for mistakes,

Fines are the last resort in communication with the health providers.

In Portugal often the media get involved and they pick up the tragedies, not the small issues. Unfortunately such cases are used to gain political advantage and usually not to empower the inspectorate.

In case of mistakes and medical failures it is important to know how to present the results to the outside world. In Portugal usually 3 cases from different settings are presented to take the political tension off. As often similar incidents are being seen in various hospitals takes usually take similar examples from similar level hospitals to show the common themes of issues happening . Effective communication and collective collaborative practice is important.

8.4.4. The EPSO Risk working group

(Denmark, Sweden, England). There has been a lot of discussions about an open reporting culture and how to use it to meet the supervisory aims. In Denmark they have discussions about using the quality databases for the inspections and (at least at the moment) they have decided not to do it. The argument is that, they are going to spoil the quality development as the providers become anxious to report the quality as result they could be picked up for the inspections.

In Sweden they had that discussions years ago and in 2006 they started with so called ‘open comparisons’ and it was huge discussion as well as when they started with the quality registers, the idea was to use it for research and to drive quality within the research and not for the public. Then there was a question why not make it open for the public? The argument was same, that it would really decrease the quality of quality data etc., but after they published, that perceived risk did not eventuate and the quality kept increasing. Now they are having the same discussions again about using the quality data for the inspections and it seems now that the public in Sweden is already quite used to open data.

The same debate has been had in England with probably the very similar outcome. Actually rather than adversely reflecting the data quality in the reporting, the quality has actually improved. Now they are looking who is not reporting and that they have the data quality problem and it says something else about what is going on in that organisation. So probably the reverse has happened. So if you publish the first time, there is always some concern and the second time there is no or less concern and the third time everyone says that it is actually quite useful as they can see how they are performing against their peer group. There is a big push in England for the transparency around health data. Also the economic sector is keen on transparency, the NHS is undertaking research to put all the data online, so the hospitals can see how their financial performance compares to their peers. So there is a big push to transparency and most of the data comes from the organisations anyway, and if they are not using

that data, then the question is what are they using to run and manage themselves? Then there comes bigger question for CQC that what for they use that data? If someone is asking which data you are processing to decide where are you going to inspect, they probably couldn't describe that completely fully and there will always be some aspect for inspectors judgement in there. So it is a question for them if the organisations are transparent with their data how CQC can be transparent with what they doing with it?

8.4.5.New Zealand

New Zealand's Health Quality Safety Commission has developed a report that openly discusses failure and the positive learning that can be taken from it <http://www.hqsc.govt.nz/assets/Reportable-Events/Publications/Learning-from-adverse-events-2015-16-Nov-2016.pdf>

8.4.6.The Netherlands

To distribute the knowledge gained in the process the supervisor can publish the results, use the results in one-on-one discussions with hospital boards to reflect on the quality of their learning process compared to peers. In the Netherlands they recognize the issue of who has the power to change. Sometimes it is not one party but entity of multiple parties and they see their role in bringing all those parties together and put enough pressure on them to collaborate.

8.4.7.Scotland

One of the lessons learned in Scotland from their strategic inspections is that at the regional level, when they are engaging with their chief officers, then instead of just providing the feedback to the senior officer the professional dialogue is really crucial. So instead having one dialogue- feedback, they are now having up to 6 formal professional dialogues during different stages of inspection and when they are progressing they starting to ask questions about their weaknesses what might occur or not and to encourage them through dialogue. It does not necessary help them on strategic level, but on service level. That way they can gather impartial information about the services vs strategic component, when commissioning those services and trying to influence that. The professional dialogue is absolutely crucial as that itself can generate change and improvement. The feedback and professional dialogue can have even more effect than strategic inspection report, where are no surprises. You get more engaged with people when discussing our report.

In Scotland when they value leadership, they do not value individual leadership, but collective leadership and accountability (on strategic level) to encourage collective responsibility. Professional dialogues start with the chief executive officers (chief officer of education, social work etc.), but they always give feedback and they always go back to the top to make sure they are accountable, not about what they found, but to take the agenda forward. They find it an important process to drive the improvement and to take ownership and responsibility at highest level.

8.4.8.Iceland

The Directorate of Health (Embætti Landlaeknir) has put emphases on a backside forward approach by starting the inspection reports with the results / outcomes of the institution.

The inspectorate put effort in the reports to keep the reports clear and simple:



[www.epsonet.eu/mediapool/72/723588/data/2018/Leifur_EPSO_17_april_Reporting_model_for_La ndlaeknir Iceland.pptx](http://www.epsonet.eu/mediapool/72/723588/data/2018/Leifur_EPSO_17_april_Reporting_model_for_La_ndlaeknir_Iceland.pptx)

8.5. Benchmarking as feedback instrument

8.5.1. Portugal

Portugal uses the National Health Assessment System (SINAS)⁶⁹ framework for benchmarking and rating of health care institutions – the National System of Health Quality Assessment – is the first project set up for assessing healthcare in several quality dimensions in Portugal.

In order to deliver clear and useful information on the quality of healthcare services, ERS⁷⁰ – the Portuguese Health Regulation Authority – created SINAS based upon three major values: accuracy, transparency and objectivity.

The assessment results are periodically published by ERS on a dedicated website, allowing healthcare providers to continuously improve their services' quality levels, enabling benchmarking both internally and between peer institutions and offering patients and general public decoded and useful information.

SINAS is designed to assess healthcare providers according to the specific type of care rendered. There are two modules currently implemented: SINAS@Hospitals, dedicated to institutions with inpatient treatment, and SINAS@Oral.Care, dedicated to dental care providers.

Five dimensions of quality were selected to be included on each of the modules:

Quality Dimensions Assessed within SINAS

⁶⁹ SINAS – Sistema Nacional de Avaliação em Saúde (National System of Health Quality Assessment)

⁷⁰ ERS – Entidade Reguladora da Saúde (Health Regulation Authority)

SINAS@Hospitals	
<i>Clinical Excellence</i>	

<i>Patient Focus</i>	

<i>Adequacy and Comfort of Facilities</i>	

<i>Patient Safety</i>	

<i>Patient Satisfaction</i>	

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SINAS@Oral.Care

<i>Registration and Licensing</i>	

<i>Organization and Procedures</i>		
<i>Adequacy and Comfort of Facilities</i>		
<i>Patient Safety</i>		
<i>Patient Satisfaction</i>		

9. Table 1 – The five dimensions of quality assessed in the two modules of SINAS

The dimension Clinical Excellence (in SINAS@Hospitals) assesses procedures and outcomes in orthopaedics' surgery, gynecological surgery, ambulatory surgery, obstetrics, paediatrics, acute myocardial infarction and stroke. In order to allow benchmarking between different types of hospitals, all exception cases are excluded from the data to be computed.

Patient Focus (also in SINAS@Hospitals) measures the extent to which the services provided by the institutions take into account the particular preferences of patients and their families.

All providers which do not comply to the legal requirements of registering on the ERS Data Base and of requiring the necessary activity license are filtered out through the assessment of the dimension Registration and Licensing (in SINAS @Saúde.Oral).

Organization and procedures (also in SINAS@Hospitals) delivers information on whether the providers have implemented measures leading to the efficient and effective functioning of the institution.

Adequacy and Comfort of Facilities, Patient Safety and Patient Satisfaction are common to both SINAS' modules.

The SINAS framework considers a two-step classification system:

First step: **Quality stars** – for each dimension assessed providers evidencing compliance with minimum quality criteria are given a star; these requirements are set out by a panel of experts on the different areas. - Second step: **Rating** – providers who received the quality star are positioned on a rating scale composed by three quality levels. Ratings' computing is based on information mainly provided by the institutions being assessed; ERS periodically audits random groups of institutions, in order to confirm the accuracy of the provided data.

SINAS uses structure, process and outcome quality indicators, selected according to their adequacy to the areas being assessed and the availability of the data. The data collection and the statistical analysis methods are chosen to meet the specific requirements of each of the quality dimension being analysed. All assessment parameters are carefully chosen, discussed and consensually approved by experts and professionals.

SINAS@Hospitals first results were published in 2010. The 73 hospitals currently involved (on a voluntary basis) in this module are being assessed in four dimensions: Clinical Excellence (procedures and outcomes in orthopaedics' surgery, gynecological surgery, ambulatory surgery, obstetrics, paediatrics, acute myocardial infarction and stroke), Patient Focus, Adequacy and Comfort of Facilities and Patient Safety (safety practices and adverse events).

The first data collection for the SINAS@Oral.Care assessment began in January 2012. The 4.869 Portuguese registered providers of dental care are being assessed in four quality dimensions: Registration and Licensing, Organization and Procedures, Adequacy and Comfort of Facilities and Patient Safety.

9.1.1.England

In CQC an advanced system of rating is used The appreciation of the CQC system- which has changes quite a bit over time - might differ depending who is looking at it and from what perspective . As the CQC system is quite heavily regulated it has relatively little flexibility .

However the predominant opinion is that it helps quality improvement bringing forward and makes the institutions more alert on their follow up activities. It has a good reputation from inspection perspective in elderly care and nursing homes as getting the stars is a market incentive and has therefore a financial value. This apparently makes the institutions more aware of the inspection validation of their institute.

For hospitals as being larger organisations this might work less effective. However also according to CQC sources the rating is working quite well in England.

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I International obligation to create compensation system

On 09 March 2011 Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare⁷¹ was adopted. According to Article 21.1 of the Directive member states shall bring into force the laws, regulations and administrative provisions necessary to comply with Directive by 25 October 2013. It is worth of mentioning that the formal side of transposition of the Directive was assessed by the European Commission by 25 October 2015. According to the Article 20 of the Directive the European Commission shall conduct an assessment of the systems and practices put in place in the Member States by 25 October 2018.

Main issues that the Directive obliged the member states to regulate were such as funding systems of cross-border health care services; creation of national contact points; possibilities to establish obligatory prior authorisation; systems of professional liability insurance, or a guarantee or similar arrangement; issuing documents regarding cross-border services etc.

To have full understanding about the obligation stated in the Directive it could be useful to refer back to previous acts connected with the issue under discussion.

European Parliament has on 15 March 2007 adopted a resolution on Community action on the provision of cross-border healthcare⁷². In point 8 of the resolution the Parliament underlines the necessity to create a mechanism for appeals on malpractice in cross-border healthcare and following in point 14 appeals to the Member States to introduce a one-stop-shop approach to complaint procedures for patients.

In the proposal for a Directive⁷³ issues of insurance were discussed in very concrete terms. In point 6.1 it is stated that the member state of treatment also has to ensure that mechanisms for patients to seek redress and compensation if they suffer harm as a result of receiving cross-border healthcare are in place. However, it is for the Member State to determine the nature and modalities of such mechanisms, for example through professional liability insurance, or a guarantee or similar arrangement which is equivalent or essentially comparable as regards its purpose. This requirement should ensure at least equivalent protection for provision of healthcare to patients residing in other Member States. Such arrangements should be appropriate to the nature and the extent of the risk, in order to avoid this requirement being disproportionate

⁷¹ Text available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32011L0024> .

⁷² Text available at <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2007-0073+0+DOC+XML+V0//EN> .

⁷³ Proposal for a directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare. Text available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0414:FIN:EN:PDF> .

in the context of the provision of cross-border healthcare and have due regard to guarantees that are already in place in healthcare provider's home Member State, where these are different.

Following Directive 2011/24/EC refers to the need to establish professional liability insurance in point 24 of the preamble⁷⁴ as well as in Article 4.2.d⁷⁵.

European Charter of Patients' Rights⁷⁶ deals with the issue of compensation in point 14 (part II) by stating that each individual has the right to receive sufficient compensation within a reasonably short time whenever he or she has suffered physical or moral and psychological harm caused by a health service treatment. The health services must guarantee compensation, whatever the gravity of the harm and its cause (from an excessive wait to a case of malpractice), even when the ultimate responsibility cannot be absolutely determined.

There were no common compensation systems in the European Union prior to the enforcement of the Directive and there is no common approach presently. Systems applicable in member states are different by concepts and details. Different systems will be explained in detail in part IV of the present report.

It is noteworthy to mention that whilst the draft Directive annexed to explanatory note in its Article 4 (I) defined "harm" as adverse outcomes or injuries stemming from the provision of healthcare, it was not contained in the Directive itself. Currently Directive does not define "harm".

II Legal and financial framework of Medical Risk Fund

II.I Legal framework

Compensation system in Latvia was established by amending the Law On the Rights of Patients⁷⁷ (LRP). Issues and means of compensation are dealt with in Articles 16, 17 and transitional provisions. Fund became operational 25 October 2013. Explanatory note to the draft makes also explicit reference to the Charter of Patients' Rights as well as Directive 2011/24/EU. It was foreseen in the explanatory note that activities of the Fund should be analysed in the long run as due to the financial possibilities and the economic situation in the country, it is not possible to secure all the material and non-financial guarantees in the start of the Fund. Therefore, all issues can be solved in the long run by evaluating the functioning of the newly established law enforcement institute, problems, needed finances, complaints, risks, applicable preventive measures, needed quality control systems in health care institutions. In addition, it was stated that for the beginning the law should provide for at least the cost of medical treatment for the patient. In the long run, the issue of the possibility of providing other guarantees (such as for example loss of future income; loss of maintenance for

⁷⁴ Member States should ensure that mechanisms for the protection of patients and for seeking remedies in the event of harm are in place for healthcare provided on their territory and that they are appropriate to the nature and extent of the risk. However, it should be for the Member State to determine the nature and modalities of such a mechanism.

⁷⁵ The Member State of treatment shall ensure that: ... systems of professional liability insurance, or a guarantee or similar arrangement that is equivalent or essentially comparable as regards its purpose and which is appropriate to the nature and the extent of the risk, are in place for treatment provided on its territory; ...

⁷⁶ Text available at

http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/health_services_co108_en.pdf .

⁷⁷ Pacientu tiesību likums. Text available at <https://likumi.lv/doc.php?id=203008> . Explanatory note with original draft presented to Seimas is available at

<http://titania.saeima.lv/LIVS11/SaeimaLIVS11.nsf/0/3D79353E2F730131C2257BDE00426F87?OpenDocument> .

relatives and dependent children; retraining to obtain new profession etc) should be addressed, but such issues as well is to be solved gradually as it requires additional financial resources from the state budget.

In addition, Law on Practising Doctors⁷⁸ was changed by invalidating article 17, which previously obliged practitioners to obtain civil insurance.

In order to put in place modus operandi of the compensation system, following sublaw acts were adopted or amended:

- Regulations of the Cabinet of Ministers No.1268 "Medical Treatment Risk Fund Rules" of 05 November 2013 (Ministru kabineta 2013.gada 5.novembra Noteikumi Nr.1268 "Ārstniecības riska fonda darbības noteikumi")(regulation 1268)⁷⁹;
- Regulations of the Cabinet of Ministers No.850 "Regulations of the National Health Service" of 01 November 2011 (Ministru kabineta 2011.gada 1.novembra Noteikumi Nr.850 "Nacionālā veselības dienesta nolikums")(regulation 850)⁸⁰;
- Regulations of the Cabinet of Ministers No.1529 "The Procedure for Organising and Financing Health Care" of 17 December 2013 (regulation 1529)⁸¹.

Main characteristics of the compensation system are as follows:

1. Patient has a right for compensation for any harm, including moral harm, in the amount of the harm caused, but not more than 142 290 euros that was caused to a patient after 23 October 2013 (LRP art 16.1 and 16.2.1; Transitional provision 1)
2. Patient has a right for compensation of medical expenses incurred to him or her (for eliminating or reducing the consequences) - in the amount of the expenses incurred, but not more than 28 460 euros (LRP art 16.1 and 16.2.2¹)
3. Harm should have been caused by medical practitioner working in health care institution (LRP art 16.1). There is no difference if service provider is public or private as well as if services rendered were paid by public funds or by patient him/herself. Not only doctors, but all medical personnel with certificates are covered by the insurance
4. Harm was caused by acts of such persons or because of failure to act (LRP art 16.1)
5. Treatments received within the framework of clinical trial are not covered by fund (Regulation 1268 art 1¹)
6. Compensation for harm and expenses is paid by Medical Risk Fund upon an application submitted to the National Health Service (LRP art 16.2 and 16.6). Format of the application is foreseen by regulation (Regulation 1268 annex 1), documents proving the expenses must be added (regulation 1268 art 4). In case application and/or annexes are incomplete, the NHS gives deadline for producing proper documentation (Regulation 1268 art 5)
7. In case of death of the patient, compensation can be claimed by heirs (Regulation 1268 art 3¹)
8. Compensation is not paid in cases of late application as well as when compensation is paid during other proceedings (LRP art 16.5)

⁷⁸ Par prakses ārstiem. Text available at <https://m.likumi.lv/doc.php?id=43338> .

⁷⁹ Text available at <https://likumi.lv/doc.php?id=262102> .

⁸⁰ Text available at <https://likumi.lv/doc.php?id=239184> .

⁸¹ Text available at <https://likumi.lv/ta/id/263457-veselibas-aprupes-organizesanas-un-finansesanas-kartiba> .

9. Proceedings should be concluded within 6 months, in exceptional circumstances it can be prolonged up to 1 year (LRP art 16.6)
10. Compensation should be transferred to applicant within 90 working days from positive decision (Regulation 1268 art 14)

Main characteristics of the Medical Risk Fund are as follows:

1. Is formed by contributions paid by health care providers in amounts determined by Cabinet (LRP art 17.1 and 17.3)
2. Fund is run by the National Health Service (LRP art 17.2; Regulation 850 art 3.26) who also has a duty to collect the contributions and pay out compensations (Regulation 850 art 4.21). More concretely - The Health Inspectorate conducts an expert assessment, prepares an opinion and determines the extent of the damage as a percentage, as well as evaluates the need for health care expenses in order to reduce or prevent the consequences of harm to the patient (Regulation 1268 art 2.1; art 7). In the framework of evaluation the Inspectorate has full access to medical documentation, is able to ask for expert opinion or to ask establishment of commission who will evaluate the case (regulation 1268 art 8). The National Health Service administers the funds of the Medical Risk Fund and on the basis of the opinion of the Inspection, decides on payment of the compensation or refusal to pay it, as well as payments of remuneration from the Fund (Regulation 1268 art 2.2)
3. Amount of compensation is established by Inspection according to annex 2 of the Regulation 1268 taking into account 10 criteria (f.e. causal link, patient participation in care process, severity of damage, contribution by the provider for remedying the situation etc.) (Regulation 1268 art 9). Inspection's statement to the NHS contains its opinion about existence and extent of damage as well as circumstances that cause refusal to pay compensation (f.e. missing causal link, no professional error, no damage etc.) (Regulation 1268 art 10 and 12)
4. Amount of the contributions by the health care providers to the fund are calculated by the NHS and invoiced once per year (regulation 1268 art 18; method in art 23-26, 28) and it will not be changed during the year (regulation 1268 art 27). Payments are normally done on quarterly basis (regulation 1268 art 20). A special formula is used to calculate the risk amount payable by each medical institution, based on the number of employees in the medical institution and the distribution of these healthcare professionals across the risk groups
5. National Health Service has a right to deduct insurance payments due from payments the service ought to pay to health care providers for their services (Regulation 1529, art 276; Regulation 1268 art 21)
6. Both National Health Service as well as Health Inspectorate are obliged to share publicly information about Medical Risk Fund (Regulation 1529, art 10.2.5)
7. Proceedings of the Fund are based on administrative law (LRP art 17.2)
8. Fund is allowed to use its resources only for settling claims (LRP art 17.4)
9. National Health Service has a right to recovery from provider who has not paid the contribution but on whose behalf the Fund has made payment of compensation (LRP art 17.5; Regulation 1268 art 22).

When comparing the Directive 2011/24/EC and regulative framework in Latvia following observations can be made:

1. Informing about the applicable rules – according to the point 20 of the preamble of the Directive 2011/24/EU member states can oblige other actors than the healthcare providers, such as insurance providers or public authorities, to provide the information on specific aspects of the healthcare services offered, if that would be more appropriate with regard to the organisation of its healthcare system.

In Latvia there is no such obligation put to the insurance provider, i.e. MRF.

2. Expanding insurance coverage against harm to treatments abroad – according to point 23 of the preamble of the Directive 2011/24/EU systems for addressing harm in the Member State of treatment should be without prejudice to the possibility for Member States to extend the coverage of their domestic systems to patients from their country seeking healthcare abroad, where this is more appropriate for the patient.

In addition - according to the Article 7.7 of the Directive state may apply same conditions as domestically, also regarding health care services that are rendered in other EU member states, including via telemedicine.

In Latvia it is not clear if the insurance covers provision of health care services also rendered outside of Latvia.

3. Existence of compensation systems – according to the point 24 of the preamble of the Directive 2011/24/EU Member States should ensure that mechanisms for the protection of patients and for seeking remedies in the event of harm are in place for healthcare provided on their territory and that they are appropriate to the nature and extent of the risk. However, it should be for the Member State to determine the nature and modalities of such a mechanism.

Latvia has established the MRF for purposes indicated in the point above. Appropriateness is yet to be analysed.

4. According to Article 3 (a) of the Directive ‘healthcare’ means health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices.

In Latvia healthcare (“treatment”, that is subject to compensation mechanisms) is defined as professional and individual disease prevention, diagnostics and treatment, medical rehabilitation and patient care⁸². Therefore Latvian definition does not contain activities with medicinal products and devices.

5. According to Article 3 (f) of the Directive ‘health professional’ means a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC, or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the Member State of treatment. In Latvia health professional (medical practitioner) is defined as person who has medical education and who deals with medical treatment⁸³. This excludes for example pharmacists, therapists etc.

6. According to Article 3 (g) of the Directive ‘healthcare provider’ means any natural or legal person or any other entity legally providing healthcare on the territory of a Member State.

⁸² Article 1 1) of Medical Treatment Law. Text available at <https://likumi.lv/doc.php?id=44108> .

⁸³ Article 1 2) of the same act.

In Latvia healthcare provider is defined as medical practitioner, state and local government institution, economic operator and commercial company registered in the register of medical institutions, complying with the minimum requirements specified in regulatory enactments for medical institutions and their structural units, which provide medical services⁸⁴.

7. According to Article 4.2 (b) of the Directive health care providers provide relevant information regarding their insurance cover or other means of personal or collective protection with regard to professional liability.

In Latvia providers do not seem to have the obligation to inform the patient about their insurance cover and other ways of remedy. It might be because of the reason that insurance is obligatory and eventually for the patient it does not matter if insurance sums are paid or not.

8. According to Articles 4.2 (c and (d) there should be transparent complaints procedures and mechanisms in place for patients, in order for them to seek remedies in accordance with the legislation of the Member State of treatment if they suffer harm arising from the healthcare they receive as well as systems of professional liability insurance, or a guarantee or similar arrangement, should exist that is equivalent or essentially comparable as regards its purpose and which is appropriate to the nature and the extent of the risk, are in place for treatment provided on its territory.

In Latvia Article 18 of the Patient Law prescribes that patients can use all legal remedies, primarily addressing the Health Inspectorate. Activities and case handling by the MRF is described in Article 17 of the Patients' Law as well as in specific regulation as indicted above.

9. According to Article 6.3 of the Directive National Contact Points should inform patients from other member states about, i.e. on patients' rights, complaints procedures and mechanisms for seeking remedies, as well as the legal and administrative options available to settle disputes, including in the event of harm arising from cross-border healthcare.

In Latvia National Contact Point is established with the NHS⁸⁵. On the homepage of the contact point⁸⁶ existence and placement of the insurance system is indicated. Work of MTF as well as methods of presenting the claim are described⁸⁷.

II.II Financial framework

It should be underlined that the state has acknowledged (in the explanatory note to the draft law) the need for additional resourcing of the Health Inspectorate because of increased workload. Accomplishing new tasks should not be done on account of handling other tasks as well as Inspectorate should be able to engage appropriate experts into its work, as needs call. Resourcing for establishing new separate department with at least following posts for the start: Head of Unit, 2 Legal Advisers, 1 Senior Expert and 1 Expert Assistant on 1. In addition at least 10 doctor's experts (7 senior experts and 3 doctor experts) will be required to carry out the expertise. Due to low level of salaries and other benefits available it has been a struggle to fill in the positions of experts (doctors) also prior to obtaining new tasks. Also from the 01 January 2014 calculation of

⁸⁴ Article 1 3) of the same act.

⁸⁵ Article 47¹ of the regulations of the Cabinet of Ministers No.850 "Regulations of the National Health Service". Text available at <https://likumi.lv/doc.php?id=239184> .

⁸⁶ Webpage available at <http://www.vmnvd.gov.lv/en/cross-border-healthcare-contact-point/regarding-cross-border-directive> .

⁸⁷ Information available at <http://www.vmnvd.gov.lv/en/cross-border-healthcare-contact-point/treatment-risk-fund> .

healthcare service tariffs was changed and the component of the annual risk payment for medical treatment was integrated into the tariffs for health care services.’

Currently there are 3 persons employed in NHS Medical Risk Fund department. Approximately twice per year two economists from NHS finance department are engaged in the work of the MRF as well.

Table 1. *Funding allocated to NHS for fulfilling MRF tasks*

Expenses, EUR

	Year 2014	Year 2015	Year 2016	Year 2017	Year 2018 (planned)
Remuneration, including:	27 799	34 807	49 236	31 637	36 52
Remuneration (Medical Risk fund Department)	26 571	33 579	48 008	30 409	35 013
Remuneration (economists – 2 persons, two weeks a year – the period of calculation)	1 228	1 228	1 228	1 228	1 439
Other expenses (work place, paper, electricity, etc)	1 800	2 700	2 700	2 700	1 806
Postal charges (invoices and official communications should be sent by post)	2 499	2 622	2 466	2 391	2 307
Total	32 098	40 129	54 402	36 728	40 565

In the HI expert doctors from the Health Care Quality Control Division also examine applications to the Medical Treatment Risk Fund. Working time per case is 40 hours.

Table 2. *Funding allocated to HI for fulfilling MRF tasks (including compensations)*

	Direct expenses (EUR)			
Expenses	Year 2014	Year 2015	Year 2016	Year 2017
Remuneration	19 906	61 470	78 620	95 422
Other expenses	271	863	937	1 347
Total	20 177	62 333	79 557	96 769

Table 3. *Resources allocated for compensations via MRF and resources used*

Year	Resources allocated	Resources used
2013	151 507.92	
2014	1 466 773.49	19 353.17
2015	1 368 225.16	1 037 119.94
2016	1 426 426.46	1 738 776.98
2017	1 366 558.02	1 015 853.72
May, 2018	760 690.96	272 700.18
Total:	6 540 182.01	4 083 803.99

Table 4. *Applications presented to the MRF*

Year	Applications received	Applications processed	Damages paid
2014	83	36	9
2015	152	116	61
2016	213	127	55
2017	207	165	51

As an illustrative example: 2017 biggest number of applications – 30 – was presented on the area of gynaecology and obstetrics. Out of those compensation was paid in 17 cases. Disciplines following were surgery with 26 applications and traumatology with 23 applications. Same 3 areas of health care have been on top 3 all years of activity of the MRF.

As regarding the calculation of the amounts to be paid, following example can be made: the payment calculated for Riga East University Hospital. The value of one risk unity in year 2018 is EUR 14.4379255410904. This coefficient should be calculated each year but it varies a little. This unity is calculated using the formula $M = A \times S / P$ (*Regulations of the Cabinet of Ministers No.1268 "Medical Treatment Risk Fund Rules" of 05 November 2013*). The varying value is P (the number of medical treatment and medical treatment support persons).

Risk group	Risk coefficient	Number of medical treatment persons in accordance to the speciality	Risk payment, EUR
Medical treatment support persons	0.5	34	245.44
I	10	204	29 453.37
II	8	274	31 647.93
III	5	512	36 961.09
IV	2	41	1 183.91

Not included in the risk group	0.5	184	1 328.29
V	1	407	5 876.24
VI	0.5	1 504	10 857.32
Total		3160	117 553.59

III Current challenges of existing system *(from interviews)*

During the evaluation process range of stakeholders as well as those who are responsible for the liability insurance system were interviewed. On the basis of data collected main problems of the current system seem to be:

1. Lack of human resources, professionalism – there are currently 3 persons in the NHS dealing with the MRF issues and additionally experts/other officials in the HI are mandated to perform different tasks for the fund. For the HI people this is in addition to their usual workload. At the beginning of the MRF expert division in HI was divided into 2 parts so 1 would be dealing only with MRF expertise. But as there were no additional funding for extra posts allocated, this settlement caused heavy workload for experts dealing with other matters than MRF. So in a short while unit was re-merged.

Therefore processing the cases takes relatively long time.

Many stakeholders highlighted that as current permanent experts to the HI are not practising health care professionals who engage in continuous professional training, and therefore are not able to assess and evaluate activities concerning all disciplines. Also using modern tools, as e-solutions, seems to be rather low among the experts and overall in MRF processes.

There is very scarce outside expert/professional associations involvement in MRF proceedings to remedy the shortcomings with the expertise. Patients are not allowed to appoint (independent) experts themselves to provide the assessment in proceedings.

2. No requirement to have a previous contact with the provider, lack of mediation options – presently person can address directly MRF without trying to settle the case beforehand with the provider. This creates unnecessary burden to the fund as number of cases could be solved among provider and patient without outside engagement. This concerns mostly issues of attitudes, communication etc.

Having an opportunity to mediation, patient ombudsman or similar created would also allow decreasing the pressure to MRF.

3. Managing the data collected – MRF does collect and process data about (alleged) medical errors and events. Such a data is not used for learning purposes as well as for identifying general problems instead of dealing with single cases only.

4. Public awareness about MRF – public awareness about the fund is very low. Also stakeholders involved, including HC providers and their unions, are not very sure about activities and frameworks of the fund.

There is a section about MRF on the webpage of the NHS⁸⁸, but it is not visible enough as well as patients found it difficult to use without further professional assistance. It is not clearly evident from the webpage how MRF proceedings differ from court proceedings (f.e faster, no fee, simpler burden of proof etc.) and if they are more complainant-friendly.

⁸⁸ Available at <http://www.vmnvd.gov.lv/en/cross-border-healthcare-contact-point/treatment-risk-fund> .

There does not seem to be an obligation for HC providers to make information about methods of complaint, including MRF, publicly available and also to inform patients about such options.

5. Engagement with stakeholders – it seems that both prior to the establishment of the system as well as during its operations there has been no thorough and wide stakeholder consultation carried out. At the same time all major players on the field – state authorities, professional unions or providers and health care workers, patient organisations, insurance companies etc – were very critical about modalities and framework of the existing system and its outcomes. Opinions and recommendations of stakeholders are not systematically analysed and discussed by policy makers. At the same time state plans to start reorganising location of the MRF and this seems to happen again without consulting the stakeholders as well as comprehensively and holistically discussing this with institutions concerned.
6. Length of proceedings – proceedings in the MRF are excessively long according to all parties consulted. There seems to be various factors influencing this, but one main obstacle is lacking efficient work methodology by experts as well as probably time for payments by NHS after making decision (90 days). It was proposed to have quicker system of proceedings for “simpler” complaints – list of compensation sums or similar.
7. Transparency of the MRF proceedings – again common stance of the providers, associations and patients was that during the proceedings hardly any information if at all is shared with parties involved. HCPs who have to deliver their account on situations disputed do not get any information about outcome of such complaint/compensation proceedings. It seems that all parties involved might have right to enquire both final expert report as well as decision made in MRF proceedings, but as they are not informed about this option, it is not taken up.
Allegedly also basis and methods of deciding on the amount of compensation payable is not simple and understandable for parties. Proportionality with the sufferings or direct loss does not seem to have real impact on the final outcome in financial terms.
8. System of reporting medical errors/incidents – there is currently no connection between outpayments, insurance premiums, proceedings and cases of possible medical errors reported. Link between voluntary reporting, liability and compensation (as well as perhaps disciplinary proceedings) could make the system more efficient and less punitive.
9. Dissatisfaction with complaints – due to the combination of various reasons listed (lack of transparency, weak expertise, proportionality etc) more than 30% of decisions made by NHS are applied to the MoH. Applications are mostly presented due to disagreement with the amount of compensation appointed.

IV Examples from selected other European Union member states

IV.1 Latvian research into other medical liability systems prior to creating MRF

During the preparation process Danish and Swedish experiences of development of treatment risk funds / institutions and their operating principles as well as financing models were studied. Some aspects, as limiting the time for presenting an application or submitting certain documents approving the occurrence of expenses, were installed also into the Latvian legal framework. At the same time and keeping in mind the financial aspect, range of compensations were limited (not covering for example loss of future income; loss of maintenance for relatives and dependent children; retraining to obtain new profession etc.).

It was also stated that it is not possible at the moment to run the Medical Risk Fund on the basis of the social security contributions or other taxes applicable to persons. Therefore costs must be borne by state (via

allocating extra funds to state-contracted health care providers). In the long run amount of funding is not clear as there is no certainty about amount of applications as well as resources needed for running the MRF⁸⁹. By launching the fund, reference was made to positive experiences from Scandinavian states⁹⁰.

Nevertheless it is clear that Latvia has chosen non-fault medical liability system. This choice is not uncommon, as generally regulation of liability issue is dependant of organisation of health care service provision and financing. In countries, where most of the services are paid by the state, usually private liberal insurance market is not used to provide medical liability insurance. In such cases there are specific state-run funds established to manage compensation issues. At the same time in countries where health care service sector is mainly private, the private insurance market is also expanding whole lot more over medical liability compensation issues⁹¹.

IV.II Overview of most used models

Most common options for insurance are following:

1. Mix of public and private insurance: compulsory insurance and unions. For example on the basis of French experience it can be said that whilst planning compulsory insurance role and participation of government should be strengthened or alternatively pools should be created in order to secure proper protection to service providers as well as solvency of insurers. In this regard solution could be more flexible proceeding of malpractices occurring during high-risk treatments securing thereby also insurance of such cases. Also redefining guilt and liability allowing running of stable compensation system could be an option.
2. Guarantee funds: those help to evaluate and cover high claims and in the long run also limit health care risks. For example in Finland the insurers' union is at the same time also guarantee fund in case of bankruptcy of insurer.
3. Sharing the responsibility to cover malpractice issues between public and private sector: if negligence is difficult to establish or actions undertaken have lead to severe harm, compensation is paid either from public or social insurance fund. At the same time in certain cases (for example in France) payer has the right to recourse against health practitioner/service provider. In addition insurance systems that are financed from public, i.e. social care, funds, can be applicable regarding certain service providers, as for example public providers.
4. Fast offering model: it is used mainly in the US. Main purpose of this model is to reduce willingness to address courts. Person, against whom the claim is presented, has an opportunity to agree within 180 days to compensate damages in periodic payments. In such a case the patient loses possibility to claim any further damages in the future. Therefore, it offers incentive to have fast agreement and prevent costly and time-consuming legal proceedings.

⁸⁹ Explanatory note to the draft law. Text available at

<http://titania.saeima.lv/LIVS11/SaeimaLIVS11.nsf/0/3D79353E2F730131C2257BDE00426F87?OpenDocument> .

⁹⁰ Muciņš R. Ārstniecības riska fonda būtība un tiesiskie aspekti. Jurista Vārdi, 08.10.2013., Nr. 41 (792). P 11.-12.

⁹¹ Policy Issues in Insurance No. 11. Medical Malpractice: Prevention, Insurance and Coverage Options. OECD Publishing, 2006. P 10.

5. General non-fault compensation system: compensation is paid immediately either from public fund (as for example in Sweden) or by private insurers. In such cases no negligence is established via judicial proceedings. Main advantages of this system is that injured person has a possibility for fast remedy and at the same time administrative and legal costs are much lower than in case of judicial proceedings. At the same time it must be said that such a mechanism causes probably more claims to be presented as well as amounts of compensation are less than in case of judicial proceedings⁹².

The scope of service providers' liability varies by countries – for example in some countries (as Austria, Greece) hospitals are not liable for the activities of contracted personnel working in hospital premises, if the person does not have treatment contract. In other countries, as the Netherlands or Spain, the hospital is always liable for all damages occurred within its territory. In Belgium half-way system is in use – hospitals can disclaim compensating whatever damage that does not have direct connection with treatment contract⁹³.

Additionally, need to establish obligatory mediation prior to compensation needs to be analysed from economical and efficiency point of view. Covering the costs of mediation as well as organisational structure depends on insurance model chosen.

IV.III Country examples

In the case of non-fault liability system methods of compensation can be different. In some countries damages are handled by regular insurance companies or their association (Finland, Slovenia), in other countries public body has been established (Denmark) or proceedings are commenced by sort of state agency (Sweden, Norway, UK).

Followingly some selected non-fault liability systems from the European Union are illustrated⁹⁴.

IV.III.I Sweden

In Sweden compensation mechanisms are regulated in Patient Injury Act⁹⁵. Insurance system is run by the Swedish Patient Insurance Association⁹⁶, which is a mutual insurance company owned by its policyholders, county councils and regions. Contributions are made by regions and amounts of fees depend of the number of residents in certain area. Private health care providers are buying their insurance from regular insurance providers.

⁹² Policy Issues in Insurance No. 11. Medical Malpractice: Prevention, Insurance and Coverage Options. OECD Publishing, 2006. P 43-49.

⁹³ Wismar M, Palm W, Figueras J, Ernst K, van Ginneken E. Cross-border health care in the European Union. Mapping and analysing practices and policies. World Health Organization 2011. P 204. Available at http://www.euro.who.int/_data/assets/pdf_file/0004/135994/e94875.pdf.

⁹⁴ In following countries fault-based systems are in use: Czech Republic, France, Germany, Hungary, Italy, Poland, Slovakia, Lithuania. In most of those countries there are mediation and other such out-of-court proceedings in place.

⁹⁵ Text available at http://www.riksdagen.se/sv/Dokument-Lagar/Lagar/Svenskforfattningssamling/Patientskadelag-1996799_sfs-1996-799/?bet=1996:799http://.

⁹⁶ Homepage available at <https://lof.se/>.

Healthcare related injuries that can be compensated mean a physical or psychological injury, illness or fatality caused by the healthcare provided and which could have been avoided; injuries related with medical devices or improper administration of medications; accidents in connection with the care (transport, premises etc). Only injury that has been caused by healthcare provided in Sweden gets compensated. Association evaluates and gives financial compensation to patients injured in health care and also contributes to a reduction in the number of health care related injuries. Compensation is paid only to cover actual costs, loss of property is not compensated, there is also upper limit for the compensation. Amount of compensation is evaluated on case-by-case basis by evaluation board. Mainly it is only the patient who can present the claim.

An injury must be reported within three years from the date person becomes aware that s/he could make a claim, but never more than ten years from the date when the injury was caused. There is no compulsory mediation proceeding foreseen by the law.

From 1976 it is not allowed in Sweden to reclaim amount of compensation from those insured, as such procedure means automatically impeachment. Nevertheless, lately there have been some doubts if this solution is reasonable⁹⁷.

IV.III.II Denmark

In Denmark patient insurance system was established 1992, regulated by Act on Appeals and Compensation in the Health Care⁹⁸. The Scheme is governed by the Patient Compensation Association⁹⁹. Patients treated at public hospitals and in private hospitals, as well as in private practice, for instance GPs, specialists, dentists, chiropractors, and so on, are covered by the system. Authorized health professionals working in municipal health plans and the county dental plan are also included.

Injuries subject to compensation may have occurred in connection with medical treatment, examination or due to medication. Donors and participants in medical trials may also claim compensation for injuries. Excluded are services provided abroad without referral as well as in case of treatment carried out by permanently employed health personnel in, for example, social institutions or nursing homes, or as permanent employees working for a provider of a company healthcare scheme.

Compensation is awarded if reviewers determine that an experienced specialist would have acted differently; or if the patient experienced a rare and severe complication that was "more extensive than the patient should reasonably have to endure"; or if there has been a failure in the medical equipment; or if the injury could have been avoided if another equal method had been used. Calculations of compensations are done case-by-case basis. Decisions can be appealed within 5 years from the date person becomes aware that s/he could make a claim, but never more than ten years from the date when the injury was caused¹⁰⁰. There is no compulsory mediation proceeding foreseen by the law.

⁹⁷ Koch B A, Koziol H (eds.) **Compensation for personal injury in a comparative perspective**. Wien; New York: Springer, 2003. P 295.

⁹⁸ Text available at <https://www.retsinformation.dk/Forms/R0710.aspx?id=192623>.

⁹⁹ Webpage available at <https://pebl.dk/en>.

¹⁰⁰ Wismar M, Palm W, Figueras J, Ernst K, van Ginneken E. Cross-border health care in the European Union. Mapping and analysing practices and policies. World Health Organization 2011. P 200. Available at http://www.euro.who.int/_data/assets/pdf_file/0004/135994/e94875.pdf.

IV.III.III Norway

In Norway, according to the Patient Damage Act¹⁰¹, patient can present an application to the Norwegian System of Patient Injury Compensation (NPE) that is a government agency subject to the Norwegian Ministry of Health and Care Services¹⁰². Compensation covers only health care services rendered in Norway, except when planned treatment in abroad was performed. Drug injuries as well as clinical trials are covered. Compensation for pain and suffering is not paid. The assessment of compensatory damages is undertaken on a case-by-case basis.

To qualify for compensation for a patient injury, three conditions must be met:

- The patient injury must be due to treatment failure;
- The patient injury must have resulted in financial loss (f.e expenses for medical treatment, medication, transport or similar; loss of income or loss of provider). For financial losses less than 10.000 NOK it is for the health care service provider to compensate the losses;
- injury must not be too old (up to three years from acknowledging).

Claims should be made by patient. In case of death of patient, by heirs.

Applying for compensation from NPE does not constitute an assessment as to whether there are grounds to criticise healthcare personnel involved in the case.

All providers who provide health care services according to the licence, must register with the NPE and pay insurance fees. Invoicing is done once per year in February/March. NPE is applicable to public providers and private providers only in cases when they render services bought by state.

IV.III.IV Finland

According to the Patient Injuries Act¹⁰³ all healthcare providers shall have patient insurance that provides compensation for injuries covered by this Act. Health care providers, self-employed healthcare professionals, pharmacies and government agencies which provide health care services are under obligation to insure. It is possible to take out a patient insurance either at your insurance company or the Finnish Patient Insurance Centre. Public undertakings are insured by the Centre. The Finnish Patient Insurance Centre itself comprises insurance companies engaged in patient insurance operations in Finland. Maintenance costs of the Centre are covered by insurance premiums. Expenses and amount of premiums are determined by the government.

The amount of the premium depends on the classification of risks involved in the operations. The insurance company determines the premiums according to its basis of premiums. The premium for a self-employed healthcare professional is usually a fixed sum. The premium for a private company or community is usually calculated based on the total salaries paid out by the company and using a factor corresponding to the risk

¹⁰¹ Text available at <http://www.lovddata.no/all/hl-20010615-053.html> .

¹⁰² Homepage available at <https://www.npe.no/en/> .

¹⁰³ Potilasvahinkolaki. 25.7.1986/585. Text available at <http://www.finlex.fi/fi/laki/ajantasa/1986/19860585> .

classification of its operations. Premiums for public sector operators is determined for each insured party individually mainly according to full liability principle.

Seven compensation criteria or types of injury are listed in the Patient Injuries Act: treatment injury, infection injury, accident injury, equipment-related injury, injury arising from damage to treatment premises or the equipment used for the treatment, injury due to incorrect supply of pharmaceuticals, and unreasonable injury. A bodily injury may be compensable under Patient Insurance when any of the compensation criteria referred to in the Act is met.

Nevertheless, there are number of injuries that are not covered: if injury happened outside of Finland; material damage connected with the injury; pure financial loss; assistance services (social care); injuries less than 200 EUR.

Compensation payable under Patient Insurance is determined by applying the provisions contained in the Tort Liability Act and the guidelines issued by the Traffic Accident Board. The decision policy of the Patient Injuries Board will also be taken into account in the compensation. As a rule, costs and losses arising from the injury will be compensated for in full. Any benefits that remain primary in respect of the compensation paid by the Patient Insurance Centre, such as the sickness allowance, national pension and guaranteed pension paid by the Social Insurance Institution of Finland (Kela), will be deducted from the compensation paid by the Patient Insurance Centre.

Decisions of the Centre are appealable.

IV.III.V UK - England

In UK – England all doctors working for National Health Service (NHS) are directly covered with insurance scheme financed by the state. This system is run by the NHS Resolution¹⁰⁴ who, i.a, provides indemnity schemes for the NHS in England and resolves claims for compensation fairly. All service providers who are part of NHS system must make yearly payments to the scheme. Amount of contributions is decided by the scheme considering the size, activities and record of complaints against given service provider. Therefore there is cross-using of the data from the registry of medical errors.

Via this scheme compensation is paid when claimant has shown clinical negligence and financial loss occurred because of it. Health care service providers who operate outside of the NHS system, are obtaining their insurance covers from regular insurance market¹⁰⁵.

¹⁰⁴ Webpage available at <https://resolution.nhs.uk/about/> .

¹⁰⁵ Policy Issues in Insurance No. 11. Medical Malpractice: Prevention, Insurance and Coverage Options. OECD Publishing, 2006. P 12.

IV.III.VI UK - Scotland

It is rather interesting to take a look at the process of creating non-fault liability insurance in Scotland. Swedish model was used as an example. After carrying out comprehensive round of consultations, it was concluded that non-fault liability insurance system must be based on following principles¹⁰⁶:

- the scheme provides an appropriate level of compensation to the patient, their family or carers;
- system should include victims of breaches of data protection;
- the scheme is compatible with the European Convention on Human Rights;
- the scheme is easy to access and use, without unnecessary barriers, for example created by cost or the difficulty of getting advice or support;
- people are able to get the relevant specialist advice in using the scheme;
- decisions about compensation are timely;
- people who have used the scheme feel that they have been treated equitably;
- the scheme is affordable;
- the scheme makes proportionate use of time and resources;
- the scheme has an appropriate balance between costs of administration (e.g. financial or time) and the level of compensation awarded;
- decisions about compensation are made through a robust and independent process;
- the scheme has an independent appeal system;
- the scheme treats staff and patients fairly/equitably;
- a reasonable time limit is set for compensation claims.

As regarding running of the system it was also considered important that:

- the scheme contributes to organisational, local and national learning, patient safety and quality improvement;
- lessons learned can be used to influence organisational risk management in the future;
- the scheme encourages and supports safe disclosure of adverse events;
- the scheme does not put barriers in place for referral to regulators of any cases which raise grounds for concern about professional misconduct or fitness to practise.

During the negotiations it was stated that predetermined amounts compensation (either in the format of table or as maximum limits) do not allow personal approach¹⁰⁷.

IV.III.VII Belgium

According to the Law on Compensation of Damages as a Result of Health Care¹⁰⁸, since year 2010 persons can address the Fund for Medical Accidents¹⁰⁹. The FMA will advise on the liability of the individual healthcare

¹⁰⁶ Consultation Report - Consultation on recommendations for no-fault compensation in Scotland for injuries resulting from clinical treatment. April 2014. Text available at <http://www.gov.scot/Publications/2014/04/6437/5>.

¹⁰⁷ A Study of Medical Negligence Claiming in Scotland. Appendix: expenditure implications of proposed no-fault scheme. June 2012. P 4. Text available at <http://www.gov.scot/Publications/2012/06/2348/5>.

¹⁰⁸ Text available at

http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=nl&la=N&cn=2010033102&table_name=wet.

¹⁰⁹ Webpage available at <http://www.riziv.be/nl/themas/medische-ongevallen/Paginas/default.aspx#.Wy342kgiM2x>.

provider concerned. This procedure is amicable and free of charge. On certain conditions, the FMA will compensate the applicant immediately. This would for instance be the case if serious injuries have been sustained even if the healthcare provider is not guilty of professional negligence; if the responsibility of the healthcare provider is not or insufficiently covered by an insurance contract; if the healthcare provider or his insurer makes a reimbursement proposal that is clearly inadequate.

Criteria for compensation is that the damage must have been occurred during provision of health care services and there must be liability of the provider established. In certain cases there is no need to establish liability (cases of abnormal accidents, causing serious damage).

In other cases, the FMA will ask the insurer of the healthcare provider to compensate the victim. Person can also ask FMAs advice about the reimbursement that the insurer of the healthcare provider has proposed. If FMA believes that proposal is clearly inadequate, they can formulate a different remuneration proposal. If person does not agree with proposal, s/he can contact the court of first instance.

Payments are calculated based on precedence existing in the common law¹¹⁰.

IV.III.VIII Slovenia

In Slovenia health-care workers must be insured against liability for damages (cases of compensation claim by patients or their relatives) as the insurance of their professional liability is mandatory. Doctors working directly with patients must be insured against liability for damages that might arise from their work. Employed doctors are insured by a health-care service provider as their employer, while private doctors are self-insured.

If a compensation claim results from a professional error in performing a health-care activity or service, the costs incurred will be covered by the insurance company. Thus, in the case of a compensation claim, the insurance company with which a health-care worker has concluded a professional liability insurance will consider the claim and, in certain cases, will be liable for civil proceedings of the insured and the costs of the defence of the insured in criminal proceedings. An injured patient may also file a claim directly with the insurance company with which the professional liability of the health-care worker is insured. As companies who provide this insurance are different, also regulations applicable to the proceedings of obtaining compensation, are different.

The insurance sum for doctors and dentists should be fixed according to individual specialisations annually by the Medical Chamber of Slovenia. The last decision issued in 2001 stipulates that a doctor and a dentist who is in direct contact with patients shall be insured against liability for damages that might arise from his/her

¹¹⁰ Information available at <https://www.health.belgium.be/en/health/taking-care-yourself/patient-related-themes/national-contact-point-cross-border-healthcare#information> . In Belgium courts handling disputes about compensation did conclude on numerous occasions that there is a need to move towards non-fault liability system. Finally state obliged all health care providers to obtain liability insurance covering civil claims. Look also **Koch B A, Koziol H (eds.) Compensation for personal injury in a comparative perspective**. Wien; New York: Springer, 2003. P 64.

work for a minimum sum of EUR 12,519. In practice, health-care providers make arrangements directly with insurance companies where the insurance sums are significantly higher¹¹¹.

V Next steps

V.I Choice of provider – public or private

Main alternatives for running the non-fault liability insurance system for health care providers is either public risk fund or obligatory private professional liability insurance.

V.I.I Public risk fund

Public risk fund will compensate for harm suffered by patient in cases where such harm could have been prevented. Compensation is processed in accordance with the law. There might be a willingness to appoint concrete amounts of compensation (table) or use maximum limits for out-payments. Compensation is paid if there is a causal link between harm occurred and provision of health care services. Independent experts of the risk fund are assessing the justifiability of claims.

Law puts obligation on the service providers to pay contributions to the fund. Such contributions form fund's budget. Due to payment obligation prices of health care services raise both in the budget for state health expenditures as well as in private market. Percentage of increase depends of the amount of contributions appointed. Contributions differ by risk, services provided, profession (doctor, nurse, midwife etc.), specialisation (surgery, internal medicine, dental care etc.), compensations paid; but level of contributions is regulated by the state via legislation.

V.I.II Private insurance market

In this case insurance cover is offered by ordinary insurance companies who are forming a centre. Liability of the health care service provider in front of the patient is insured. Insurance is paid out if harm is done while providing health care services and it could have been avoided. Patient shall address his/her claim to the centre who shall establish the existence of the insurance case, harm and its severity. Payments by the service providers depends on the risk as assessed by insurers and prices of insurance influence prices of health care services despite of the contributor.

Amount of compensations can be controlled via appointing maximum limit for out-payments.

Differently from the public system also profit of the insurance companies as well as need for re-insurance are taken into account when deciding on the price of insurance. At the same time prices of insurance are more accurate and personal than in the case of state-run system. Benefits of private system are lack of political influences as well as less-bureaucratic and faster proceedings. Also competition effect between insurance companies might be present.

¹¹¹ Information available at http://www.nkt-z.si/wps/portal/nktz/home/healthcare/pli/!ut/p/b1/04_Sj9CPykssy0xPLMnMz0vMAfGjzOLNDHwdPTwNDD38Q_yNDTzDvAxc3U39jCz8TIEKlpEVVHibOQEVuPobhJo6GroHGxDS76UflZ6TnwS0KIw CIUxFrPACgxwAEcD CZYGJjr-3nk56bqF-RGVAZ76joCACRAMmU!dl4/d5/L2dJQSEvUUt3QS80SmtFL1o2XzQxRUlHM08wSTBOUjAwQUdLMFZMRTQwMFEx/

Regardless of the system activity costs (including salaries, expert fees) must be covered. Similarly, and in order to lessen the burden for the insurer, possibility to appoint (obligatory) mediation or similar pre-proceeding should be addressed. This should increase the efficiency and help to control costs of the system.

V.II Next steps

On the basis of the information collected from various stakeholders following immediate suggestions for revising the medical liability insurance system in Latvia could be made:

1. The Minister of Health could as next steps carry out a comprehensive analysis about the following issues: financial resources in its disposal for running the MRF system in short and long run; possible domain for the fund in present institutional structure (considering state authorities, professional unions etc); competences and resources needed for purposeful medical liability insurance system in short and long term; method of deciding on compensation (expert-based or list-based); establishing prior obligatory mediation proceedings between parties; options for combining reporting and compensation systems etc.
2. Outcomes on analysis on policy level can be combined into a report that should be comprehensively, constructively and openly discussed with stakeholders. This includes other state bodies, associations, academia (including economical sciences) etc. Consultations could be thematic i.e by working groups maximising the input from parties.

After hearing all stakeholders and carefully considering their input final report can be made providing the ground for decision of the model appropriate for Latvia.

Assistance for constructing the framework for stakeholder engagement could be enquired from other countries, as, for example, Estonia and Scotland, who have successfully performed such exercise within the framework of creating medical liability insurance.

3. Whatever model will be used for liability insurance in the future the system should clearly address at least the following issues:
 - definition of complainant;
 - scope of the insurance;
 - the cross border elements;
 - transparent and efficient proceedings for claimants;
 - methodologies for calculation of compensation;
 - damages to be compensated;
 - information about the system;
 - assistance available for settling the disputes prior to application and during the proceedings;
 - avenues of application after the decision etc.

As the trigger for creating an insurance system was implementation of the EU Directive 2011/24, it should be kept in mind that insurance coverage and other details should be in accordance with the stipulations in the Directive.



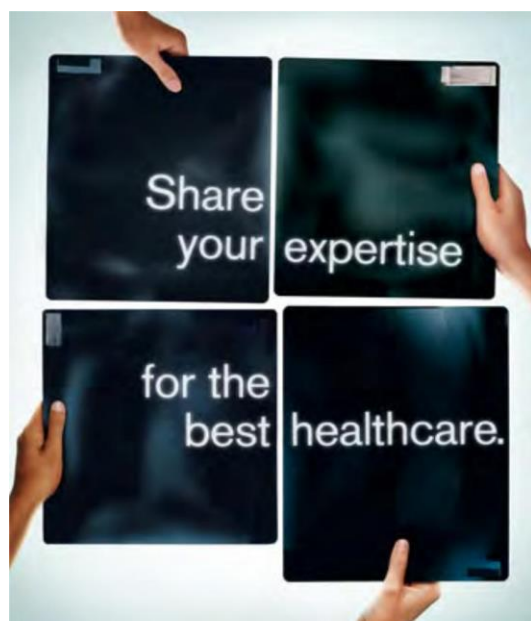
European
Reference
Networks

Appendix 6

THE SELF-ASSESSMENT CHECKLIST TOOL
FOR HEALTHCARE PROVIDERS
- ERN Assessment Manual for Applicants¹¹²

ERN Assessment Manual for Applicants

Self-Assessment Checklist for Healthcare Providers in Active PDF



An initiative of the

Version 1.1 April 2016



¹¹² http://ec.europa.eu/chafea/documents/health/8-self-assessment-for-hcp_en.pdf

Preamble

This document contains the Self-Assessment Checklist for Healthcare Providers in Active PDF. It is part of series of nine documents that include the following:

1. ERN Assessment Manual for Applicants: Description and Procedures
2. ERN Assessment Manual for Applicants: Technical Toolbox for Applicants
3. ERN Assessment Manual for Applicants: Operational Criteria for the Assessment of Networks
4. ERN Assessment Manual for Applicants: Operational Criteria for the Assessment of Healthcare Providers
5. Network Application Form
6. Membership Application Form
7. Self-Assessment Checklist for Networks in Active PDF
8. Self-Assessment Checklist for Healthcare Providers in Active PDF
9. Sample Letter of National Endorsement for Healthcare Providers

This series of documents of the Assessment Manual and Toolbox for European Reference Networks has been developed in the framework of a service contract funded under the European Union Health Programme.

SELF-ASSESSMENT CHECKLIST FOR HEALTHCARE PROVIDERS

INTRODUCTION

In accordance with the requirements outlined in the Implementing Decision 2014/287/EU Annex II (b), the membership application to join a Network must be submitted in response to a call for interest published by the Commission and must include: the completed application form with the self-assessment questionnaire and supporting documentation required in the assessment manual (See page 23 of the *ERN Assessment Manual for Applicants*).

The self-assessment provides Healthcare Providers with the opportunity to evaluate themselves against the specific legislated criteria and conditions before submitting their application to the European Commission.

In addition, the self-assessment provides a mechanism for both the Independent Assessment Body and the Healthcare Provider to collaborate on assessing compliance against the Operational Criteria. The information submitted will help support a thorough documentation review and plan the on-site audit.

DESCRIPTION OF THE SELF-ASSESSMENT TOOL

The following self-assessment checklist is divided into nine (9) distinct sections. These include the following:

General criteria and conditions for Healthcare Providers¹

1. Patient Empowerment and Patient Centred Care
2. Organisation, Management, and Business Continuity
3. Research, Education, and Training
4. Expertise, Information Systems, and e-Health Tools
5. Quality and Safety

Specific criteria and conditions for Healthcare Providers with regard to the area of expertise, disease or condition²

6. Competence, Experience, and Outcomes of Care
7. Human Resources
8. Organisation of Patient Care
9. Facilities and Equipment

¹ Commission Delegated Decision (2014/286/EU) – Annex II

² Commission Delegated Decision (2014/286/EU) – Annex II

These nine (9) sections are based on the requirements set out in the Delegated Decision 2014/286/E Annex II. Each section includes multiple items to help the Healthcare Provider evaluate its readiness to submit an application. These items are based on those Operational Criteria that the European Commission and Independent Assessment Body will use to assess compliance with the legislation. Note that a complete self-assessment must accompany the Application Form for the application to be considered.

INSTRUCTIONS FOR COMPLETING THE SELF-ASSESSMENT

1. Establish a multidisciplinary team consisting of the Healthcare Provider's Representative and care provider representation.

The team should be given sufficient time to complete the self-assessment. Completing the self-assessment as a team increases the value of the process and accuracy of the information. It is estimated to take approximately three to four meetings with time allocated between meetings pending volume of items requiring further investigation or the need to submit required documentation to support evidence of compliance in that area. A team leader should be appointed to organize the group, assign tasks, and coordinate the self-assessment effort.

2. Read and review the Operational Criteria in its entirety before beginning the Self-Assessment process. If possible, make copies and send them to team members before the first meeting.
3. Discuss each individual element in the Self-Assessment Checklist and evaluate the progress in implementing it. As necessary, verify the level of implementation with other individuals outside of the team. Document this information in the "Comments" section of the checklist.
4. Once consensus is reached, complete the table below by marking the box that most appropriately captures the current status of compliance with the criterion, using following rating scale and scoring guide:



Rating	Guidelines
0: No activity / Not Implemented	All Criteria: this rating is used when there is no action plan in place or there is insufficient evidence to support compliance. This rating may also be used when the practice is not implemented in any of the Healthcare Providers of the Network (if applicable).
1: Partially Implemented	All Criteria: this rating is used when there is an action plan in place or there is some evidence to support compliance. This rating may also be used when the practice is implemented by some of the Healthcare Providers of the Network (if applicable).
2: Fully Implemented	All Criteria: this rating is used when there is sufficient evidence to support compliance. This rating may also be used when the practice is implemented by all of the Healthcare Providers of the Network (if applicable).





5. Repeat the process for each element. Once complete, tally up the score for each section using the template provided in **Appendix A**. Refer to those areas in which your percentage performance indicates the greatest opportunities for improvement.
6. Use this information to develop an Action Plan to improve readiness to submit the application and complete the assessment process.
1. Prior to finalizing and submitting the self-assessment, a process to validate the results internally should be followed. The purpose of the internal validation is to:
 - Provide a level of quality assurance;
 - Confirm that the self-assessments are accurate and therefore can be shared externally;
 - Identify any inconsistency in practice across the Network; and
 - Identify areas of best practice that could be shared across the Network.

It is the Network's responsibility to determine how the internal validation will be completed. The Network must ensure that the process used meets the following requirements:


- The process is fair and robust;
 - The process is agreed to by all Healthcare Providers;
 - Accountability for the self-assessment is agreed to by the Chief Executive Officer of the Healthcare Provider; and
 - The process includes patient and family involvement.
7. At the conclusion of the internal validation, the self-assessment team should check and record any changes in the self-assessment.
 8. Complete and sign the *Declaration Form* in **Appendix C** of the self-assessment.
 9. Submit the completed Self-Assessment along with the Application Form **no later than the deadline** for applications in response to the Call for Expression Interest. The Healthcare Provider **must** have ready at the time the application is submitted all supporting documentation listed in **Appendix B**. These documents should be made available to the IAB, at their request.

THE SELF-ASSESSMENT CHECKLIST TOOL FOR HEALTHCARE PROVIDERS



1. PATIENT EMPOWERMENT AND PATIENT CENTRED CARE			
1.1 The Healthcare Provider has strategies in place to ensure that care is patient-centred and that patients' rights and preferences are respected.			
Measure Elements	Rating (0 or 1 or 2)	Comments	 *
1.1.1 The Healthcare Provider's commitment to patient-centred care is formally and consistently communicated with patients and their families.			
1.1.2 Processes are in place to assist patients and their families in knowing who is providing their care, and the role of each person on the multidisciplinary care team.			
1.1.3 Patient education materials appropriate for readers of varying literacy levels and for speakers of different native languages are available.			
1.1.4 The Healthcare Provider provides patients and their families with written information about the facility, the organization, and its specific area of expertise.			

1.1.5 The Healthcare Provider gives patients and their families written information about their rights and responsibilities.			
1.1.6 There is a policy and procedure in place to disclose unanticipated outcomes and complications to patients and their families, as appropriate.			
1.2 The Healthcare Provider provides patients with clear and transparent information about the complaints procedures and remedies and forms of redress available for both domestic and foreign patients.			
Measure Elements	Rating (0 or 1 or 2)	Comments	
1.2.1 Patients and their families are given information about how to file a complaint, report violations of their rights, and raise concerns about their care and/or safety.			
1.3 The Healthcare Provider regularly collects information on patient care experience within the Network's area of expertise and uses this information to make ongoing improvements.			
Measure Elements	Rating (0 or 1)	Comments	
1.3.1 The Healthcare Provider routinely measures or facilitates the measurement of patient and family experience using a standardised validated questionnaire. This information is periodically reported to all healthcare professionals and managers involved in delivering care, patients and families, and the general public.			


1.4 The Healthcare Provider protects the privacy and confidentiality of patient health information.



Measure Elements	Rating (0 or 1 or 2)	Comments	 *
1.4.1 The Healthcare Provider ensures access to medical records and clinical information is in compliance with EU data protection provisions and national implementing measures, in particular, Directive 95/46/EC.			



1.5 Patient informed consent to share personal health information complies with the requirements set out in Article 2(e) of the Directive 2014/286/EU.

Measure Elements	Rating (0 or 1 or 2)	Comments	 *
1.5.1 If patient personal health information is exchanged, patients are informed of their rights under the applicable data protection rules and informed consent is obtained. The Healthcare Provider has a policy and standard procedure for obtaining informed consent. The Informed consent is documented in the patient's medical record.			

1.6 The Healthcare Provider maintains transparency by providing information to patients and the general public about clinical outcomes, treatment options, and quality and safety standards that are in place.

Measure Elements	Rating (0 or 1 or 2)	Comments	 *
1.6.1 The Healthcare Provider presents patients and their families with reliable information on clinical outcomes in a form that is useful to them.			
1.6.2 All relevant information must be provided to patients in an anonymized format, including claims data, patient registry data, clinical data, and patient-reported outcomes.			



1.6.3 Every patient is provided with a full description of the available alternatives for tests and treatments, as well as the pros and cons for each, and the potential risks and benefits.			
1.6.4 The Healthcare Provider disseminates information to patients and their families on patient safety standards and safety measures to reduce or prevent errors.			
1.7 The Healthcare Provider is transparent about all possible conflicts of interest related to treatment and/or research activities.			
Measure Elements	Rating (0 or 1 or 2)	Comments	 *
1.7.1 The Healthcare Provider ensures disclosure of all financial and non-financial conflicts of interest related to treatment and/or research activities.			

2. ORGANISATION, MANAGEMENT, AND BUSINESS CONTINUITY			
2.1 The organization follows a documented set of organization and management rules and procedures for services provided within the Network's area of expertise.			
Measure Elements	Rating (0 or 1)	Comments	 *
2.1.1 Management and staff and/or clinician roles and responsibilities specific to the area of expertise are clearly defined in an organization chart.			
2.1.2 The Healthcare Provider establishes and maintains a set of policies and procedures addressing aspects of management and activities or services within the Network's area of expertise.			
2.1.3 There are policies and procedures for managing cross border patients within the Network's area of expertise.			


2.2 The Healthcare Provider shares information with patients and their families about any tariffs that may be in place for the reimbursement of care, including how these are calculated.

Measure Elements	Rating (0 or 1)	Comments	 *
2.2.1 The Healthcare Provider provides patients and their families with easy access to information regarding any tariffs that may be in place, services, and benefits.			

2.3 The Healthcare Provider has a business continuity plan.

Measure Elements	Rating (0 or 1)	Comments	 *
2.3.1 The plan includes the provision of essential medical care in the case of unexpected resource failure, or referral to alternative resources, if necessary; and maintaining stability, technical capacity and expertise of the provider, such as a plan for human resources and updating technology.			




2.4 The Healthcare Provider establishes procedures and/or inter-agency or shared care agreements to support ease of access and coordination with other resources, specific units, or services necessary for managing patients.

Measure Elements	Rating (0 or 1)	Comments	 *
2.4.1 There are procedures for emergencies and patients presenting outside normal working hours. Patients within the Network's area of expertise can be admitted without delay to a suitable hospital ward service area, where necessary.			





2.4.2 When necessary, the Healthcare Provider has easy access to other centres or highly specialised units outside its own facilities necessary for diagnosis, treatment, and delivery of care to patients.			
2.5 The Healthcare Provider has available and maintains good general facilities in accordance with its area of expertise.			
Measure Elements	Rating (0 or 1 or 2)	Comments	☰ *
2.5.1 Treatment of patients takes place in dedicated clinical areas that are easily accessible, clean, comfortable, quiet and appropriately equipped.			☰
2.6 There are policies and procedures in place to communicate with clinicians post discharge, including cross border.			
Measure Elements	Rating (0 or 1 or 2)	Comments	☰ *
2.6.1 The Healthcare Provider provides local clinicians with complete discharge summaries post discharge for all patients.			☰
2.6.2 Where possible, the Healthcare Provider uses information and communication technologies, such as eHealth tools, telemedicine/tele-expertise, and case management tools to follow-up post discharge.			

3. RESEARCH, EDUCATION AND TRAINING

3.1 The Healthcare Provider participates in education and training activities, such as continuing medical education and distance learning, aimed at staff, students, and other care professionals.

Measure Elements	Rating (0 or 1)	Comments	 *
3.1.1 The Healthcare Provider delivers university, post-graduate, or specialised level of education and training in the Network's area of expertise.			
3.1.2 The Healthcare Provider has a defined set of objectives for its education and training activities.			
3.1.3 The Healthcare Provider provides evidence that resources are available, i.e. human, technical, or physical structure, to support education and training activities.			
3.1.4 Education and training activities are delivered to providers involved in the same chain of care within and outside the Healthcare Provider facility.			
3.1.5 The Healthcare Provider evaluates the effectiveness of its education and training activities on an annual basis.			


3.2 The Healthcare Provider has the capacity to carry out research activities and demonstrated research experience.

Measure Elements	Rating (0 or 1)	Comments	 *
3.2.1 The Healthcare Provider provides evidence that adequate resources are available, i.e. human, technical, or physical structure, to support research activities.			
3.2.2 The Healthcare Provider leads and/or participates in research activities and clinical trials, at both a national and international level, within the Network's area of expertise.			
3.2.3 The Healthcare Provider follows a set of Standard Operating Procedures (SOPs) that govern research activities.			
3.2.4 There is a procedure to review the ethical implications of research activities.			
3.2.5 The Healthcare Provider maintains and manages records of research activities and clinical trials in accordance with institutional policies and set laws and regulations.			


3.2.6 The Healthcare Provider shares the results of its research activities and clinical trials through scientific publications. The results should be disseminated to other centres and professional and patient associations.			
3.2.7 The Healthcare Provider evaluates the effectiveness of research activities.			

4. EXPERTISE, INFORMATION SYSTEMS, AND E-HEALTH TOOLS

4.1 The Healthcare Provider is able to exchange expertise with other providers and provide support to them.

Measure Elements	Rating (0 or 1 or 2)	Comments	 *
4.1.1 The Healthcare Provider offers an advisory service to exchange expertise with other professionals and caregivers involved in the patients' treatment.			
4.1.2 The Healthcare Provider maintains an accurate database of patients under its care within the Network's area of expertise.			


4.2 The Healthcare Provider safeguards the use of medical data within the Network's area of expertise.






Measure Elements	Rating (0 or 1 or 2)	Comments	 *
4.2.1 The Healthcare Provider follows established procedures to manage, safeguard, and exchange medical data. These procedures are in accordance with the EU data protection legislation, in particular, with Directive 95/46/EC and with Article 2 (e) of the Delegated Decision 2014/286/EU.			

4.3 The Healthcare Provider fosters the use of telemedicine and other e-health tools within and outside its facility.

4.3.1 To support the use of telemedicine and other e-health tools, the Healthcare Provider fulfils the minimum interoperability requirements and when possible, uses agreed to standards and recommendations.			

4.4 The Healthcare Providers coding and information system is in line with nationally and internationally recognised systems.

Measure Elements	Rating (0 or 1)	Comments	 *
4.4.1 The Healthcare Provider uses a standardised information and coding system for rare or low prevalence complex disease(s) or conditions(s).			
4.4.2 The Healthcare Provider has procedures in place to monitor and maintain data quality.			


5. QUALITY AND SAFETY			
5.1 The Healthcare Provider regularly monitors the quality and safety of the care it provides to patients with rare or low prevalence complex diseases or conditions.			
Measure Elements	Rating (0 or 1 or 2)	Comments	 *
5.1.1 The Healthcare Provider has a quality assurance or management system in place that includes processes to regularly monitor the quality of its performance within the Network's area of expertise. The information it collects is used to make ongoing quality improvements.			
5.1.2 The Healthcare Provider regularly collects and monitors process and outcome indicators.			
5.1.3 The Healthcare Provider has a patient safety programme or plan in place adapted to the Network's area of expertise.			
5.1.4 There is a procedure in place to report, document, investigate, and learn from adverse events and complications. The Healthcare Provider uses this information to make ongoing improvements.			

5.1.5 The Healthcare Provider contributes performance and outcome data to evaluate the Network, as a whole.			
5.2 The Healthcare Provider demonstrates a commitment to using best practice knowledge and evidence based health technologies and treatments.			
Measure Elements	Rating (0 or 1 or 2)	Comments	📄 *
5.2.1 There is a process to periodically review and share best practices, review the results of clinical audits, review new evidence-based treatments and therapies, and discuss difficult cases.			
5.3 The Healthcare Provider develops and/or uses clinical practice guidelines in their area of expertise.			
Measure Elements	Rating (0 or 1 or 2)	Comments	📄 *
5.3.1 The Healthcare Provider collaborates with other members of the Network or centres of expertise to develop and/or select clinical practice guidelines following a standard evidence-based procedure.			📄


5.3.2 The Healthcare Provider implements, where possible, clinical practice guidelines agreed to or developed by the Network.			
5.3.3 Clinical practice guidelines are regularly reviewed to ensure they reflect current research and best practice information.			

6. COMPETENCE, EXPERIENCE, AND OUTCOMES OF CARE

6.1 The Healthcare Provider maintains its competence in the Network's area of expertise.

Rating Measure Elements	(0 or 1 or 2)	Comments	 *
6.1.1 The Healthcare Provider regularly monitors and documents its patient activity specific to the Network's area of expertise, disease or condition.			
6.1.2 To maintain its competency and expertise, the Healthcare Provider serves the minimum/optimal number of patients and/or procedures per year as defined by the Network based on professional/technical standards or recommendations.			

6.2 The Healthcare Provider demonstrates good clinical care and outcomes.

Rating Measure Elements	(0 or 1 or 2)	Comments	 *
6.2.1 There is evidence that the treatments and advice offered are recognized by international medical science in terms of safety, value, and/or potential positive clinical outcome.			
6.2.2 The Healthcare Provider shows evidence of good clinical care and outcomes according to available standards, indicators, and knowledge as defined by the Network.			

7. HUMAN RESOURCES

7.1 The Healthcare Provider has a team of trained professionals with the required competencies within the Network's area of expertise.

Measure Elements	Rating (0 or 1 or 2)	Comments	
7.1.1 The Healthcare Provider identifies and documents the skills and professional qualifications required for the staff performing activities critical to the quality of patient care.			
7.1.2 There is a sufficient number of staff with the necessary qualifications to perform the specialized function.			
7.1.3 Each core team member should undertake a minimum number of procedures and/or care for a minimum number of patients in a given year as defined by the Network. The multidisciplinary team should discuss a minimum number of patients per year.			
7.1.4 The Healthcare Provider retains records of staff training, professional development, and maintenance of competencies. There is a process to routinely assess staff skill to ensure adequate performance of specialized tasks.			


8. ORGANIZATION OF PATIENT CARE			
8.2 Comprehensive care is delivered by a multidisciplinary and specialised care team.			
Measure Elements	Rating (0 or 1 or 2)	Comments	
8.2.1 The Healthcare Provider documents the characteristics of the multidisciplinary team.			
8.2.2 There is a designated leader and chair of the multidisciplinary team.			
8.2.3 There are documented procedures to support the organisation and functioning of the multidisciplinary care team.			

<p>8.2.4 There are regular structured meetings between multidisciplinary team members.</p>	<div></div> <div></div> <div></div>		
<p>8.2.5 Patients receive a periodic clinical or multidisciplinary review. The timeframe is defined based on the area of expertise, disease or condition; and its severity.</p>	<div></div> <div></div> <div></div>		
<p>8.2.6 The multidisciplinary team evaluates its performance on an annual basis.</p>	<div></div> <div></div> <div></div>		

9. FACILITIES AND EQUIPMENT

9.3 The Healthcare Provider has the necessary facilities and equipment to attend to patients specific to the area of expertise, disease, or condition as defined by the Network.

Measure Elements	Rating (0 or 1 or 2)	Comments	
9.3.1 The Healthcare Provider has available within the centre or easy access to the necessary equipment and facilities to provide good quality patient care.			
9.3.2 There is access to a specialised laboratory service capable of carrying out all tests required to diagnose the rare or low prevalence complex disease(s) or condition(s) as defined by the Network.			
9.3.3 There is access to a range of diagnostic technologies as appropriate to the rare or low prevalence complex disease(s) or condition(s) as defined by the Network.			
9.3.4 Based on the area of expertise, the Healthcare Provider has the capacity to process, manage, and exchange information and biomedical images, or clinical samples with external providers.			

* The Symbol  indicates the requirement to have ready at the time of the application a specific document as evidence of compliance. These documents are to be submitted at the request of the IAB. See Appendix B for the full listing of supporting documentation required.

APPENDIX A: SCORING TABLE

Self-Assessment Scoring Table			
GENERAL CRITERIA AND CONDITIONS			
Patient Empowerment and Patient Centred Care			
Total Score out of a Possible 30	0	Percent of Total	0.00%
Organisation, Management, and Business Continuity			
Total Score out of a Possible 20	0	Percent of Total	0.00%
Research, Education and Training			
Total Score out of a Possible 24	0	Percent of Total	0.00%
Expertise, Information Systems, and E-health Tools			
Total Score out of a Possible 12	0	Percent of Total	0.00%
Quality and Safety			
Total Score out of a Possible 18	0	Percent of Total	0.00%
SPECIFIC CRITERIA AND CONDITIONS			
Competence, Experience, and Outcomes of Care			
Total Score out of a Possible 8	0	Percent of Total	0.00%
Human Resources			
Total Score out of a Possible 8	0	Percent of Total	0.00%
Organization of Patient Care			
Total Score out of a Possible 12	0	Percent of Total	0.00%
Facilities and Equipment			
Total Score out of a Possible 8	0	Percent of Total	0.00%
OVERALL			
Subtotal Score for General Criteria	0	Percent of Total	0.00%
Subtotal Score for Specific Criteria	0	Percent of Total	0.00%
GRAND TOTAL SCORE out of a Possible 140	0	Percent of Total	0.00%

APPENDIX B: LIST OF SUPPORTING DOCUMENTATION FOR HEALTHCARE PROVIDERS (not provided in this report)

ATTACHMENT A – STRATEGIC PLANNING AND GOVERNANCE

- Measure 1.1.1 Mission and/or Core Values ([English_Summary](#))
- Measure 2.1.1 Organization chart ([English_Summary](#))
- Measure 1.7.1 Conflict of Interest Policy ([English_Summary](#))
- Measure 2.3.1 Business continuity plan ([English_Summary](#))

ATTACHMENT B – PATIENT EMPOWERMENT ([English_Summary of all B measures](#))

- Measure 1.1.3 Sample of Patient Education Materials
- Measure 1.1.5 Written Material Describing Patient and Family Rights and Responsibilities
- Measure 1.3.1 Patient Experience Survey and Sample Patient Experience Reports
- Measure 1.5.1 Informed Consent Policy and Procedure (**English translation of one sample + documents in original language**)

ATTACHMENT C – ORGANISATION OF CARE ([English_Summary of all C measures](#))

- Measure 2.1.3 Policies and Procedures for Managing Cross Border Patients or planned actions and timelines for developing policies and procedures ([English_Summary](#))
- Measure 2.6.1 Discharge procedure and Discharge Template ([English_Summary](#))
- Measure 5.3.1 Clinical Practice Guidelines

ATTACHMENT D – QUALITY AND INFORMATION SYSTEM ([English_Summary of all D measures](#))

- Measure 2.5.1 Third party reports and/or inspections on the quality care environments ([English_Summary](#))
- Measure 5.1.1 Quality Improvement Plan
- Measure 5.1.2 Process and Outcome Indicators (Dashboard) and their definitions
- Measure 5.1.3 Patient Safety Plan
- Measure 5.1.4 Detailed Example of Root Cause Analysis and Description of Process Improvement

ATTACHMENT E – RESEARCH AND TRAINING ([English_Summary of all E measures](#))

- Measure 3.1.2 List of teaching objectives ([English_Summary](#))
- Measure 3.1.3 List of Teaching Staff and Qualifications ([English_Summary](#))
- Measure 3.2.2 List of grants and research projects over the last 5 years ([English_Summary](#))
- Measure 3.2.3 List of Standard Operating Procedures (SOPs) that govern research activities ([English_Summary](#))
- Measure 3.2.4 Research Policy and Procedure

APPENDIX C: DECLARATION FORM

TO BE COMPLETED BY THE PERSON LEADING THE SELF-ASSESSMENT	
Person Leading the Self-Assessment	
Name:	
Title:	
Contact Email:	
Assessment Purpose	
Application Type	<input type="checkbox"/> Initial Approval <input type="checkbox"/> Network and/or Healthcare Provider Renewal
Self Assessment	
Date:	
Outcome	<input type="checkbox"/> Full Compliance with the Operational Criteria <input type="checkbox"/> Partial Compliance with the Operational Criteria <input type="checkbox"/> Not Yet Compliant with the Operational Criteria
Notes Relevant to the Self-Assessment (if any)	
Signature of the Healthcare Provider Representative	
Signature:	
Declaration of the Network Coordinator	
<p>I confirm that this self-assessment is an accurate and true reflection of the compliance status of the Healthcare Provider against the Operational Criteria and that all supporting documentation listed in Appendix B are prepared and ready for submission, at the IAB's request.</p>	
Signature:	<div> <div>Name:</div> <div>Date:</div> </div>

