Report on a proposed
No-fault compensation model
Phase 5

Support for improving quality of healthcare and patient safety in Slovenia

RFS REFORM/SC2020/021
AARC - Consortium

The project is funded by the European Union via the Structural Reform Support Programme and implemented by NTT DATA, in cooperation with the Directorate General for Structural Reform Support of the European Commission

July 2022

ABBREVIATIONS

CoO	Code of Obligations
HC	Health Care
ICT	Information Communication Technology
MoH	Ministry of Health
MoJ	Ministry of Justice
MCS	Medical Chamber of Slovenia
NFC	No-Fault Compensation
OWG	Operational Working Group
PC	Pharmacist Chamber
PS	Patient Safety
RM	Risk Management
QoC	Quality of Care

INDEX

EXECUTIVE SUMMARY

The aim of the document on **No-Fault Compensation (NFC)** is to add to the overall efforts on introducing and enhancing the Quality of Care (QoC) and Patient Safety (PS) in Slovenia and to support the Ministry of Health (MoH) of developing legal basis for compensation of injured patients from sentinel and other adverse events during their treatment.

The right to compensation in Slovenia is currently not formally recognized as a specific patient right so it must be processed in the civil procedure if the patients decide so. In order to obtain compensation for harm arising out of medical treatment received, the elements needed to establish negligence under the law of delict (medical malpractice etc) must be satisfied. Thus, pursuers need to show that there was a duty of care that was breached by the defender and that breach caused the compensable harm. Therefore payment of compensation is either through an out-of-court settlement, also through insurance or through the courts.

Compensation for health-related damages is addressed in the general provisions of the Slovenian civil law (Code of Obligations - CoO). Healthcare (HC) professionals can be discouraged to disclose adverse events, as they fear that the compensation mechanism may be used to collect evidence for criminal and other proceedings against them. Therefore, they often act defensively and minimize or hide adverse events as a defence against potential litigation. The lack of a NFC option in Slovenia, which would provide a safe environment for HC professionals to focus on quality and safe HC for patients rather than on defending their professional decisions, is recognized as an obstacle in implementing the system for reporting and learning from sentinel and other adverse events. Existing tort system is costly, cumbersome, prone to delay, and too capricious in its operation to be defensible. The adversarial and blame orientated nature of this system is not conducive to the culture of openness required by clinical governance. Judicial prove of guilt is necessary for the injured person to claim a compensation.

As said compensation is an inevitable part of the overall QoC and PS and contributes to safer, more prudent practice of medicine, introducing and satisfying elements of just culture.

On the other hand introducing NFC may produce reduction in legal and administrative costs and a lower level of payouts offset the costs of greater numbers of claimants. The advantage is that claims can be investigated promptly, without the restriction of communication typical of the adversarial process. The system is deemed more equitable and efficient. Cognisant that a NFC system may seem to protect offending doctors and providers, emphasise that negligent professionals would face disciplinary procedures.

The present system is deemed to be as harmful, unpredictable, and unjust for both, patients and medical staff.

Situation analysis (Phase 2.2.) was carried out with consultation with the main key stakeholders and the Report was produced. Furthermore comparative analisys of the Slovenian compensation system and three NFC have been done and a few other jurisdictions looked at more in detal, namely Swedish, Danish and New Zealand's. Those countries have a long lasting tradition of compensating harm to the patients. Swedish from 1975 (not compulsory until 1997; Danish since 1992, Finland since 1987 and New Zealand since 1972 (in effect since 1974 as a part of broader NFC scheme; later in 2005 heavily amended in section of health). Mapping their key features and assessing their relevance and transferability in the Slovenian context showed direction and juridical, economical, organisational and other impacts. It showed the direction in which to propose elements of future Slovenian NFC.

Key players ie. MoH, Ministry of Justice (MoJ), Medical Chamber of Slovenia (MCS), Pharmacist Chamber (PC), HC providers and other were consulted and 4 workshops organised in order to discuss open topics on judicial, legal, economical/financial and organisational questions on future NFC scheme. NFC models of three orher countries were discussed in order to see their elements that may be transferable to Slovenian model. Web meeting was held with representatives of Swedish competent body Löf region mutual insurance company (LöF) for NFC where Swedish model was discussed in terms of conceptual and operational issues.

The Report describes in detail proposed compensation model with regard to definitions of medical injury, based on which the right to compensation is established; furthermore who is entitled to decide whether and when someone is entitled to compensation and how to ensure the neutrality/independence of such an authority; the overall organization of appeal system, including aspects such as time limits for introducing claims, the applicable criteria for compensation, the minimum and maximum compensation amounts etc.; the estimated impact of NFC with regards to court litigation, legislative and institutional changes needed; the proposed sources of financing of the NFC; in addition whether the mechanism is to be applied in parallel with the current compensation system (and based on which criteria or conditions) or being replaced etc.

In the report the advise to the MoH on the necessary governance and legal changes required to implement the agreed compensation model is included.

The proposed compensation model is based on the following conceptual pillars:

1. Promoting just culture, promoting no shame and blame policy in HC
2. Ensuring transparency, accountability and learning from adverse events
3. Encouraging patients to avoiding long lasting and cumbersome litigation processes at civil courts
4. Decriminalisation of human errors
5. Building capacity of health care system overall

Report of a situation analysis (of the national context of PS & patient RM, patient compensation, and QoC, the main gaps in regards to QoC, PS, and NFC were identified), and recommendations on governance and organization of HC system in Slovenia were proposed.

This document contains:

1. Introductory chapters and description of tort and NFC systems
2. The proposed model of NFC in Slovenia
3. The description of roles, responsibilities and accountabilities of key stakeholders in processing of NFC claims
4. The description and justification of individual elements of the proposed model
5. Recommendations for introducing the proposed model

In the next steps NFC law in HC should be produced and instituted in Slovene national jurisdiction. Several bylaws and other legal documents may definitelly be needed and produced for the operation of independent national body dealing with QoC, PS and NFC in order of NFC scheme to become operational. Also bylaws for other stakeholders, especially health care providers may need to be produced and/or amended and regulated by statute (law) if necessary.

1. INTRODUCTION

1.1. Background

In the process of care every step can contain an inherent risk. The nature and scale of risks vary greatly, based on the context of health care provision and its availability, infrastructure and resourcing within and across countries. The challenge for all health systems and all organizations providing health care is to maintain a heightened awareness to detect safety risks, as well as to address all sources of potential harm.

In broader sence PS also include the awareness of the patients and providers rendering medical service, that patients can be compensated for medical injuries that are inevitable part of the medical activity. Having efficient, fast, affordable and non complicated ways to be compensated has been recognised as the social benefit in the system.

When a person book a procedure or an appointment with a medical professional, they expect the utmost in professionalism and knowledge. They visit a doctor trusting that they will make the right and best decisions for their health and that they will be in good hands. Unfortunately, that isn't always the case, and sometimes result of a treatment isn't as expected no matter whether medical negligence is in question or other reasons for health damage to the patient can occur.

In Slovenia and most other countries the whole point of a filing a medical negligence claim is to be awarded compensation, which is determined by the specifics of the case.

In simple terms, the medical negligence that has occurred as a result of medical malpractice, states as a result of misdiagnosis, a medical accident, or a preventable issue. While some of these issues may not be life-threatening, or life-altering, some medical negligence can cause lasting and serious damage to the individual.

While one may be on-board with filing a claim, the idea of going to trial isn't exactly appealing to the majority of people. The good news is that in the majority of these cases they don't end up going to trial. They are usually settled before a trial would take place, which alleviates some of the stress and worry that the injured person is going through. Settlement can be through direct claim to the practicing doctor, service provider, insurance company if there is one.

Compulsory malpractice insurance for all doctors, private practices and for public entities (primary care units and hospitals) is in place in Slovenia since 1999. All practicing doctors have liability insurance and insurance policy since late 2000. There is no firm data on the number of claims per year and paid settlements as there is also no statistical data on court cases and pecuniary damages awarded. There have been some cases in the long period of over 20 years or so when the damage awarded has been of a few hundreds of thousands of Euro. The highest one was 700.000 €.

At present in the Slovenia, compensation for medical injuries can be sought through tort litigation, with payouts made through out-of-court settlements or through the courts. Guilt of the provider/doctor must me proved in order to be successful in claiming pecuniary damages.

NFC schemes provide an alternative, and perhaps more egalitarian method to redress claims resulting from medical injury.

To minimize the number of damage claims and compensations awarded PS mechanisms are a framework of organized activities that creates cultures, processes, procedures, behaviours, technologies and environments in health care that consistently and sustainably lower risks, reduce the occurrence of avoidable harm, make error less likely and reduce impact of harm when it does occur. The practice of PS involves coordinated action to prevent harm to patients, caused by the processes of health care themselves. PS is a strategic priority for modern health

care and is central to countries' efforts in working towards universal health coverage. As a theme of scholarship and research, PS draws on the concepts and methods of many disciplines, including health services research, applied psychology, behavioural science, ergonomics, communication science, accident theory and systems research.

1.2. Short description of the project

The MoH is currently carrying out a project, funded by the EU through DG REFORM, whose main objective is to support the Slovenian MoH in capacity building to develop a National strategy on QoC, CRM, and PS, and a legal framework for a NFC model. One of the outcomes of the project that should, over the longer term, contribute towards improving the QoC and PS in Slovenia is development of a NFC scheme reduced criminal prosecution and civil litigation.

1.3. Aim

The aim of this document is to propose concrete model and options to introduce NFC system into Slovenian hHC system and in Slovenian jurisdiction. Positive experiences from other countries, especially Nordic countries with a long tradition of NFC.

1.4. Types of compensation models and their elements

1.4.1. Introduction

Slovenian current fault-based system for handling claims of alleged medical injury requires people pursuing damages to prove negligence in the courts or insurance settlements. The process is inefficient, long lasting with unpredictable results and stressful for all concerned. Cases can take years to be settled or decided upon. Expert hired witnesses, with different professional status, are called upon because the busiest specialists are reluctant to become involved in what can be a time-consuming and intimidating exercise. And these aren't the only weaknesses in the existing system. Someone who has clearly suffered a medical injury may be unable to identify the individual or entity legally responsible, or be unable to prove negligence in court.

What's more, the final outcome may be unsatisfactory even if a claimant succeeds. Lump sum damages (the usual form settlement) may not cover the long-term costs of care and other expenses because of inaccurate actuarial predictions, poor investment, mismanagement or misuse.

While it's sometimes argued that the threat of negligence claims helps reduce errors in healthcare and maintain high standards of clinical care, there's no objective empirical evidence for this.

Indeed, other researchers have pointed out that since errors are not intentionall, it is unlikely that the threat of negligence claims act as deterrent. But there's clear evidence that the threat of a law suit increases medical costs by promoting defensive medicine and overtreating, leading to higher HC costs without a certainty it is beneficial for the patient. There is a clear evidence the threat of legal action discourages doctors from reporting avoidable adverse events.

The system persues criminalization of human errors instead of implementing a just culture and there is no specific law on NFC but a draft proposal was created a couple of years ago. So consideration of an NFC system in Slovenia is not a novel. It has been firstly discussed about two decades ago but not accepted at that time by decision makers.

However, there is some evidence analysing the individual and contextual factors contributing to the process of engaging with compensation schemes, an identification of the circumstances that could support uptake or an understanding of the pathway from contextual mechanisms to

different types of models. In that context and beside all other factors, there are at least two questions raised:

1. What individual or contextual factors advocate and motivate one for engaging in no-fault type compensation schemes after medical injury?
2. How are NFC schemes thought to improve outcomes for people with medical injuries?

1.4.2. Tort Law based compensation

In general, there are two basic compensation models in health care in place with some variants. Proof of guilt - tort - contractual breached based and fo-fault based.

Obligation law approaches the treatment of the doctor-patient relationship with two aspects namely contractual (business) tort law, and non-business tort law.
Business indemnification liability as liability for damage results as an infringement for contractual obligations. In the case of non-business liability, the subjects of the relationship were not in a business relationship with each other before the damage occurred.

In Slovenia, obligational legal relationship between a provider of HC services and patients are treated through the institute of contractual compensation liability and no longer through the institute of tortious liability for damages, as was the case once. The relationship between the HC professional and the patient is generally of a contractual nature regardless of whether the servise was provided through public or private entity. In the case of an office based physician, the doctor is directly responsible to the patient, while in the case of a primary care unit or hospital the contract is concluded between patient and the institution, which makes it liable under the rules of liability for workers, and rules of responsibility for one's own conduct. The relationship between the patient and the HC professional is an obligation relationship that creates rights and obligations/responsibilities. It is the patient's responsibility for payment for health services and the obligation of the HC professional to render health services. In doing so, it is important that the HC professional contractually commits they will take all due care to trat the patient, but this obligation does not guarantee the success of the treatment. Some systems may look at it as a mandate contract which meand the provider/doctor would guarantee to do all efforts but not guarante the result. Liability for a breach of contract is based on a breach of contractual due diligence.

To define provider/doctors act as a civil tort, it must be unlawful. Unlawfullness is excluded or an act as of general rule “volenti non fit iniuria” does not mean inadmissible interference with intervention to integrity of the person when the affected person consents to it. Therefore it is considered that a medical procedure performed lege artis, with the consent of the patient, cannot be the basis for claiming damages, although desired and expected result was not achieved and the patient's health may have worsened.
According to the legal construction shown, there is therefore a basis for a claim for damages:

- When the deterioration of health is the result of the doctor's or other healthcare worker incorrect or unprofessional conduct;
- When the doctor's conduct was professionally sound, but he did not have a patient consent for it.

Both in domestic and in comparative law including case law it is percieved an increasing shifts in the direction of recognizing compensation for cases where the patient has not given informed consent or the doctor did not perform their explanatory duty with all due diligence. Namely, it has been believed that the fundamental duty of law is to protect the patient's right to choose. The law must ensure that the doctor meets all aspects of informed consent and explanatory

duty to the patient. When he fails to fulfill this duty or this duty has not been appropriatelly met and the risk of not informing the patient (but should) causes to patient they suffer damage, the doctor is responsible for it. It is informed consent itself, unpropriatelly done, a cause for the doctor to be responsible for the results of the treatment automatically. It is a question of patients choice if they would know the risks they would still undergo a procedure.

The conditions for the successful assertion of damage arising from contractual liability are:

- Legally recognized damage: it is reflected in the deterioration of the patient's health status due to an inadmissible interference that is inadmissible either because of patient disapproval either due to violation of the rules of the profession;
- Breach of contractual obligation: reflected in breach of due diligence;
- Causal link between breach of contract and damage: HC professional.

The health care institution is only liable for the damage it has or should have expected to cause as a possible consequence of a breach of contract (the principle of predictability).

An overview of the assumptions that must be met for both types of liability, the issue of infringement appears to be emphasized as decisive in both cases, due diligence or conduct contra legem artis. In this regard, both responsibilities merge and intertwine in some way. Therefore the literature on medical liability deals primarily with the notion of healthcare error or error in treatment, regardless of whether the individual system recognizes a contractual or tort basis.

When the patient is taken to court in a civil lawsuit, there are various types of compensation patient can recover. The idea behind the civil suit is to help patient become the person one was before the adverse event (accident or incident) happened. Of course, this is not always possible if the injuries were life threatening or debilitating, but the compensation is meant to make up for any wrongdoing that occurred and the suffering that patient have experienced. That being said, here are some of the most common types of compensation patient may receive:

- Cover costs – If patient had to undergo extensive medical procedures, physical therapy, or counseling as a result of the avoidable adverse event, patient can sue for the costs of these services that were a direct result of the adverse event. These costs are easy to prove since patient/hospital will give them. The future costs may also be a part of the compensation, but those are sometimes not as easy to predict;
- Compensation for suffering – Suffering constitutes many different aspects of what patient went through as a result of the avoidable adverse event. There could be standard pain and suffering for which there can be different calculations to determine what that is worth, but there is also emotional trauma that patient may have experienced. That may also include costs for treatment as is the case with Post Traumatic Stress Disorder;
- Cover lost wages – If the patient has been unable to work at the job patient held leading up to the accident, patient may be able to recover their lost wages. Again, this is easy to prove as employer can contest to the dates patient has missed from work and the amount of money they would have made by working on those missed days. Lost wages can cover a temporary time period or the rest of their life, should they be rendered unable to ever return to work again.

1.4.3. No-fault based compensation

NFC system was perceived back in 1990s a**s a big novelty** in terms of comparing to classical legal standards of civil law used for compensations.

NFC is comparably **quite different set of rules for justifying a material and procedural rules** of the, or rather different ones the types of innocent compensation schemes the authors like to explain on the basis of pictorial concrete case. This is the case of two patients who both underwent surgery in hospital remained paraplegic. In one of two cases, the patient succeeds in compensation to prove to the court that the damage was caused by the doctor's negligent conduct, therefore he is awarded (relatively high) compensation, but in the second case the patient is not, he manages to prove it and remains without compensation, as it was an accident or a complication in treatment. The question that arises at this point is whether it is right or fair for one to get (much) compensation, others nothing. Or maybe it wouldn't be more right and fairer to do so in such cases, compensation was paid to all patients undergoing the procedure treatment suffered this kind of (severe) damage, regardless of the circumstance or was the doctor careless or not.

The **components entailed in NFC system** for healthcare injuries **vary** across high-income countries. The main differences focus on the definition of eligibility criteria to determine fault and how schemes are funded and organised. There are different approaches to compensating people who have experienced a healthcare injury, namely: As for eligibility criteria for compensation, avoidability standard in Nordic countries is that: injuries could have been avoided if the care provided had been of optimal quality and Unavoidable injuries: (in Denmark) - rare and severe consequences of treatment that exceeds what a patient should "reasonably be expected to endure".

To make compensation schemes **attractive** to claimants, they must offer payments comparable to damages awarded through litigation and include broader eligibility criteria, to ensure that schemes remain more appealing than the tort-based system. The schemes differ in the extent to which claimants can access the court system. In Scandinavia and New Zealand, claimants may appeal the decision of ineligibility made by claim assessors and, if unsuccessful at this first appeal stage, can take their case to the courts.

The access to courts is available if appealing a decision of NFC. Nordic schemes are funded by patient insurance through public and private health care providers. The Nordic countries operate an "avoidability" standard, compensating patients who have experienced injuries that could have been avoided under optimum conditions, for example, where the injury would not have occurred under the care of the best health practitioner system. Here it is referred to as the "experienced specialist" rule. New Zealand has put in place the broadest eligibility criteria, with a no-fault standard applicable to any unexpected treatment injury. The only scheme to operate without a financial cap is in France and all but the New Zealand schemes aim to cover both economic and non-economic costs.

Mechanisms to improve access to justice:

- Compensation scheme need to remain more attractive and appealing then the tort-based system by: offering broader eligibility criteria than would be accepted in the tort system; capping the amount of damages that could be awardedin a court case;
- Unlike the tort system, which favours those who can afford legal representation, compensation schemes can improve access to justice by ensuring they are: free to access; accessible to all eligible parties;
- Compensation system that has transparent processes can achieve justice through: representation of the claimant; improving the consistency of decision making via the use of medical experts;

- Compensation schemes can be more efficient and ensure improved access to justice by creating a firm wall between compensation procedures and disciplinary procedures, as doctors are more ready to hand over the relevant information.

Access to courts

Kachalia et al. (2008) provide an overview of the criteria for compensability of medical injury in three countries (Denmark, Sweden, New Zealand), in order to compare them to the tort system in the US. They discuss the avoidability criterion in Scandinavia as an example of the administrative schemes broadening out the eligibility criteria. The avoidability standard has a lower threshold than the negligence standard, commonly used by the tort system, so a greater number of claims can be made in the administrative scheme than would be accepted in court. It introduces the idea of judging provision against the best possible care available at the time of the incident, in terms of specialist physicians, treatment and drug choice. In Denmark, they adjudicate more strictly than in Sweden, but to balance this, have added an endurability criterion which is compensation for catastrophic injuries. These injuries result in disabilities of such severity that exceed a level which patients could be reasonably expected to endure, whether the injury is avoidable or not. This is more widely applied than the one allowed in Sweden for hospitalacquired infections (Kachalia et al. 2008). New Zealand has the broadest eligibility criteria, with compensation claimable for any injury caused by medical treatment (since 2005) and is perhaps the truest 'no-fault' system. It is limited by the requirement that the injury is caused by active treatment, so it does not cover injury caused by omission, such as late diagnosis. It also covers loss of wages and is only open to those of employable age.

Capping damages

In compensation processes, damages can cover both economic losses and non-economic costs, usually referred to as 'pain and suffering'. New Zealand limits payments to economic costs, most importantly lost wages as a result of the injury. It does not pay non-economic damages, but schemes in other countries do make a one-off payment for this. Majority of NFC schemes operate a financial cap, Sweden app 22.000 €, Denmark app 30.000 € and New Zealand app 12.000 €.

Equality to access

All the 'no-fault' schemes are free to eligible parties. In Scandinavia, claimants can access the system without physician support, but in New Zealand, a doctor makes the claim on behalf of the claimant. In New Zealand. Roughly 1 in 30 potentially compensable claims were made, but of those claims made, 60% succeeded. The final characteristic of interest to claim was the type of injury. In New Zealand, those with temporary disability, or families of those that had died, did not tend to claim. Bismark et al. (2006) concluded that patients and their families did not see enough economic advantage in doing so. In their conclusion, Bismark et al. (2006b) commented that these patterns of claiming were common across all schemes, whether in New Zealand or Nordic countries.

Transparency process

Transparency of process achieves justice through the representation of the claimant, and mechanisms that improve the consistency of decision making through the use of medical experts and the consideration of precedents. Considering the two types of schemes under comparison, the mainly administrative schemes from Scandinavia and New Zealand, and those with a greater influence from the tort system, it is apparent that they rely on different mechanisms to achieve trustworthiness. The administrative schemes place greater emphasis on medical expertise and referral to previous decisions to ensure consistency of decisions

(Kachalia et al. 2008), whilst the tort-influenced systems allow more opportunities for medical and legal representation (Barbot et al. 2014; Siegal et al. 2008).

Representation

Representation by lawyers may increase trust in the system by clarifying the medical issues for the client and acting as an ally against the state and the medical establishment. Many times claimants were more likely to consult lawyers if offered a generous compensation payment. This might reflect distrust in the medical establishment and a desire to understand whether the offer was fair. Lawyers in these circumstances may prove helpful in facilitating an early settlement if they can confirm that the offer was reasonable. It can be found significant problems with the involvement of legal representation as for example more adversarial legal process slow down the system of decision making and soure relations between the claimant and the compensation authorities. This makes cases more difficult to deliver in a timely and acceptable way. Another issue are inconsistencies in decision making by political appointees, due to their lack of medical or legal training.

Compensation decoupled from disciplinary procedures

Creating a clear distinction between compensation procedures and disciplinary procedures enables improved access to justice and a more efficient compensation scheme, since physicians are more ready to hand over the relevant information. The compensation schemes in Nordic countries and New Zealand operate parallel systems of compensation and disciplinary procedures where the compensation system does not report to the authorities on individual doctors for disciplinary reasons.

Clinical practice

There may be significant differences in mechanisms under which tort reform and NFC schemes are thought to lead to improvement in clinical practice outcomes.

- **Defensive medicine:** NFC system may reduce unnecessary tests and procedures and improve access to health care for patients considered riskier by clinicians because doctors are less likely to practise positive and/or negative defensive medicine to protect themselves from litigation. The effect of malpractice pressure on physician behaviour is referred to as defensive medicine. This arises as doctors attempt to protect themselves against potential litigation by over-cautious ordering of tests and conservative treatment, i.e. positive defensive medicine, or by restricting or denying care or treatment to patients considered as riskier by clinicians, either because of the seriousness of their illness or because of socio-economic determinants, i.e. negative defensive medicine. The costs of defensive medicine to the health system far outweigh the damages awarded in malpractice litigation, given the extent of under-claiming for medical injury, so it has always been a topic of great interest to international policy makers. Researchers have also examined defensive medicine's effect on the practices of doctors, access to care and outcomes.
- **Patient safety:** PS can be improved as a result of the introduction of NFC system. The two key outcomes identified in the past focus on how different mechanisms can support clinicians to more readily admit to errors and the extent to which mechanisms can be put in place to enable learning from those errors. Admitting to error: NFC system can significantly improve PS by enabling physicians to disclose iatrogenic injury through the removal of personal liability, applying the avoidability criterion and decoupling compensation from disciplinary procedures. The NFC system stand in contrast to the tort system, where it is suggested that the dominant paradigm is more likely to be one

of health professionals' silence, where claims of negligence against individual physicians can create strong feelings of guilt, a loss of self-confidence and damage to reputation. This can lead many clinicians to be reticent about sharing information about adverse events with patients, colleagues or the responsible authorities in health establishments. By removing individual liability, it is argued, NFC systems enable greater disclosure and increase the possibility of learning from medical error. Many advocate a move from negligence to an avoidability standard in order to reduce the psychological pressures of disclosure for doctors, where the notion of substandard care is replaced with one of suboptimal care. This change in standard accepts the possibility that avoidable injuries can happen despite the excellence of the physicians and the high quality of the care offered at hospitals. In Nordic countries and the New Zealand, the compensation schemes are decoupled from disciplinary procedures. This enables doctors to disclose errors without damaging their reputations and their future careers. In the 2005 New Zealand reforms, the ACC was no longer required to report individual clinicians to professional disciplinary boards to establish medical error, as the eligibility criteria was changed to include all treatment injury. Before the reforms, it was found that compensation procedures were delayed, as doctors defended themselves by withholding information as they challenged claims made against them.

- **Learning from error:** NFC systems can improve PS by enabling the pooling and sharing of information about medical errors and by reframing the compensation process as a PS strategy rather than a risk management (RM) strategy. The emphasis on establishing negligence under the tort-based system can lead to malpractice cases being seen as a random event not associated with quality, and therefore the litigation process misses the opportunity to support health care providers to understand the causes of avoidable injury and try to prevent recurrences. Administrative compensation schemes seek to reduce the pressure of tort liability which encourages a wall of silence about adverse outcomes, in order to increase the possibilities for learning from error. No-fault schemes enable learning from error through the centralised compiling of error information as part of the claims process, and making this information available to interested parties, such as research and PS experts. In the tort system, information on medical error is often buried in a disparate and fragmented set of proprietary databases maintained somewhere in the system, which may not be accessible for research and quality improvement purposes. The adversarial nature of litigation procedures can also lead to a bias towards only collecting information on the process of care in relation to its relevance for proving cases of negligence rather than identifying failure in the health care system.

Health outcomes

The negative impact of litigation on health can often arise because claimants are encouraged to maintain their injured status in order to claim compensation, i.e. secondary gain, and they are exposed to the stress of medical examination, delays in decision making and the adversarialism inherent in the litigation process, i.e., secondary victimisation.

With the NFC system and changes in tort system it may improve the **physical health** of patients by shortening the length of time to claim closure including a rehabilitative element to the claim award. It can also improve the **mental health** of patients by shortening the length of time to claim closure and removing the adversarial element of the tort system.

Health and well-being of medical professionals

There are no firm and clear data on studies to prove of better health and well-being of health professional when changing from tort to NFC system. Anyhow these processes, often influenced by litigation practices, may cause feelings of anger, shame and misery for the

doctors and nurses. They may experience a loss of confidence in their abilities and some doctors may claim greater use of defensive medicine as a result. There is a consensus among researchers that no-fault schemes will benefit the health and well-being of doctors and nurses, or not damage their health, at least. Tort reforms may directly benefit doctors economically in the countries with compulsory insurance for doctors malpractice. Insurance premiums for doctors may be lowered. The extent of the benefit to well-being may be tempered by the high expectations of themselves that doctors and nurses hold, so that criticism and fault finding may be particularly costly to them, psychologically, whether liability is established or not.

1.4.4. Situation in Slovenia

Currently a general compensation scheme for no-fault preventable adverse events does not exist is Slovenian legislation. There is only a NFC scheme available for damages caused by an obligatory vaccination - CDA (Communicable Diseases Act).

- In 1999 The Law on Medical Services enforces mandatory insurance for medical malpractice for all practicing medical doctors;
- No link to be found in the law between insurance, QoC, data collection of adverse events, feedback to the MoH, insurers and health services providers;
- Compensation normaly based on proven guilt of malpractice with the burden of proof on plaintiffs themselves; only a vey few cases may not need a proof of guilt if claim is addressed to insurances (minor cases);
- Fault system of liability for damages is based on culpable liability;
- Civil Code entitlement to compensation for damages;
- Assumptions for liability for damages, which must be expressed cumulatively, are:
    - Unlawfulness, which can be expressed as unlawful conduct or the unlawfulness of the consequences of certain actions,
    - Causal link,
    - Damages and in the case of culpable liability also fault or culpability;
- Employee may be peronally liable for damages unless they prove they acted as was necessary under given circumstances. If employer pays compensation they can claim reimbursement from employee;
- If a medical procedure performed “lege artis” and injury occurs, no compensation claims are awrded;
- The basis for the claim for damages therefore exists:
    - When the deterioration of health is the result of the health professiona's incorrect or unprofessional conduct;
    - When the doctor's conduct was professionally impeccable, but he/she did not have the patient's consent for it.

Current fault based system doesn’t satisfy anyone. Regulation of liability in HC, which the injured party asserts in the context of civil (court) proceedings, has a number of shortcomings that are becoming increasingly apparent with the increase in the number of lawsuits filed against HC providers and sometimes even against HC professionals at the same time. The trend of increasing litigation has been observed in recent years, which is why the reform of the regulation of liability in HC is (urgently) necessary in our country as well.

Fault based compensation in Slovenia brings high costs and length of the procedure, difficulty of proving guilt and liability and consequences in causing defensive medicine. Criminalization of human errors does not improve PS incident reporting and stimulates PS improvements.

Negative consequences of excessive penalization of human errors are covering up their own errors for fear of severe penalties, which means that errors are not analysed, which makes it impossible to learn from them; HC professionals are numb, anxious, alienated, depressed, confused, have sleeping disorders and workplace dissatisfaction. In the society of accusation they feel ashamed, guilty and full of doubts about their own abilities. Simple human mistakes

that are not the result of rec kless or negligent conduct are too often taken as a sufficient ground for conviction. It does not contribute to trust between the patient and the doctor.

1.4.5. Conclusions and implications

The number and value of litigious claims for medical injury compensation lodged against the providers and/or insurances has been rising substantially in recent few decades and years. Maternity services comprise one of the areas of highest clinical negligence claims in terms of both number of claims and costs. This may be due in part to the fact that injuries resulting from birth trauma can impact significantly on the morbidity of newborn infants.

Review of pros and cons of tort vs NFC system suggests that NFC systems can confer benefits on key stakeholders: namely patients, health professionals and health system as a whole. Possible benefits range from improved targeting of compensation to those most deserving of it, to speedier physical recovery after injury. However, the complexity of the interactions between compensation processes, individual circumstances and the health systems in which the schemes are embedded make it difficult to establish strong causal pathways, most notably regarding health outcomes. The shape of the future Slovenian schemes may be highly influenced by the health system context which, in turn, is affected by the prevailing political opinion about the role of the state in health care.

2. NO-FAULT COMPENSATION MODEL

2.1. Motives for introducing NFC

Since there is a fault based insurance in place the complainants aim, in most cases, to prove a doctors/provider guilt in order to get the legal basis for civil procedure and to be compensated for their damage. Chambers, especially the medical chamber are under heavy pressure from patients and public to play a “role of a judge” for civil lawsuits and also criminal cases. Namely medical chamber is one of the bodies processing patients complaints against doctors which may in case of malpractice result in disciplinary procedure against the doctor.

Chambers have developed their rules i.e. bylaws on the basis of legal provisions in order to process complaints for alleged misconduct and/or breach of ethical rules of profession, against HC professionals.

The number of damage claims in HC is increasing over time, which is consequently causing a more frequent practice of defensive medicine and in most cases a more negative relationship between doctors or other HC professionals and patients.

The classical system of fault based compensation is unfavourable for parties to the dispute. Procedure render proving fault and causal relationship may be more difficult, while judicial proceedings are lengthy and litigation costs are generally high.

As long as healthcare continues to foster a "blame and shame culture", underpinned by fear of litigation and by doctors themselves, errors will keep on happening. Both doctors and patients have colluded to create an impossible expectation of perfection, which makes it impossible to admit errors, let alone learn from them and prevent them from happening again.

Competent authorities for processing complaints struggle to get adequate health professionals to process complaints. The whole procedure is usually lengthy, complaint processing is not based on contradictory principles (adversarity) and many complainants think they are biased. There is no firm statistical data available on the type and quantity of complaints as well as results of procedures. Some data show the number of complaints is steadily rising.

2.2. Methodology

In this project analysis of the current compensation model for sentinel and other adverse events has been conducted, a few other national models has been looked at. Models of NFC has been studied particularly from Sweden, Denmark and New Zealand. A non-exhaustive desktop literature review on those systems has been made in order to find the characteristics of those systems by main elements of their system.

Methodology for conducting comparative analysis included desk research and non-exhaustive literature review, review of the information and critical reading, identification of the main stakeholders to interview, conduction of the interviews, analysis of the results of the interviews and elaboration of the report on the comparative analysis.

Systems in countries with the long lasting and great development in the field of the NFC were scrutinised and looked into their whole spectrum of processes and mechanisms of NFC.

Details of findings for each county are described in appendix A.

2.3. Key findings of comparative analisys – short overview

As said three countries have been looked at to see their NFC systems. **Swedish, Danish, New Zealands**.

Key findings:

- In all thtee countries health care spenditure is higher then Slovenian, for app 20 – 25 % GDP measurement and in real terms this also means app 50 – 100 % more € per capita for health; universal coverage and public financing; all have Beveridge HC model; still comperable to Slovenia;
- NFC in place for decades for compensation of injured patients;
- National or other public bodies deal with NFC cases; common public body for all personal injuries beside health related in New Zealand (ACC);
- No proof of negligence or fault needed for compensation to be awarded;
- NFC publicly funded (Sweeden, Denmark), combination of publicly and privatelly (New Zealand);
- Disciplinary measures and criminal liability procedures are detached from NFC system, but particularly serious cases may be submited to the public prosecutor (Denmark, New Zealand);
- Compulsory reporting on incidents to competent body for improving QoC & PS;
- Damages/injuries covered by the NFC when there is pain and suffering, permanent injury, additional medical and other expences, a loss of ability to work, lost earnings, at:
    - Examination, care, treatment or similar measure provided that the injury could have been avoided either by a different performance of the chosen procedure or by the choice of another available procedure which, from a medical point of view, would have met the need for care in a less risky manner;
    - Defects in medical devices used in examination, care, treatment and improper handling thereof;
    - Incorrect diagnosis;
    - Transmission of infectious agents that have led to infection in connection with examination, care, treatment or similar action;
    - Accidents in connection with examination, care, treatment or similar measures or during the procedure;
    - Dispensing of medicinal products in contravention of regulations or instructions;
    - In some other cases;
- Damages/injuries that are not covered by the NFC:
    - If to long time has passed from the time patient received treatment;
    - If the damage is the result of proper treatment that was vital;
    - Injuries caused by medicines do not provide the grounds for compensation if the medicine is prescribed or delivered correctly;
    - If the patient was injured while being treated for a traffic accident, they need to contact the traffic insurance company in the first place. The same applies if the patient is being cared for due to an occupational injury;
    - Damage that are a consequence of the patient´s basic disease;
    - If the injury is a necessary part of the treatment;
    - In case of some minor damages of up to a certain sum;
    - In some other cases.
- In order for an injury to be compensated, it must have been avoidable. All medical and dental care treatment involves risks of complications that are unavoidable. No compensation is paid for such complications;

- The principal difference among the countries has to do with the initiation process: in Sweden, it is the patient who must initiate the process; in Denmark, both patient and professional can either start it; and in New Zealand, the provider must fill in the form claimed and signed by the patient;
- Compensation processes vary in each individual jurisdiction, but all of them consist of basic steps namely: filling of the claim, investigation, decision on claim, refunding and in case the patient is not satisfied with a decision all systems include possibility for injured patient to file an appeal;
- Reporting system is confidential and non-punitive;

In all countries competent authorities monitor, supervise, evaluate and initiate prevention mechanisms to ensure the effectiveness of the NFC model. The procedures are country-specific, such as: registers and databases, reports or prevention programmes.

2.4. Definitions

2.4.1. Errors in healthcare, adverse event, near miss and informed consent

Errors in healthcare represent an important public health problem and pose a serious threat to PS. The growing awareness of the frequency, causes and consequences of error in medicine reinforces an imperative to improve our understanding of the problem and to devise workable solutions and prevention strategies. Errors can occur anywhere in the health care system. In primary care units, hospitals, clinics, surgery centers, nursing homes, pharmacies, and patients' homes and can have serious consequences. Errors can involve medicines, surgery, diagnosis, equipment, or lab reports.

The concept of error typically regards an action, not its outcome, and its meaning becomes clear when separated into different categories, error, diagnostic error etc. One wrong action may or may not lead to an adverse event either because the abovementioned action did not cause any serious damage to patients' health condition or because it was promptly detected and corrected. The concept of error refers to the adverse outcome of an action. The responsibility for the emergence of errors in HC systems is shared among the nature of the HC system that is governed by organizational and functional complexity, the multifaceted and uncertain nature of medical science, and the imperfections of human nature. Errors should be examined as errors of the HC system, in order to identify their root causes and develop preventive measures.

The accepted generic definition of an error is a failure of planned action. When an error occurs, an agent of omission or commission can reach a patient and can cause harm or does not hurt a patient. An adverse event can be due to error, some violation of healthcare practice (preventable adverse events) or complication of patient disease or healthcare procedure that can not be prevented regarding the current knowledge.
Prevenatble adverse events can result in measurable disability, prolongued hospitalisation or both. It may be unintended injury or complication that results in disability, death or prolongued hospital stay and is caused by health care provider raher than the patients disease. Although adverse events typically result from healthcare intervention, not all adverse patient outcomes are the result of error. Reflecting this fact, many investigators suggest that only preventable adverse events be attributed to healthcare error. Talking of PS adverse event is considered to be preventable when there is a failure to follow accepted practice (current level of expected performance for the average practitioner or system that manages the case) at an individual or system level.Negligent adverse events represent a subset of preventable adverse events that satisfy the legal criteria used in determining negligence.

Negligent adverse event results in injury caused by substandard medical management. Adverse patient outcomes represent a limited subset of healthcare errors but are nevertheless epidemiologic significance. The vast majority of errors do not result in injury to patients because the error was identified in time and mitigated; because the patient was resilient or because of simple good luck.

Outcome-dependant definitions of healthcare error can provide valuable insight into the costs, morbidity and magnitude of harm resulting from such events. Nonetheless, quality improvement initiatives require understanding of the processes that lead to such errors. Building a safer health care system will depend on success at designing processes of care that ensure patients are protected from the threat of injury. Therefore, a definition of healthcare error should capture process or system failures (latent failures) that cause errors, irrespective of outcome (a process-dependant approach).

On the other side process-dependant definitions of healthcare error should capture the full spectrum of errors, namely, errors that result in adverse patient outcomes as well as those that expose patients to risk but do not result in injury or harm.
Errors that do not result in injury are often referred to as near misses, close calls, potential adverse events or warning events. Near miss would then be any event that could have had an adverse patient consequence but did not, and was indistinguishable from a full-fledged adverse event in all but outcome.

The bottom line of definition of healthcare error it can be stated as an act of omission or commission in planning or execution that contributes or could contribute to an unintended result. This definition of healthcare error includes explicitly the key domains of error causation (omission and commission, planning and execution), and captures faulty processes that can and do lead to errors, whether adverse outcomes occur or not.

In addition to a healthcare error non-fulfillment of the explanatory duty (to obtain informed consent) that the HC professional has towards the patient, it is also considered a breach of professional duty. In doing so the duty to explain is defined as the duty of the physician to provide to the patient information in an understandable way that is relevant to the decision on treatment, which means that the HC professional must draw the patient's attention to inconveniences or complications that may occur due to the treatment. Failure to comply with the explanatory note duty (informed consent) may be legally relevant for damage claim if the patient would decide notmto undergo medical procedure if they would know the extent of risks involved.

2.4.2. Legally acknowledged damage

Damages are monetary compensation that is awarded by the competent body. In order to justify a damage claim the damage must be legally recognised according to the legal standards in place. Medical malpractice damages can include damage for physical and mental pain and suffering, loss of future earning capacity, other material damage and a loss of enjoyment of life. In most health care cases claims constitute of compensatory but not punitive damages in addition.

2.4.3. Medical malpractice

Medical malpractice has been defined in professional literature as "any act or omission by a physician during treatment of a patient that deviates from accepted norms of practice in the medical community and causes an injury to the patient.

2.4.4. Compensable injury – personal injury

A personal injury is a physical injury where bodily damage has been suffered. For example, an injury such as a fracture may be accompanied by the symptoms of pain and aching. However, lodging a claim based solely in symptoms (such as pain or arching) without an identifiable injury will not be accepted.

2.5. Points of consideration when choosing each individual solution to the Slovenian model

There are several issues that need to be highlited as additional points for consideration:

- **Choice of model:** there are common elements to no-fault schemes that have been established in various countries/jurisdictions, however, the inclusion of certain elements reflect particular historical, socio-cultural, institutional and legal trajectories that may not easily be transfered into the modelling of Slovenian national setting. The existence of a well-funded and comprehensive national social security system, as well as a predominantly publicly-funded health system, also appear to be important complementary elements which contribute to the success of no-fault scheme.
- **Equality of coverage**: two issues are important on this point: (1) there may be disparity between those who have the same injury: one which is caused through illness and the other through injury which is covered by a no-fault scheme. This may result in very different compensation and care trajectories, as well as anomalies in cover; (2) coverage under a NFC scheme may be limited to particular categories of medical injury, as opposed to providing coverage for personal injury caused through accidents more generally (car accidents, work-based accidents etc.,). While it has been suggested that it is inevitable that policy choices are made about the extent of coverage under NFC, issues of justice and fairness as between citizens may require further consideration and/or justification of such choices.
- **Costs and affordability**: it is generally accepted that administration costs associated with no-fault schemes are much lower than the legal and other costs of clinical negligence claims brought under delict/tort-based systems. Affordability of NFC must be attended and constantly monitored and adjusted. If not, this may in turn adversely affect the provision of adequate compensation to injured patients.
- **Professional accountability**: how to best facilitate professional accountability in the context of NFC schemes is a recurring issue in discussion. Professional accountability is being an important objective for injured patients who have pursued a variety of legal and other actions (including resort to the criminal law). Setting up a NFC scheme the issue of professional accountability may be entirely separate from the NFC scheme. Focus should facilitate good relations with the medical profession, as well as enhance quality and safety in health care. But the question remains, however, as to how health practitioners should be incentivised to engage in safe practice with patients and whether, and if so what, role NFC scheme should have in this regard.
- **Healthcare error and PS:** is asserted that one of the advantages of no-fault schemes is that the removal of a fault-based approach offers the opportunity to collect valuable data on medical error, as well as to engage in both systems learning to facilitate error prevention and therefore enhance PS. Collecting, analysing and disseminating medical error data to relevant institution, as well as instituting incentives to encourage error prevention, are necessary elements to bringing about systems improvements in the quality and safety of health care.

2.6. Objectives and principles of the proposal

The proposal aims to establish NFC system in HC which seeks to replace the current regime of contractual (civil) liability. It is to be a new state-established compensation scheme from which payments will cover compensation in the event of damage caused to the injured patient while being treated in a health care unit. Establishment of a NFC system will not cut off other social security systems (health insurance, disability and pension insurance) and other forms of state reimbursement schemes (e.g. compensation for compulsory vaccination).

NFC scheme will provide an alternative route to financial compensation for harm allegedly caused through medical treatment. Although there is still a need to establish causation, an important feature of is that there is no need to prove negligence in order to be eligible for payment of financial compensation. This is in addition to the need on the part of injured patients to meet particular eligibility criteria.

2.7. NFC attributes that need to be incorporated in Slovenian model

2.7.1. General elements of the proposed model

- A social/community response to personal injury which will include a recognition of community responsibility; comprehensive entitlement; full rehabilitation; fair and adequate compensation and administrative efficiency;
- Introduce NFC as a patient right if they have suffered harm as the result of medical treatment. The legal and social goals of the NFC scheme are to enhance the public good and reinforce the social contract underpinning slovenian society by providing for a fair and sustainable scheme for managing personal injury that has, as its overriding goals, minimising both the overall incidence of injury in the socieaty and the impact of injury on it. Public trust and patient satisfaction in the scheme should be high with te efficient and effective model;
- Easy and broad access by injured patients to compensation;
- An expanded eligibility criteria for cover that facilitates greater access to justice for patients who suffered medical injury than would be the case in relation to clinical negligence claims brought under delict/tort-based systems;
- Promotion of better, as well as less defensive relationships between patients and health practitioners when medical injury has occurred; An emphasis away from attaching blame to individual health practitioners with a view to promoting learning from medical error and enhancing PS;
- Greater efficiency in terms of both time and costs than would be the case in relation to the management of clinical negligence claims brought under delict/tort-based systems;
- Rehabilitation can proceed in a more timely fashion, without having to wait until legal action in the courts is resolved;
- NFC scheme is suggested to have public funding;
- Financial compensation need to be lower for comparative injuries in clinical negligence claims brought under tort based;
- Limitations on the extent to which cover is provided should be set: there need to be caps on certain categories of compensation and compensation for no-pecuniary losses such as pain and suffering;
- Simpler and easier access to justice; access to courts should stay in place, injured patients should firstly go through NFC settlement; if not satisfied, they can claim compensation or additional compensation in civil procedure at the courts;
- Initiating and submitting claims need to be free form any cost for the injured patient;

- NFC insurance and compensation itself need to stay detached from (other) national social insurances;
- So called patient insurance should be compulsory from the beginning;
- Including fostering of good relations between health practitioners and patients; the promotion of safety and quality in care through learning from medical error;

2.7.2. Specific elements of the proposed model

2.7.2.1. Legal basis

Proposal:

- **New legislation** to be produced and **adopted:**
  - Law on NFC in health care
  - Law on QoC and PS
    (technically both subjects may be covered in one law so it is up to political decision to go with that or not; usually both subjects are tackled separately in legislation)
- **Current legislation** to be **amended:**
  - Law on patients rights
  - Law on health care activities
  - Law on health care and health insurance
  - Law on pharmacist
  - Law on medical services
  - Other laws and sublegal acts regarding the topic and decisions made in the primary law.

Grounds, arguments and justification:

- NFC scheme is to be a novelty to Slovenian health system, therefore new legislation (and bylaws) has to be produced in order to have it in Slovenian jurisdiction as a well operated function in place. Health care is judicialy a very complex system and some existing laws and bylaws have to be amended.
- Putting all of that in place and have it operational will need a a lot of government and HC stakeholders efforts. It may be a process lasting for more than a year or two.

2.7.2.2. Administration of the NFC scheme

Proposal 1:

- Slovenian NFC scheme should be run and be operated by **independent public non-for-profit body** (i.e. **Agency** (government founded) or **even preferably Institute** (health care stakeholders and providers founded) or partly founded from both) as a legal entity organized and operated for a social benefit. Competent for all types of patient health related injuries including pharmaceutical.
- Due to contents of the activities, efficient use of the resources (medical, legal, economist and organisational staff) it should be idealy the same Institute (body) that operates QoC and PS management on a nation level. It should be tax exempted and/or tax deductable.
- As such it should be accountable to the founders, program recipients and the public community in general and completely independent from the government. The more nonprofits focus on their mission, the more public confidence they will have.

Grounds, arguments and justification:

Government as such operate on a systemic way meaning adopting policy pepers and programs, resolutions etc. They introducie legislation, control public entities in terms of whether they do or they do not follov legislation in their activities and producing results they have been founded for;

- Runing QoC, PS and NFC scheme are non political activities and therefore activate for operating exclusively staff being educated and experienced in the field of expertise they need.

System should ensure long-term affordability of the scheme, and the longevity and success of the scheme in the context of a well-funded and comprehensive national social security system.

Proposal 2:

- **Supervisory and operational structure of independent body** should be constituted from:
  - The Board, consisting of founders, patient organisations representatives
  - Chief executives should cover areas such as:
    - CEO - business administration
    - CMO – medical profession
    - CIO – informatics administration
  - Other structures according to the needs

Grounds, arguments and justification:

- Every businesses require structure to grow and fulfil their vision, business plan and give expected results. Planning the structure ensures there are enough human resources with the right skills to accomplish goals, and ensure that responsibilities are clearly defined. Each part of the structure should have job description that outlines duties, and each job occupies its own position on this non-for-profit entitys organization chart.

2.7.2.3. Funding

Proposal 1:

- Financial support: Compensations and operational costs may be ensured through an patient insurance scheme - PIS with one of contributors or a combination of more contributors:
  - Health insurance institute of Slovenia, out of health care services budget;
  - Health care providers (public and private (within the public network providers and outside it))
  - Preferably with combination of both (ei.e. 1/3 from providers and 2/3 from health insurance)
- The amount of costs in real terms should be determined by the government and should provide sufficient funds to run the operation of the NFC scheme.

Grounds, arguments and justification:

- General state budget may not be as feasible and good solution due to intransparency and no motivation for health care sector overall in efforts for QoC and PS.
- It is estimated that annual cost of the NFC scheme shall be between 5 to 10 million EUR and will slightly increase over time.

2.7.2.4. Eligibility, burden of proof

Proposal 1:

- **Avoidability rule**: the scheme should not require proof of fault or malpractice in order to compensate a claim against a health provider. The avoidability rule is used instead of negligence to determine which injuries are eligible for compensation. This alternative standard resides between negligence and strict liability. The scheme should compensate patients who have experienced injuries that could have been avoided under optimal circumstances, in that the injury would not have occurred in the hands of the best health practitioner or health system, known as the ‘experienced specialist’ rule. This higher

standard, setting the benchmark at excellent care as opposed to acceptable care should be introduced.

- **Experienced specialist rule:** There are a number of aspects to applying this rule. Consideration is given to the risks and benefits of treatment options other than the one adopted and the retrospectivity rule may be applied. A retrospective approach may be taken in some cases in evaluating whether the injury was avoidable. In such circumstances, it is necessary to consider whether previously unknown clinical information was potentially discoverable at the time of the treatment and therefore whether the injury could have been avoided.

Grounds, arguments and justification:

- The standard of care for medical providers should be ment as the level of care that a reasonably competent and skilled medical professional, who has a similar background to and practices in the same medical community, would have provided to a patient under the same set of circumstances.

Proposal 2:

- **Burden of proof:** Despite the fact that it is a NFC scheme, the injured patient must in order to justify the case and receive compensation, prove that the damage (injury) occurred in the course of treatment – burden the burden of proof of causation is on the injured patient. In this case, the preponderance of the evidence standard applies more than 50% of probability an injury is a result of an adverse event.
- **Avoidability rule and accidents:** ground for compensation claim is that injury could have been avoided by the health care provider or if the accident occured during the treatment.

2.7.3. Types of medical injury coverage

2.7.3.1. Treatment injury

Proposal 1:

Types of coverage that the NFC scheme should cover are:

- Treatment injury – avoidable injury; experienced specialist rule; will consider alternative and retrospective aspects of treatment provided.
- Diagnostic injury – avoidable injury; experienced specialist rule (no retrospective element).
- Material-related injury – unavoidable injury but there are special circumstances; injury due to a defect in, or improper use of, medical products or hospital equipment.
- Infection injury – unavoidable injury but there are special circumstances; infectious agent transmitted from an external source during the delivery of care, and the infection's severity and rarity outweigh the seriousness of the patient's underlying disease and the need for the treatment that caused the infection.
- Accident-related injury – unavoidable injury but there are special circumstances; injury from accident or fire that occurs on health care provider's premises where patient is receiving treatment.
- Unreasonable injury (the consequence must be unreasonable, disproportionate to the patient's illness/injury originally treated and overall health; patient has suffered a permanent severe illness, injury, or loss of life).

Grounds, arguments and justification:

Broader aspects of types of medical injuries covered are explained in other general chapters of this report.

Proposal 2:
Threshold disability criteria shall apply. What are described as “insignificant injuries” cannot be compensated under the scheme, even if they are otherwise eligible. An injury is considered to be insignificant if it causes only slight pain and suffering, no permanent functional disability, no aesthetic injury, or the costs incurred do not exceed 700 Euros.

2.7.3.2. Drug injuries inclusion

Proposal:

- Slovenian NFC scheme **should include injuries related to and caused by medication** (drug injuries). It is important to note that both drug-related injuries should be covered (that arising due to incorrect prescription of administration of incorrect medication and compensation for other drug-related injuries.
- Inclusion should be compulsory and pharmaceutical companies and drug dealers should contribute to the “insurance budget” according to their market share and type of used drugs on Slovenian market. In case of wrong prescription or giving drugs to the patient by error provider is responsibe not the pharma industry or drug dealers.
- The scheme should cover drug-related injuries caused by pharmaceuticals and vaccines that are marketed, regardless of whether the producer, importer, or any doctor has been negligent. Compensation should be paid regardless of which drug may have been the cause, as long as it can be established that the injury was caused by one (or more) drug(s).

Grounds, arguments and justification:

- Treating patients with drugs only or along with other treatment methods is inevitable part of most treatments.
- Reference NFC schemes have all included drug injuries into their schemes that way or another. Sweden and Finland formally operate voluntary schemes since pharmaceutical companies and importers which operate in these jurisdictions voluntarily pay contributions to enable the schemes to operate. In Denmark and Norway, the schemes are on a statutory footing. In Sweden, Denmark and Finland the no-fault schemes for medical injury were introduced prior to the one for drug injuries. In Norway, both schemes were introduced at the same time. National medical scheme was introduced before the drug scheme. The wording and operation of the drug injuries schemes in all four countries are not identical, but they are broadly similar.
- The schemes operating in Sweden, Finland and Norway are funded by contributions from the pharmaceutical industry in the form of a percentage levy set annually based on individual companies’ turnover of national sales. In contrast, the scheme in Denmark is funded by the state from general taxation. As between the four countries, there is variation regarding which body administers the drug injuries scheme. In Denmark, for example, the body that administers NFC scheme for medical injury also administers the drug injuries scheme, but this is not the case in the other three countries. The drug injuries schemes should be viewed as secondary, rather than primary sources, of compensation. Potential claimants are therefore encouraged to seek financial support and/or compensation for which they be eligible under national social security systems and no-fault schemes. As a result of this approach, awards of compensation made under these schemes are relatively modest. Broadly speaking, the schemes make top-up payments for pain and suffering and loss of amenity and cover any shortfall in the provision from other sources of loss of income. Broadly similar approaches are taken in practice as between the schemes with respect to determining causation and proof (although different terminology is used). Deadlines operate with respect to the filing of claims, and appeal mechanisms are in place.

2.7.3.3. Processing claims and entitlement

Proposal 1:
A claim must be filed within 2 years from the time that the patient became aware of the injury and within 7 years from the time the injury occurred. Compensation authority must process each claim within 6 months period at the latest, except in complicated cases where decision must be final within 9 months from filing completed claim.

Grounds, arguments and justification:
Subjective deadline of 2 years may seem sufficient to file a claim and a period of 7 years as an absolute deadline may be acknowledged as the right one to file a claim. Some jurisdictions have even shorter deadlines and some longer ones.

Proposal 2:
Handlers managing the claims should typically have medical and/or legal backgrounds depending on the case.

Proposal 3:
Entitlements to compensation under the scheme should be determined by reference to the personal injury compensation rules set out in the relevant legislation. An injured person is entitled to be compensated fully for their loss. Compensation payments therefore should consist of two general components – pecuniary and non-pecuniary damages. Pecuniary damages cover loss of income and medical expenses incurred due to the injury, but not covered by other insurance. Non-pecuniary damages should compensate for pain and suffering including fear, disability and disfigurement and inconvenience. Levels should be set according to schedules based on injury type, severity and duration.

Proposal 4:
Family members can initiate the claim in cases where the patient has died or is incapacitated. Claimants are not required to obtain the support of physicians before lodging a claim. Where a patient has died, the family may be entitled to funeral costs, loss of financial support, and psychological support.

Proposal 5:
A claimant should also be eligible for a lump sum payment due to permanent impairment. Once it is determined that any disability a claimant has suffered is now permanent, then a medical assessment takes place confirming the degree of disability. The disability compensation should then paid as a lump sum in line with according tables.

Proposal 6:
Compensation for the loss of ability to work is paid in accordance with the individual patient's employment situation. Compensation for loss of income and future loss of pension entitlements due to the medical injury are paid as annuities.

Proposal 7:
Once the claim has been examined, written decision should be issued. The decision should then be sent to the claimant, health specialist or treating institution.

Proposal 8:
Entitlements under the scheme should include the following:

- Medical treatment expenses

- Other necessary expenses caused by the injury
- Temporary incapacity
- Permanent functional incapacity
- Permanent cosmetic incapacity (permanent impairment to a person's appearance)
- Loss of income
- Certain family members and others who are particularly close to the injured person may be eligible to receive reasonable compensation for necessary expenses and loss of income as a result of taking care of the injured person during a period of recuperation.
- Loss of life (funeral expenses and other related costs; necessary maintenance may be granted to those entitled to this compensation (e.g. spouse and children under the age of 18 years and in some cases children under 21 who are students; may also be extended to cover non-married partners).

Proposal 9:
Both, pecuniary and non-pecuniary damage should be reimbursed in the form of a monetary compensation. Agency (Institute) should determine the pecuniary damage based on the costs incurred by the injured patient and based on the lost of earnings, and determine the amount of non-pecuniary damage in such a way that this reflects generaly recognised impairment in such cases, consdering also individual circumstances, but at the same time ensures equality among several injured patients in a similar case. Regarding the determination of the costs of persons supported by the deceased they supported them, they should be measured according to all the circumstances of each individual case. In any case, they may not be higher than the amount that the injured patient would have received if they had remain alive.

Proposal 10:
Injured patient should be obliged to file a claim and go through the NFC process as a first instance.
Decision is made by 3 people, in complicated cases by 5 people. In each case (at least) one should have medical and one legal expertise. Decision should be accepted unanimously. Each commission should consist of two permamnent members and one or more additional members.
If injured patient is not satisfied with a decision, they can appeal to an appeal commission where a decision is made by the commission constituted of 3 or 5 people in complicated cases. Each commission should consist of at least three permamnent members and the rest of additional members. Decision should be accepted by majority votes of the commission.
If they are not satisfied with a second stage decision, they may file a claim directly from the health care provider or go to civil court.
Head of the commission must be a judge by profession with extensive experience in dealing with civil law cases.
All members of the commissions shall be free from political influences or appointments. They should be perons not involved in government structures and with impeccable reputation.
Commission may ask to be consulted by independent consultants from different fields of expertise who can provide expertise from medica, judicial, economic, insurance, social, psychological and other fields of expertise and have impeccable reputation. They have to hold a status of court expers.

Proposal 11:
Permanent members of the commissions are appointed by the Agencys (Institute) Board, president of the commissions and his/her deputy are appointed from the list of at least 7, proposed by the president of Supreme court of Slovenia.

Proposal 12:
Internal organisation of the competent Agency or Institute shall be defined in bylaws with detailed provisions on the structure, rules of procedure for compensation processes and other necessary rules of conduct.

2.7.3.4. Compensation sums and limitations, payments:

Proposal for mental pain:

- Compensation for mental pain is determined in accordance with the principle of just compensation depending on the circumstances of the case, the degree and duration of the pain and the type of injuries;
- Compensation for damage when person is disfigured is not recognized if the value of the damage does not exceed 2,000 Euros;
- Spouse or partner in a registered partnership, or a partner who lived in extramarital union or a partner who lived in a civil partnership, or, in the case of a minor, his or her parent, in the event of the beneficiary's death, has the right to compensation for mental pain under this law in the amount of a maximum of 10,000 Euros;
- Children of the injured has in the case of their death the right to compensation for mental pain in the amount of a maximum of 20,000 euros;
- Compensation for the death of a loved one can be paid jointly to all relatives of that person at a maximum of 60,000 euros.

Proposal for loss of earnings:

- Compensation is awarded as a lumpsum according to the health insurance legislation for the time injured person is absent from work and only in the case injured person does not receive any compensations under pension and disability legislation;
- Maximum compensation may be limited to 25.000 Euros.

Medical treatment costs:

- Compensation of costs related to treatment is recognized in the amount of the total costs of health services from compulsory health insurance, which depends on the type of injuries or health impairments of the insured person in general;
- Compensation of this costs is only awarded if the injured person is not entitled to cost coverage on the basis of compulsory health insurance.

Funeral costs:

- Compensation is adequate to an average funeral costs in the region where person has lived.

Additional limitations:

- The compensation determined for each type of damage is reduced by compensations, refunds and all other payments received by the injured person for the same type of damage and under any other basis;
- For the compensation paid for each type of damage will be is reduced in the case of the same type of damage that the injured person has claimed on another basis, unless otherwise stipulated by law, other regulation or contract;
- Compensation amount for the:
  - physical pain or health impairment,
  - mental pain,
  - fear,
  - lost earnings,

- lost livelihood and
- funeral expenses

may not exceed 80.000 Euros combined in total except in the case if the injured person is under 18. in this case compensation shall be limited to 150.000 Euros. If there are birth related neurological damages in question compensation is limited to 250.000 Euros.

Proposal for compulsory vaccination damages:

Compensation in the case of compulsory vaccination should it produce a person to be injured, should stay a competence of the government and current legislation which stipulates the objective responsibility of the state and to be compensate from the state budget.

Proposal for change of compensation tarrifs:

Limitations shall be changed by the government decision on the basis of statistical data. Compensation payments shall be made in the course of 30 days from the day of final decision. Transfer and inheritance of the right to compensation is not possible.

2.7.3.5. Review and appeal mechanisms

Proposal 1:

If a claimant is unhappy with the decision made by the Agency (Institute) regarding their eligibility and/or entitlements under the scheme, then they should be able to access and apply to the appeal commission, still within the Agency (Institute). The Panel shall aim to promote fair and consistent decision on the claim and issue opinions at the request of claimants and health care providers. The appeal panel is also an advisory body and therefore its opinions shall also operate as recommendations, so there should be a high level of compliance.

Proposal 2:

Bringing a claim before the commission should be free of charge for the claimant, who shall benefit from being able to have the matter heard by experts in the field before making a decision on whether to bring a tort-based claim in the courts if not successful.

2.7.3.6. Complaint process and professional accountability

Proposal 1:

Patients rights ombudsmen should assist patients who experience difficulties in their relationship with health providers. They aim to assist and take a practical approach to resolving complaints. They shouldn't have any decision making powers on medical injury claim processing.

Proposal 2:

The competent professiona chamber or other body to deal with complaints where patients allege incompetence on the part of health practitioners should remain with their power to deal with complaints as for now. Eventual disciplinary action should stay and be kept entirely separate from the NFC claim.

Proposal 3:

As for the healthcare error analysis of it with a view to enhancing PS should become encouraged through the use of root cause analysis of events which led to claims for medical injury under the NFC. Mechanisms ind competencies to the Agency (Institute) should be set up and economically incentivised by it. Providers of services should receive regular updates providing details on all claims for medical injury under the NFC scheme that originated in their hospitals. Discussions should be held on the data, as well as what can be done to avoid such medical injuries in the future.

Proposal 4:
Decriminalisation of human errors should be part of legislation change. Health care can only be improved if al stakeholders realize that its quality and safety does not rest solely on the shoulders of health professionals, but is largely dependent on of how things are arranged or organised in the medical institution and from knowledge and principles how to resolve everyday problems and issues.

Grounds, arguments and justification:
The criminalization of human errors does not improve PS incident reporting and stimulates PS improvements.
Excessive penalization of human errors in HC has the following negative consequences:

- HC professionals often choose to cover up their own errors for fear of severe penalties, which means that errors are not analysed, which makes it impossible to learn from them
- Because of the tag “scapegoat” HC professionals are numb, anxious, alienated, depressed, confused, have sleeping disorders and workplace dissatisfaction - in the society of accusation they feel ashamed, guilty and full of doubts about their own abilities
- "The method of accusation, which is traditionally and stubbornly used in the medical profession to reduce adverse events due to errors, is the most unsuccessful way to prevent them"
- Simple human errors that are not the result of reckless or negligent conduct are too often taken as a sufficient ground for conviction
- The emergence of defensive medicine and the concealment of errors, which prevents the development of medical science
- Mistrust between the patient and the doctor

2.7.3.7. Medical documentation, data collecting, processing and data disclosure

Intention of introducing NFC is also that processing of claims is fast, efficient and non-public. Helthcare providers should be able to collect, process and pass medical data and medical records to the Agency (Institute) in due time.

Proposal 1:
Within QoC and PS health care activities providers should systematically collect and store data of patient treatment (full patient medical record) regardless of adverse event detected or not, in electronic form and pass them to the patient and/or to the Agency (institute) on their request within a period of 8 days, in complex cases no later than in 15 days.
Documentation should also include answers (comments and explanations) to the questions raised by the Agency (Institute).

Proposal 2:
All medical records, data on claim requests, all documentation should be kept confidential by all parties. Disclosure is not possible even to other government authorities like police, public attorneys and any type of courts. Those can request or seize medical records from the health care provider if they desire so.

Proposal 3:
Disclosure of case records and especially decisions can be done only by the injured patient, but only the part not concerning to decisions of the Agency (Institute).
If the patient is awarded compensation, they should not disclose to anyone any of the data on their case.

2.7.3.8. Patient rights ombudsmen

Proposal:

The responsibilities of the Patient Rights Ombudsmen will also have to be extend to help claimants with giving basic information, offering professional help on the complaint and compensation claim procedures and giving concrete directions in the areas of exercising rights in the field of NFC scheme in HC and representation of the injured patients in proceedings.

3. RECOMMENDATIONS

Recommendation 1: Move from fault based towards no-fault based compensation in the case of avoidable adverse events should further support efforts of overall QoC and PS measures.

Recommendation 2: MoH should prepare adequate new legislation and amend current when applicable in order for NFC system to become effective in a couple of years time.

Recommendation 3: As a basis to further develop NFC systems from Sweden and Denmark seems to be most adequate for Slovenia although they would need many alterations and adjustments needed for specific Slovenian health care system and jurisdiction.

Recommendation 4: Associations of health professionals should take the opportunity to introduce educational programs in order to facilitate and use Quality and PS measures and benefit the move from current shame and blame relationship amongst health professionals themselves and between them and patients. Hiding adverse events should eventuali became a matter of the past.

4. CONCLUSIONS

In order to introduce NFC scheme as a big novelty in Slovenian legislation steps towards firm commitment must be taken and plan for introduction followed. Long lasting discussion and proposal to introduce NFC may represent a hughe quality step forward towards current negative sides of costly, lengty and complicated procedures for receiving compensation in current fault based compensatory processes. In conditions where there is not so much common points in partnership between health professionals and health care providers when patient claims to suffer medical injury all parties involved may benefit substantially.

5. APPENDICE

5.1. Comparative analysis

Comparative analysis of no-fault compensation models of other EU and non-EU national systems

Support for improving quality of healthcare and patient safety in Slovenia

The project is funded by the European Union via the Structural Reform Support Programme and implemented by NTT DATA, in cooperation with the Directorate General for Structural Reform Support of the European Commission

- Draft version -

October 2021

European Commission | REPUBLIC OF SLOVENIA MINISTRY OF HEALTH | AARC NTT DATA

Glossary

A list with the abbreviations that will appear in this documents is presented below:

- ***ACC:*** *Accident Compensation Corporation*
- ***CRM:*** *Clinical Risk Management*
- ***DHW:*** *Department of Health and Wellbeing*
- ***EC:*** *European Commission*
- ***GDP:*** *Gross Domestic Product*
- ***HAI:*** *Healthcare Associated Infection*
- ***IT:*** *Information Technology*
- ***IVO:*** *Health and Social Care Inspectorate*
- ***MoH:*** *Ministry of Health*
- ***NBHW:*** *National Board of Health and Welfare*
- ***NE:*** *Neonatal Encephalopathy*
- ***NZ:*** *New Zealand*
- ***FACS:*** *Pressure Injury prevention and Fetal Anticonvulsant Syndrome*
- ***OECD:*** *Organisation for Economic Co-operation and Development*
- ***PFF:*** *Patient Insurance Association*
- ***PS:*** *Patient Safety*
- ***QoC:*** *Quality of Care*
- ***SRSP:*** *Structural Reform Support Programme*
- ***TRI:*** *Thematic Research Index*
- ***WHO:*** *World Health Organization*

Index

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01/ Objectives, expected results and phases of the project

02/ Objectives, expected results and phases of the project
General and specific objectives of the project

General objective

To contribute to **institutional, administrative and growth-sustaining structural reforms** in Slovenia, in line with **Article 4 of the SRSP Regulation**

Specific objectives

To support the initiatives of national authorities to design their reforms **according to their priorities,** taking into account **initial conditions** and **expected socioeconomic impacts**

To support the national authorities:
(1) in **enhancing their capacity** to formulate, develop and implement reform policies and strategies
(2) in **pursuing an integrated approach**, ensuring **consistency between goals and means** across sectors

In Slovenia, **to support the Slovenian Ministry of Health (MoH)** in capacity building to develop a National strategy on quality of care, clinical risk management and patient safety, and a legal framework of non fault compensation model

02/ Objectives, expected results and phases of the project
Expected results of the project

Direct results

Over the longer-term, to **contribute towards improving the quality of healthcare and patient safety in Slovenia**

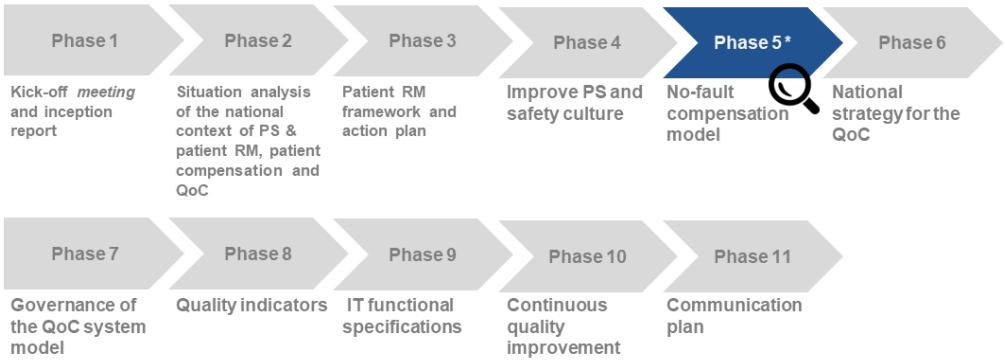
Indirect results

- **Improved knowledge** of challenges and opportunities in **patient safety and quality of care**
- Strengthened **patient safety culture** and **patient clinical risk management**
- Improved **strategic planning and governance** of the quality of healthcare system
- **Revised set of indicators for quality of care for hospitals**, **specialist outpatient care** and **primary care** available, tested and communicated

02/ Objectives, expected results and phases of the project
Phases of the project

The phases of the project will be approached around the following **dimensions**:

02/ Objectives, expected results and phases of the project
Phase 5 of the project



02/ Objectives, expected results and phases of the project

Phase 5 of the project

Phase 5

No-Fault Compensation Model

Objective of the phase

- To analyse the compensation model for sentinel/ other adverse events against other national models
- To identify a no-fault compensation model adapted to the Slovenian context
- To build capacity for the future preparation and implementation of the identified model

T 5.1: **To carry out a comparative analysis of the Slovenian compensation system and those of Sweden, Denmark and New Zealand** in order to map their key features and assess their relevance and transferability to Slovenia

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02/ Methodology - Phase 5

03/ Methodology - Phase 5
Methodological process summary

A comparative analysis of no-fault compensation models used in other countries will be carried out using different methodologies. This comparative analysis entails:

1. **Country selection*** for conducting the comparative analysis
2. Research **protocol elaboration** with a thematic research index (TRI)
3. Desk research and **non-exhaustive literature review**
4. Review of the information and **critical reading**
5. Identification of the main **stakeholders to interview**
6. **Conduction of the interviews** (subject to the availability of the responsible person in each country)
7. **Analysis of the results** of the interviews
8. **Elaboration of the report** on the comparative analysis

** The conduction of the interviews was subject to the availability of the persons/departments responsible for each case under analysis*

03/ Methodology - Phase 5
Country selection

Countries/regions with great development in the field of QoC and PS, with a wide spectrum of processes and mechanisms to ensure the quality and safety of patients have been selected:

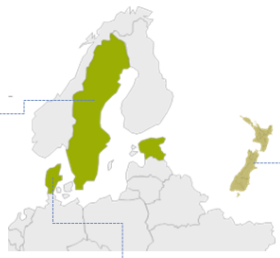
Sweden
Population:
- 10.036.391 inhabitants

Population density:
- 22.1 inhabitants/km ^{2}

Health expenditure:
- 11% GDP

GDP/Capita:
- EUR 43.681,77

Financing of the health system mainly with local taxes, universal coverage



New Zealand
Population:
- 4.723.562 inhabitants

Population density:
- 18.16 inhabitants/km ^{2}

Health expenditure:
- 9.21% GDP

GDP/Capita:
- EUR 32.641,77

Financing of the health system mainly with local taxes, universal coverage

Denmark
Population:
- 5.817.581 inhabitants

Population density:
- 137 inhabitants/km ^{2}

Health expenditure:
- 10% GDP

GDP/Capita:
- EUR 51,93

Financing of the health system mainly with local taxes, universal coverage

03/ Methodology - Phase 5
Research protocol elaboration

A research protocol was drawn up for the development of this phase of the project:

03/ Methodology - Phase 5
TRI elaboration

To analyse the country case studies, comparative elements of each of the axes were standardized. **TRI's themes** have been structured around the **following topics**:

No-Fault Compensation Model

- Compensation to patients injured
- **Cooperation with judicial authorities** and or other authorities
- **Determination of the compensation**
- **Standards of care**
- **Effectiveness** of the chosen system
- The sources of **funding and the financial impact** of the system
- **Transparency** of the reporting mechanisms
- **Advantages and disadvantages** to the model

03/ Methodology - Phase 5

Desk research and non-exhaustive literature review

To guide the search for information and to carry out structured analysis, a **TRI** has been developed with key issues to be identified in each of the selected regions/countries.

Review of literature according TRI and critical reading of information

- Critical Reading according to TRI
- Synthesis of information found

Official literature sources consulted (non-exhaustive list)

Country sources	• *Danish Ministry of Health* • *Danish Patient Compensation Association* • *Danish Act on the Right to Complain and Receive Compensation*	• *Patient Insurance Association PFF* • *Patient Cadet Act* • *Löf Insurance* • *Scottish government*	• *Accident Compensation Corporation* • *Ministry of Health New Zealand* • *The official website of the New Zealand government* • *New Zealand Legislation*
Transversal sources	*World Health Organisation (WHO) // Eurostat // Organisation for Economic Co-operation and Development (OECD)*		

03/ Methodology - Phase 5

Interviews

In order to complement the information gathered through the desk research, and address those topics that could not be found, **interviews were conducted with the experts/responsible persons in each country/region** in the field of PS and CRM:

Design and call for interviews

- Elaboration of the script for semi-structured interview
- Identification of those responsible for the teleconsultation projects of the selected region/country
- Request for interview with EC and MoH's support

Round of interviews

- Duration of approx. 1h30
- Via video call or phone call
- Expert from **Sweden***:
- Expert from **Denmark***:
- Expert from **New Zealand***:

Analysis of the results of the interviews

- Exploitation of the results of the interviews
- Drawing of conclusions

** The conduction of the interviews and the election of the experts will be determined after assessing if it's necessary or not to carry out those interviews*

03/ Results - Phase 5

03/ Results- Phase 3

Overview

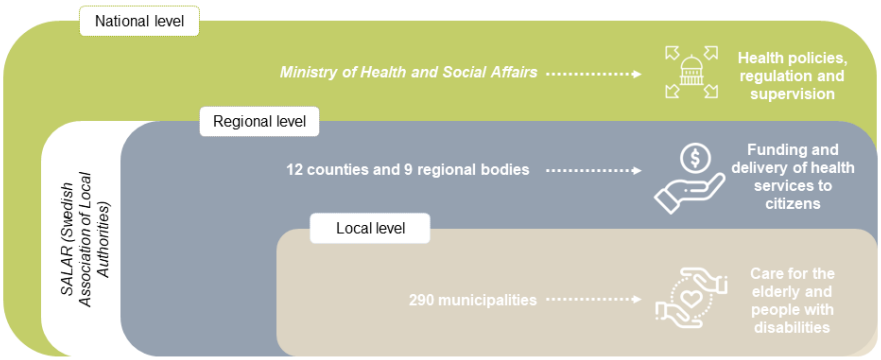
The following slides aim at characterising the main highlights of each of the selected countries regarding **their no-fault compensation model**:

1. Health System organisation
2. Organisational Overview
3. Legal background
4. Coverage, administrative process and compensation determination
5. Effectiveness of the system
6. System financing
7. Transparency reporting

Sweden

Swedish health system
Health system organisation

The health system in Sweden is decentralised on 3 levels: national, regional and local.



Determination of national standards of care:
- *The National Board of Health and Welfare is a government agency under the Ministry of Health and Social Affairs that compiles information and develops standards to ensure good health, social welfare and high-quality health and social care for the whole population.*

No-fault compensation model
Organisational Overview

Below it is presented an overview of the Swedish Patient Insurance Association:

Overview: Patient Insurance Association (PFF)

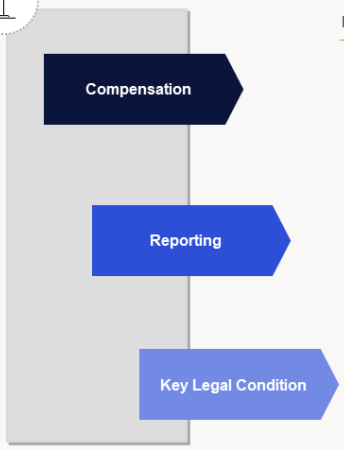
Description	Responsibilities
• *PFF is a non-profit organization founded in 1996.* • ***Insurance companies that notify patient insurance in Sweden are members of the association.*** *The members finance the association's activities.*	• *Manage* ***injuries caused by uninsured caregivers and pay patient compensation*** • ***Charge uninsured healthcare providers a special fee****, known as a patient insurance fee* • *Claim back compensation paid by uninsured healthcare provider* • *Administering the Patient Cadaut Board* • *Promote the common interests of members, including* ***providing information on the obligation to cover***

PFF PATIENTFÖRSÄKRINGSFÖRENINGEN

No-fault compensation model
Legal background

Below there are presented the key findings of the legal background of Sweden:

Legal background of the Swedish no-fault compensation model



Key findings

- *The* ***Swedish patient injury act*** *was introduced in 1996. It* ***allows patients to receive financial compensation for injuries in care and obliges caregivers to have patient insurance*** *that covers the liability. The obligation to have patient insurance covers everyone who conducts health care .*
- ***Compensation under the Patient Injury Act and the Patient Injury Insurance does not require proof of negligence or fault****. In cases where the medical staff have acted with negligence, there are disciplinary measures available and in severe cases criminal liability. The National Board of Health and Welfare (Socialstyrelsen) handles disciplinary cases. The board may intervene with injunctions and prohibitions and is entitled to give warnings or other reprimands.*
- *According to the* ***Patient Safety act****, if a patient suffers an injury or disease in connection with his/her medical treatment, or is exposed to risk because of his/her treatment****, the provider is obliged to report the incident to the National Board of Health and Welfare****. Patients and relatives can also make referrals to the National Board of Health and Welfare.*
- *According to the Patient Injuries Act, a care provider is obliged to have a patient insurance.*

No-fault compensation model

Coverage, administrative process and compensation determination

Below it is presented both the damages/injuries covered and not covered by the compensation model in Sweden:

Definition compensable injury:

"In order for an injury to be compensated, it must have been avoidable. All medical and dental care treatment involves risks of complications that are unavoidable. No compensation is paid for such complications."

Damages/Injuries covered by the compensation

- *Examination, care, treatment or similar measure provided that the **injury could have been avoided** either by a different performance of the chosen procedure or by the choice of another available procedure which, from a medical point of view, would have met the need for care in a less risky manner*
- ***Defects in medical devices** used in examination, care, treatment and improper handling thereof,*
- ***Incorrect diagnosis***
- ***Transmission of infectious agents** that have led to infection in connection with examination, care, treatment or similar action*
- ***Accidents in connection with examination, care, treatment** or similar measures or during the procedure*
- ***Dispensing of medicinal products in contravention of regulations or instructions***

Damages/Injuries not covered by the compensation model

- *Patients will not receive compensation **if the damage is the result of proper treatment that was vital.***
- *Injuries caused by medicines do not provide the grounds for compensation if **the medicine is prescribed or delivered correctly.***
- *If the patient was injured while being treated for a **traffic accident,** he/she needs to contact the traffic insurance company in the first place. The same applies if the patient is being cared for due to an occupational injury.*
- ***Damage that are a consequence of the patient´s basic disease** will not be compensated.*

No-fault compensation model

Coverage, administrative process and compensation determination

Below it is presented the administrative process depending on the disposition of the mandatory insurance:

Administrative Process

Procedure in the case the healthcare provider disposes of the mandatory insurance

Filling a claim to the healthcare provider´s insurance → **Decision*** → **Healthcare provider refunding***

- *The **patient must be the one to initiate the process**.*
- *Firstly, the patient must ask the caregiver where he/she has his/her patient insurance. The patient has the right to know.*
- *PFF does not have a register.*
- *Patient must **send the report to the healthcare provider´s insurance***

Procedure in the case the healthcare provider does not dispose of the mandatory insurance

Filing a claim to the PFF → **PFF investigation** → **Decision** → **(PFF refund)** → **Possibility to appeal**

- *In the case of **no insurance provider the patient must fill in the claim and send it to the PFF.***
- *First, the **PFF reviews the case** to determine whether the patient qualifies for a compensation.*
- *Based on a **further investigation** the PFF decides on the compensation.*
- *If PFF provides compensation to an uninsured healthcare provider´s patient, **the association has the right to claim a refund from the provider for the amount paid.***
- *If the patient is not satisfied with the PFF´s compensation decision, **he/she can request a review from the Patient Cadet Board.***

* *No information was found concerning how the insurances decide the compensation and proceed to a particular refunding.*

No-fault compensation model
Coverage, administrative process and compensation determination

Below it is presented how the patient's compensation is determined in Sweden:

Determining the patient´s compensation

In this case, we are referring to the decision procedure of the PFF:

Assessment Method
A ***retroactive assessment*** *is based on consideration of whether the injury could have been avoided, purely hypothetically, with knowledge of treatment outcome.*

Criteria/rules for the determination of the compensation

1. ***Damages for personal injury can be adjusted*** *if* ***the injured party has contributed to the damage*** *intentionally or through gross negligence.*
2. *If the obligation* ***to pay damages is unduly burdensome in view of the financial circumstances of the debtor****, the damages may be adjusted according to what is reasonable.*
3. *The* ***right to compensation for physical and psychological suffering and for particular inconveniences is lost*** *if the* ***injured party dies*** *before a claim for such compensation has been made.*
4. *If* ***two or more are to compensate*** *for the same damage, they shall* ***jointly and severally pay the damages****.*
5. *An injured party who has been awarded damages for a violation shall not be ordered to pay the costs of the person liable for damages in a case where damages arising from the offence are examined.*

No-fault compensation model
Effectiveness of the system

The effectiveness of the **Swedish no-fault compensation model** is examined through the following criteria:

Learning Mechanisms and Prevention Efforts

- *A number of* ***authorities are responsible for monitoring*** *different aspects of* ***PS, as well as the caregivers*** *themselves.*
- *Several national stakeholders report follow-up in the field of PS and there are different registers and databases at authorities and national organizations.*
- ***Regional supervisory units of the National Board of Health and Welfare (NBHW) receive reports and carry out inspections.***

Evaluation models

- *No information was found on evaluation models*

Surveillance System

- ***The Health and Social Care Inspectorate (IVO) oversees all healthcare in Sweden*** *(except healthcare within the Armed Forces) by inspecting the health activities and investigating certain notifications. IVO is also responsible for supervising licensed healthcare professionals.*

No-fault compensation model
System financing

Below it is presented how does it works the Swedish financing system regarding no-fault compensation model:

Financing system

Private healthcare provider	Healthcare provider under region-financed care
• ***Private physicians must cover the cost of their insurance themselves.***	• *The Patience Compensation Insurance is* ***financed by premiums paid by county councils.*** • *If health provider performs region-financed care, he/she may be insured through the Löf regions' mutual insurance companies.*

According to the Patient Injuries Act, ***the obligation to have a patient insurance covers everyone who provides health and medical care.*** *In case the health provider* ***does not dispose of health insurance****: the physician risks having to* ***pay a patient insurance fee to PFF****.*

No-fault compensation model
Transparency Reporting

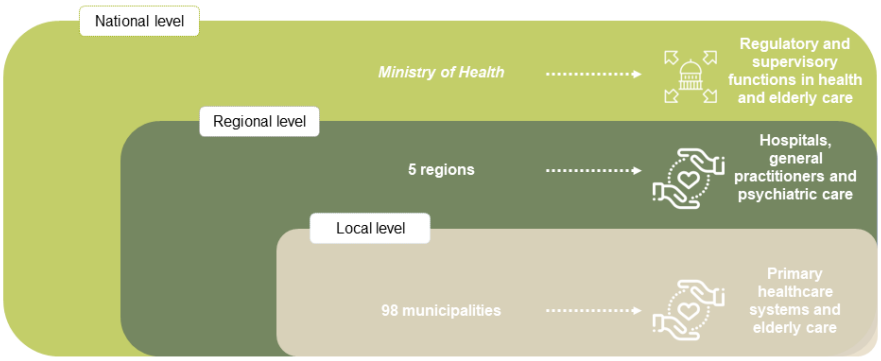
Transparency Reporting

- *No information was found concerning transparency reporting within the Swedish no-fault compensation model*

Denmark

Danish health system
Health system organisation

The healthcare system operates across three political and administrative levels: national, regional and local.



Determination of national standards of care:
- ***The Danish Healthcare Quality Programme*** *is a national system intended to support a continuous quality improvement of the Danish healthcare service as a whole. It is a method to generate persistent quality development across the entire healthcare sector in Denmark.*

No-fault compensation model
Organisational Overview

Below it is presented an overview of the Danish Patient Compensation Association:

Overview: Danish Patient Compensation Association

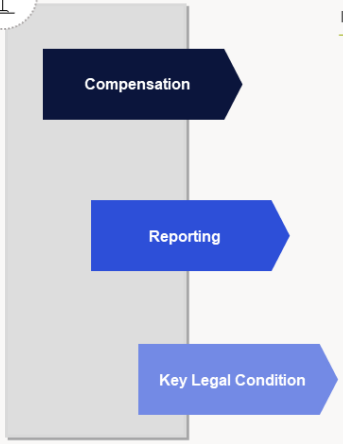
Organisational Overview	Responsibilities
• *The administration of the Danish Patient Compensation Act has been entrusted to an association – the Patient Compensation Association (In Danish: Patienterstatningen).* • *The Danish Patient Compensation Association is an independent body. Its task is to help patients injured in connection with treatment.*	• *Ensure effective specialist handling of patients' compensation cases* • *Guarantee security and service for patients and healthcare personnel* • *Assure that registered injuries are used in injury prevention work.*

Patienterstatningen
– behandlings- og lægemiddelskader

No-fault compensation model
Legal background

Below they are presented the key findings of the legal background of Denmark:

Legal background of the Danish no-fault compensation model



Key findings

- *The Danish Patient Compensation Act was introduced in 1992. After its introduction, **patients were no longer required to prove that an error** had occurred to gain compensation. Now it simply had to be highly likely that there was a connection between an injury and the treatment or examination undergone by the patient. **Nor was the patient any longer required to conduct the case**, as an institution was established to ensure that patients received the compensation to which they were entitled according to the law.*
- *According to the 2004 Danish Patient Safety Act: **"All authorised health personnel are responsible for informing the injured party** if they become aware of injuries in their undertaking that will give entitlement to compensation".*
- *The **reporting system is confidential and non-punitive**, and reports can be submitted anonymously. The aim of the system is to improve PS through the monitoring, analysis and knowledge sharing of adverse events. Furthermore, **having a learning focus rather than a blame or accountability focus** is thought to reduce the repetition of mistakes and to positively motivate reporting.*

No-fault compensation model

Coverage, administrative process and compensation determination

Below it is presented both the damages/injuries covered and not covered by the compensation model in Denmark:

Definition compensable injury:
"Injury may occur in connection with medical treatment, examination or due to medication. It does not matter if the institution is private or publicly owned."

Damages/Injuries covered by the compensation

- *A patient may be entitled to compensation if you have suffered **physical or psychological harm** in connection with: misdiagnosis, delayed examination and treatment, treatment for the illness, an operation, a rehabilitation program and health care*
- *The law gives the patient the right to compensation for the following, where applicable: **Loss of ability to work, lost earnings, pain and suffering, permanent injury, medical expenses and other losses.***
- *Patients can claim compensation for serious **side-effects caused by the use of medicines.***
- *If the injury **results in death**, compensation may be sought by **dependants for the loss of the provider**, as well as **funeral expenses** and payment of a transitional sum to the surviving relatives.*

Damages/Injuries not covered by the compensation model

- *If more than 10 years have gone by since the patient received treatment or medicine for an illness, the case is always invalid.*
- *The right to compensation can **only be granted if the patient was treated in Denmark**, or if the medicine the patient received was handled and purchased in Denmark or via a Danish website.*
- *The Patient Compensation Association **does not grant damages for loss of glasses, jewelry and so on.***
- *If the patient sustains an injury while receiving **dental treatment**, he/she must report the damage to the Danish Dental Association's Dental Injury Compensation Scheme*

No-fault compensation model

Coverage, administrative process and compensation determination

Below it is presented the administrative process:

Administrative Process

All compensation claims are assessed by the Danish Patient Compensation Association

Filing a claim for compensation

- ***Patients and professional can either register electronically** at www.patienterstatningen.dk by using the patient's NemID or **print out an application form, fill it in, and send it by post.***

Investigation

- *Once the Danish Patient Compensation Association receives an application, it reviews it to make sure it has all the information needed. **A caseworker prepares the case and decides whether it is necessary to have a medical consultant** assess the case. A case will most often be assessed at a meeting with our medical consultants.*

Decision

- *The case will be dismissed if there is no basis for awarding compensation. **If the case is recognised, it is in some cases possible to calculate the compensation or parts of it immediately.***

Possibility to appeal

- *Patients **may file an appeal at no cost if their claim is rejected**. Appeals are reviewed by a seven-member board of doctors, patient representatives, an attorney and two representatives of the Danish health care system.*

Average duration of 6-7 months

No-fault compensation model
Coverage, administrative process and compensation determination

Below it is presented how the patient's compensation is determined in Denmark:

Determining the patient´s compensation

Assessment Method
Cases are assessed by case workers and medical consultants based on the rules listed bellow. The amount of compensation depends on many conditions, including how great your injury is and what consequences it has had for the patient. The patient can only be compensated for the damage caused by the treatment itself.

Criteria/rules for the determination of the compensation

1. **The specialist rule:** *If the association assess that an **experienced specialist in the specific area would have acted differently** and your injury could thereby have been avoided, the patient will be entitled to compensation.*
2. **The fairness rule:** *If everyone has acted correctly and thereby no mistake has been made, but the patient is still left with **extensive complications which exceed what might, in fairness, be endured** – she/he may still be entitled to compensation under this rule.*
3. **The device rule:** *If the **injury has been caused by a fault in technical equipment** (for example a defect x-ray machine, syringe, or prosthetic), the patient is entitled to compensation under this rule.*

No-fault compensation model
Effectiveness of the system

The effectiveness of the **Danish no-fault compensation model** is examined through the following criteria:

Learning Mechanisms and Prevention Efforts

- ***Danish Patient Safety Authority** is responsible for making sure that knowledge gained from patient complaints and compensation claims is used preventively. Particularly serious cases may be submitted to the public prosecutor with a view to bringing the case before a court.*
- *The **Region's PS unit receives the analysed reports from the hospital in order to take action at the regional level** and to ensure that the data are anonymised before being forwarded to the National Board of Health.*

Evaluation models

- *In **2006 an external Evaluation Centre evaluated the Act on Patient Safety**. The study showed, that 2/3 of doctors and nurses agreed that reporting had lead to positive changes.*

Surveillance System

- *The **Danish Health and Medicines Authority is the regulator of the system**, and as such it is responsible for surveillance, counselling and supervision.*
- *The Statens Serum Institute is responsible for research-based health surveillance, oversight of information technology in the Danish healthcare system, and prevention and control of infectious diseases, biological threats and congenital disorders.*

No-fault compensation model
System financing

Below it is presented how does it works the Danish financing system regarding no-fault compensation model:

Financing system

Private healthcare provider	Public healthcare provider
• ***The regions cover the costs of compensation including that of private healthcare providers*** *with the exception of some treatments provided where the insurance company will pay.*	• ***The regions cover the costs of compensation.*** • *The MoH covers the costs of compensation in cases related to injuries caused by pharmaceuticals.*

Everyone that is treated in the public or private health service is covered by the Danish Act on the Right to Complain and receive Compensation within the Danish health service.

No-fault compensation model
Transparency Reporting

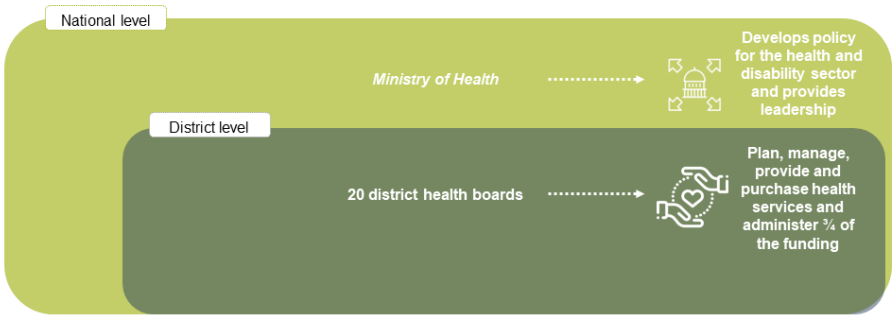
Transparency Reporting

- *No information was found concerning transparency reporting within the Danish no-fault compensation model*

New Zealand

New Zealandic health system
Health system organisation

The healthcare system operates across two political and administrative levels:



Determination of national standards of care:
- *The MoH and Standards New Zealand are working together with the sector to review standards related to health and disability services.*

No-fault compensation model
Organisational Overview

Below it is presented an overview of the organisation of the Accident Compensation Corporation:

Overview: Accident Compensation Corporation

Description	Responsibilities
• The Accident Compensation Corporation (ACC) is a ***Government agency that provides comprehensive, no-fault personal injury cover*** for all New Zealand residents and visitors to New Zealand. • ACC may also contribute to a wide range of medical and related costs associated with accidents, including doctor's visits, treatment from various other health professionals, surgery, X-rays and prescription costs.	• The ACC provides coverage through the no-fault scheme. The cover helps ***pay for the costs of recovery.*** • ACC works on ***preventing injuries*** by collaborating with partners and communities. • ACC helps ***service providers become ACC providers*** to help them lodge and manage claims and make invoicing easier. • ACC works with business and works to help them ***manage employee injuries***, while rewarding them for having a safer workplace.

No-fault compensation model
Legal background

Below they are presented the key findings of the legal background of New Zealand:

Legal background of the Danish no-fault compensation model

Key findings

Compensation

- *The Accident Compensation Act 1972 (NZ) **abolished the common law right to sue for compensatory damages for personal injuries in New Zealand.** The Act **introduced a no-fault universal insurance scheme** providing limited financial compensation for treatment, rehabilitation and loss of earnings.*

Reporting

- *Under the 2005 provisions, **the ACC is not required to report all medical error to the relevant professional body and the Health and Disability Commissioner**. Instead, ACC must report information to the relevant professional body if it considers there would be a risk of harm to the public.*

Key Legal Condition

- *The ACC provides **compulsory insurance cover for personal injury for everyone in New Zealand, whether a citizen, resident or visitor**. ACC is a statutory legal system covering all personal injury suffered by accident in New Zealand.*

No-fault compensation model

Coverage, administrative process and compensation determination

Below it is presented both the damages/injuries covered and not covered by the compensation model in New Zealand:

Definition compensable injury:

"A personal injury is a physical injury where bodily damage has been suffered. For example, an injury such as a fracture may be accompanied by the symptoms of pain and aching. However, lodging a claim based solely in symptoms (such as pain or arching) without an identifiable injury will not be accepted."

Damages/Injuries covered by the compensation

- *The patient will also be covered if the medical **staff failed to give him/her the medical treatment** when he/she needed it.*
- *The main ACC entitlements are: **treatment and rehabilitation, weekly compensation for lost wages or salary, lump-sum compensation for permanent disabilities and support for family members after fatal injury.***
- *A **mental injury may be covered if it is caused by a physical injury** caused my treatment.*

Damages/Injuries not covered by the compensation model

- *The cover doesn't include things that are a necessary part or **ordinary consequence of the treatment**.*
- *Injuries solely by **resource allocation** decisions.*
- *If the injury is a **necessary part of the treatment**.*
- *Illness, sickness, or contagious diseases, e.g. measles*
- *Stress, hurt feelings or other **emotional issues**. This **is unless they're linked to an injury we already cover***
- ***Conditions related to ageing**, e.g. arthritis*
- *Most hernias*
- ***Injuries that happen over time**, unless an activity at work is causing it*
- ***Damage to items** that don't replace body parts. This includes hearing aids, glasses, pacemakers and gastric bands.*

No-fault compensation model

Coverage, administrative process and compensation determination

Below it is presented the administrative process:

Administrative Process

All compensation claims are assessed by the ACC

Filing a claim for compensation	Initial Decision	Second Assessment and final decision	Possibility to appeal
• *The **patient claims by lodging an ACC 45 Injury Claim Form. The form must always be completed by a treatment provider** such as a doctor, physiotherapist or ambulance driver.* • *Usually, they will send the form to ACC for the patient. The treatment provider must only fill out the form with the patient´s consent.*	• *ACC's service centre staff will make an initial decision about whether the patient is covered. The patient will receive a letter telling him/her about this initial decision.*	• *The ACC service centre staff then decide what level of risk the patient´s claim involves. (No risk, low-to-medium risk, high risk).* • *Treatment injuries are usually considered complicated claims.* • [redacted]	• *If victims are unsatisfied with the decision, they can request a review. And if they are not satisfied with the review, they then have the right to court appeal.*

Investigation can take up to 9 months

***** *No information was found concerning how the decision process is done*

No-fault compensation model
Coverage, administrative process and compensation determination

Below it is presented how the patient's compensation is determined in New Zealand:

Determining the patient´s compensation

Assessment Method
All Treatment Injury Claims are considered by ACC on the basis of the specific circumstances of each patient. Differences in the underlying health conditions or the context of the treatment can mean that a claim that is accepted for one patient may not be accepted for another patient.

Criteria/rules for the determination of the compensation

1. An injury has occurred that has **resulted in physical harm or damage to the patient**
2. The injury has been **caused by the treatment**
3. The **injury is not a necessary part of an ordinary consequence of treatment**, having regard to the clinical knowledge at the time of the treatment, and the underlying health conditions of the patient.

No-fault compensation model
Effectiveness of the system

The effectiveness of the **Danish no-fault compensation model** is examined through the following criteria:

Learning Mechanisms and Prevention Efforts

- *The ACC aims to reduce injuries in New Zealand that are related to treatment from registered health providers. To do this, it is working with the health sector and leading and supporting prevention programmes. The **ACC has committed a $45 million investment to treatment safety programmes** between 2017 and 2022.*
- *It is working with the health sector to prevent a wide variety of treatment injuries. **These include: healthcare associated infections, medication safety, pressure injuries, neonatal encephalopathy and surgical harm**.*
- *The ACC is running the following prevention programmes: Neonatal Encephalopathy (NE) prevention, Healthcare Associated Infection (HAI) prevention, Pressure Injury prevention and Fetal Anticonvulsant Syndrome (FACS).*

Evaluation models

- *In 2014 State Services Commission, the Treasury and the Department of the Prime Minister and Cabinet conducted a **review of the ACC including an evaluation of the treatment inury system** (The Performance Improvement Framework).*
- *The report suggested that the **ACC could make greater use of variable levies to encourage people to take care and to invest in prevention** (eg, in the treatment injury area). It also enounced the **lack of engagement with some key players in the Health sector**, for example with the Health Quality and Safety Commission over treatment injury.*

Surveillance System

- *No information was found on surveillance systems*

No-fault compensation model
System financing

Below it is presented how does it works the New Zealandic financing system regarding no-fault compensation model:

Financing system

Private healthcare provider	Public healthcare provider

- *ACC is funded from **multiple sources** - including businesses, petrol revenues and wages. Funds from each source are spent on injuries relevant to where they occurred.*
- *The funds in **the treatment injury account are drawn from the Earner Account and Non-Earner Account**. The Earner Account funds are used to meet the treatment injury costs of people in employment, the Non-Earner Account funds are used to meet the treatment injury costs of people not in the workforce.*

No-fault compensation model
Transparency Reporting

Transparency Reporting

- *No information was found concerning transparency reporting within in New Zealand´s no-fault compensation model.*

04/ Conclusions

03/ Results- Phase 3

Overview

The following slides aim at characterising the main highlights of each of the selected countries regarding **their no-fault compensation model**:

1. Health System organisation
2. Organisational Overview
3. Legal background
4. Coverage, administrative process and compensation determination
5. Effectiveness of the system
6. System financing
7. Transparency reporting

04/ Conclusions

The following are the main conclusions of the comparative analysis on No-fault compensation models:

Health-system organization

1. In all analysed countries, health expenditure varies around 10% of GDP, and all of them follow the Beveridge healthcare model.

Organisational overview

2. All studied countries in this benchmark have a **national association** that **leads, supervises, analyses manages and tries to ensure compensation** for patients in cases of damages/injuries.
   - 2.1. In Sweden and Denmark, the Patient Insurance Association (PFF) and the Patient Compensation Association, respectively, are **independent bodies**.
   - 2.2. In the case of New Zealand, the Accident Compensation Corporation (ACC) is a **government agency** that not only provides no-fault personal injury cover for all New Zealand residents and visitors, but also participates in prevention strategies.

04/ Conclusions

The following are the main conclusions of the comparative analysis on No-fault compensation models:

Legal background

Compensation

3. The three analysed countries base on **a No-fault compensation model according to specific national** legislation (approved in the 90s in the case of the two European countries, and in the decade of 70s in New Zealand) that determines patients' rights to receive compensation and the procedure to allow its implementation when the damage is a consequence of treatment.
   - 3.1. The **Swedish Patient Injury Act** allows patients to receive financial compensation for injuries and obliges everyone who conducts health care to have patient insurance that covers the liability. Compensation does not require proof of negligence or fault. In cases where the medical staff have acted with negligence, there are disciplinary measures available and in severe cases, criminal liability.
   - 3.2. In Denmark, similarly, the **Danish Patient Compensation Act** does not oblige the patient to prove error if it is highly likely that there was a connection between an injury and the treatment or examination undergone by the patient.
   - 3.3. In New Zealand, **the Accident Compensation Act 1972** introduced a no-fault universal insurance scheme providing limited financial compensation for treatment, rehabilitation and loss of earnings.

Reporting

4. According to the respective **Swedish and Danish Patient Safety acts**, **the provider must report incidents to a responsible public body.**
   - 4.1. In the case of New Zealand, the ACC is not required to report all medical error to the relevant professional body and the Health and Disability Commissioner. Instead, **the ACC must report information to the relevant professional body if it considers there would be a risk of harm to the public.**
   - 4.2. In Denmark, it is explicit that the **reporting system is confidential and non-punitive** since the aim of the system is to improve patient safety through the monitoring, analysis and knowledge sharing of adverse events.

04/ Conclusions

The following are the main conclusions of the comparative analysis on No-fault compensation models:

Coverage, administrative process and compensation determination

Compensable injury

5. The three analysed countries understand a **compensable injury as the damage that is a consequence of the medical diagnosis or treatment and that is not a complication of the injury itself, that could have been avoided and that is identifiable**.

    5.1. The organization in each country specifies in detail the injuries that are covered or not covered by the compensation system.

Administrative process

6. In the three studied cases, the **administrative process is standardized and similar. It consists of 4 phases**: filling of the claim, investigation, decision and refunding. In case the patient disagrees with the final decision, there is the possibility to appeal.

    6.1. The **principal difference among the countries has to do with the initiation process**: in Sweden, it is the patient who must initiate the process; in Denmark, both patient and professional can either start it; and in New Zealand, the provider must fill in the form claimed and signed by the patient.

04/ Conclusions

The following are the main conclusions of the comparative analysis on No-fault compensation models:

Coverage, administrative process and compensation determination

Determining the patient's compensation

7. All analysed countries make a **systematic evaluation of submitted claims to determine the compensation according to specific criteria.**

    7.1. The amount of compensation depends on several conditions, including how great the injury is and what the consequences were for the patient.

    - In Sweden, the assessment is based on consideration of whether the injury could have been avoided, with knowledge of treatment outcome, according to a list of criteria which helps determining the compensation.
    - In Denmark, the amount of compensation depends on many conditions, including how great the injury is and what consequences it has had for the patient. The patient can only be compensated for the damage caused by the treatment itself. Criteria/rules for the determination of the compensation are based on three rules: the specialist rule (the specialist could have acted differently to avoid the injury); the fairness rule (everyone has acted correctly but the patient is still left with extensive complications); and the device rule (the injury has been caused by a fault in technical equipment).
    - In New Zealand all injury claims are considered by ACC on the basis of the specific circumstances of each patient. Differences in the underlying health conditions or the context of the treatment can mean that a claim that is accepted for one patient may not be accepted for another patient.

04/ Conclusions

The following are the main conclusions of the comparative analysis on No-fault compensation models:

Effectiveness of the system

8. All the analysed countries own **authorities that monitor, supervise, evaluate and initiate prevention mechanisms to ensure the effectiveness** of the no-fault compensation model.

    8.1. The procedures are country-specific:

    - In Sweden, there are different **registers and databases** at authorities and national organisations **to report follow-up** on patient safety. Regional supervisory units of the National Board of Health and Welfare (NBHW) receive those reports and carry out inspections.
    - In Denmark, the knowledge gained from complaints and compensation claims is used preventively. The Region's patient safety unit receives the analysed reports from the hospital in order to take **action at the regional level**.
    - In New Zealand, the ACC works with the health sector and leads and supports **specific prevention programmes** to prevent treatment injuries.

04/ Conclusions

The following are the main conclusions of the comparative analysis on No-fault compensation models:

System financing

9. The no-fault compensation model is a **universal coverage system** in the three cases studied. **Financing is particular** to each country, although it **tends to differentiate between public and private providers**.
    - In Sweden, according to the Patient Injuries Act, the **obligation to have a patient insurance** covers everyone who provides health and medical care. **Private healthcare providers must cover the cost of their insurance themselves. For healthcare providers under region-financed care, patient compensation is financed by premiums paid by county councils**. In case the health provider does not dispose of health insurance: the physician risks having to pay a patient insurance fee to PFF.
    - In Denmark, **the regions cover the costs of compensation including that of private healthcare providers** with the exception of some treatments provided where the insurance company will pay. The Ministry of Health covers the costs of compensation in cases related to injuries caused by pharmaceuticals.
    - In New Zealand, since the ACC is funded from multiple sources, **funds from each source are spent on injuries relevant to where they occurred**. Furthermore, the funds in the treatment injury account are drawn from the Earner Account and Non-Earner Account, according to the employment status of the injured.

Transparency reporting

10. Regarding to transparency reporting, **no information was found** in any of the studied countries.

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