



Modernisation of the system for monitoring and implementing measures for sentinel and other adverse events in Slovenia (SenSys)

Workshop II

Date: 13. -14. 6. 2018

Time: 9.00-15.30





Project „Šilih“

dr Vesna Zupančič
vesna.zupancic@gov.si

mag. Mateja Radej Bizjak

:



The project Šilih based on:

- the judgment of the European Court of Human Rights in the case of Šilih against Slovenia,
- two decisions of the Constitutional Court of the Republic of Slovenia in the case of Šilih from the year 2009 and 2016 and,
- court settlement concluded with the parents Šilih 23. 12. 2016, after 23 years since the death of their son, Gregor Šilih (1993).

Projekt Šilih temelji na:

- sodbi **Evropskega sodišča za človekove pravice**
- dveh odločbah **Ustavnega sodišča Republike Slovenije** v zadevi Šilih iz leta 2009 in 2016 in
- **sodni poravnavi**, sklenjeni z zakoncema Šilih 23. 12. 2016, po 23. letih od smrti njunega sina, Gregorja Šiliha (1993).

What did happen to him?

In 1993, Gregor Šilih was 20 years old.

May 3, 1993:

He visited the one of the Slovene hospital because he had nausea and urticaria.

The doctor ordered the intravenous injection of two medicines glucocorticosteroid (Dexamethason) and antihistamine (Synopen).

His condition has worsened very soon. An anaphylactic shock followed. He was transferred to a unit of intensive therapy.

A few hours later, his heart stopped. He stopped breathing. Reanimation was partially successful. Gregor was connected to a respirator. He was in a coma. His brain was too damaged.

The next day he was transferred to University clinical centre, where he died **May 19, 1993.**

Kaj se mu je zgodilo?

1993- Gregor Šilih star 20 let
3. 5.- obisk bolnišnice zaradi slabosti in urtikarije; intravenozna aplikacija dveh zdravil, hudo poslabšanje zdravstvenega stanja- anafilaktična reakcija. Sledila namestitvev v enoto za intenzivno terapijo, potrebna reanimacija, priključitev na respirator, poškodbe možganov, koma.

Sledila je premestitev v UKC, kjer je umrl 19. 5. 2018,

The parents struggle for recognition of responsibility and fair compensation

Starši se borijo za priznanje odgovornosti in pošteno nadomestilo



There was a suspicion of causing death by negligence /sum povzročene smrti zaradi malomarnosti

„She could not do anything for four years, and the son who took over the company was not skilled enough for the task. At the same time they were all residents of town in favor of the doctor, so our shop at the time run out“



"Štiri leta ni mogla storiti ničesar, sin, ki je prevzel podjetje, ni bil dovolj usposobljen za nalogo. Hkrati so bili vsi prebivalci na strani zdravnice, zato je bilo kupcev v njihovi trgovini zelo malo..."

„After 23 years I am mentally and physically exhausted, but I know that we are right, and therefore we can not leave the matter“.

Po 23 letih sem duševno in fizično izčrpan, vendar vem, da imamo prav, zato ne moremo zapustiti zadeve ".

Franja (1949) and Ivan Šilih (1940)

Why the Šilih project is important?

Description of the project by surname Šilih is an expression of commitment to implement measures:

- that will be within reason to avoid the inefficiency of state institutions in determining liability in case of patient's death during medical care and intolerable suffering of relatives.

On the proposal of the Ministry of Justice and the Ministry of Health, the Government of the Republic of Slovenia (02400-1 / 2017/4) of 26 October 2017 approved the Šilih Project and the measures envisaged therefrom.

Poimenovanje projekta po priimku Šilih je izraz zaveze,

da se izvedejo ukrepi, ki bodo v okviru možnega **preprečili neučinkovitost državnih institucij pri ugotavljanju odgovornosti v primeru smrti med zdravstveno obravnavo in nedopustno trpljenje svojcev.**

Na predlog Ministrstva za pravosodje in Ministrstva za zdravje je bil s sklepom Vlade RS 26. 10. 2017 potrjen Projekt Šilih in iz tega izhajajoči predvideni ukrepi.

Purpose of the Šilih Project

Is identify and approve measures to:

- reduce and prevent sentinel and other adverse events during health care,
- the effective exercise of the right to adequate, quality and safe health care,
- For an effective judicial procedure

The Šilih project is divided into two parts, on health and justice.

Complementary measures were needed, since individual measures can have an effect only if they are jointly and collaboratively established in both areas.

Namen Projekta ŠILIH

učinkovito uveljavljanje pravice do ustreznega, kakovostnega in varnega zdravstvenega varstva, spremljanje in preprečevanje škodljivih dogodkov in vzpodbuditi prizadevanja za učinkovit sodni postopek.

[MP in MZ v sodelovanju](#)



- Within the framework of the project, the Ministry of Health has planned 15 measures:

Measure 1Z: Creation of an e-brochure on patient rights and pre-trial and judicial protection in the event of a sentinel event occurring during health care.

The e-brochure will provide basic information in a user-friendly manner and will be available on the websites of the competent institutions and, if necessary, it can also be printed to be accessible to patients.

Ministrstvo za zdravje je načrtovalo 15 ukrepov:

Ukrep 1Z: Izdelava e-brošure v zvezi s pacientovimi pravicami ter predsodnim in sodnim varstvom v primeru škodljivega dogodka, do katerega pride med zdravstveno obravnavo.



- **Measure 2Z:** Obtaining data and preparing the analysis of the assessment to the situation

The Ministry of Health prepared specific questionnaires for healthcare providers.

Approximately half of the health care centers and hospitals responded.

Ukrep 2Z: Pridobitev podatkov in priprava analize za oceno stanja

Ministrstvo za zdravje je izvajalcem zdravstvene dejavnosti v decembru 2017 poslalo posebne vprašalnike z zahtevo po povratni informaciji do 31. januarja 2018.

Odzvala se je približno polovica zdravstvenih domov in bolnišnic.

The assessment of the situation involved 5 areas of procedure:

- (1) deals with violations under Patients' Rights Act (regular resolution of misunderstandings, first deals, second deals, other procedures on-line resolution of misunderstandings),
- (2) internal supervisions related to sentinel events (regular and extraordinary internal control),

V oceno stanja je bilo vključenih 5 področij postopkov:

- (1) obravnave kršitev po Zakonu o pacientovih pravicah
- (2) notranji nadzori povezani s škodljivimi dogodki



- 3) professional supervision with advisory services related to sentinel events (regular and extraordinary expert supervision with counseling),
- 4) reporting and analysis of sentinel and other adverse events (dealing with sentinel and adverse events)
- 5) pre-trial procedures related to sentinel events (mediation, compensation claims (before filing a lawsuit), civil litigation, pre-trial proceedings, criminal proceedings, average compensation, average cost).

(3) strokovni nadzori s svetovanjem povezani s škodljivimi dogodki,

(4) poročanje in analiza opozorilnih nevarnih dogodkov in drugih škodljivih dogodkov in

(5) predsodni postopki, povezani s škodljivimi dogodki.

- **Measure 3Z:** Promotion of mediation and other forms of peaceful dispute resolution in the framework of procedures under the Patients' Rights Act.

The Ministry of Health sent a letter to the public health service providers, with which they alerted the operators and encouraged the greater use of the procedures for informal and prompt resolution of disputes provided by the Patients' Rights Act.

- **Measure 4Z:** Preparation of the national report on the state of protection of patients' rights in 2017, with particular emphasis on cases of adverse events in medical care.

Preparation of the report takes place.

Ukrep 3Z: Promocija mediacije in drugih oblik mirnega reševanja sporov v okviru postopkov po ZPacP.

Ukrep 4Z: Priprava državnega poročila o stanju na področju varstva pacientovih pravic za leto 2017 s posebnim poudarkom na primerih škodljivih dogodkov v zdravstveni obravnavi.

Števila posameznih aktivnosti zastopnikov pacientovih pravic glede na leto njihovega delovanja

Leto	Število obravnavanih pacientov/ vprašanj pacientov	Število neformalnih posvetovanj	Število prvih obravnav	Predložitev anonimiziranih zapisnikov
2014	6.703	1.443	85	506
2015	8.398	1.272	172	497
2016	8.180	1.888	151	723
2017	10.338	1.211	199	922
SKUPAJ	33,619	5814	607	2648

Najpogosteje kršene pravice pacientov:

- pravica do primerne, kakovostne in varne zdravstvene oskrbe,
- pravica do spoštovanja pacientovega časa,
- pravica do obveščenosti in sodelovanja,
- pravica do seznanitve z zdravstveno dokumentacijo,
- pravica do vnaprej izražene volje,
- pravica do proste izbire zdravnika in izvajalca zdravstvenih storitev,
- pravica do drugega mnenja,

Raziskava pri Komisiji za pacientove pravice

Leto	Zahteve za drugo obravnavo	Način rešitve
2014	ni podatka	ni podatka
2015	37	1 odrejen zunanji strokovni nadzor, za ostalo ni podatka
2016	27	5 zadeve rešenih v tekočem letu, za ostalo ni podatka
2017	49	27 zaključenih postopkov 4 vložena tožba na Upravno sodišče ostali v teku



- **Analiza evidence podlagi novele ZPacP-A v povezavi s sodnimi postopki**

Do sedaj je v evidenci zavedenih 37 sodnih postopkov. Najstarejši datum uvedbe postopka je iz leta 2014.

Razlogi za uvedbo postopka so bili: strokovna napaka - huda telesna poškodba (prevladujoči razlog), nestrokovno ravnanje pri zdravljenju, nepravočasno zdravljenje, neustrezna obravnava, smrt pacienta, opustitev spremstva, opustitev nadzora nad delom specializanta med operativnim posegom, sum kaznivega dejanja malomarnega zdravljenja in opravljanja zdravilske dejavnosti, tožba zaradi plačila odškodnine, itd.



- **Measure 5Z:** Implementation of internal supervisions for healthcare providers.

The Ministry of Health verifies compliance for the period of the first six months of the entry into force of the novel Health Care Act.

The regular administrative supervision program for 2018 was adopted.

Information will also be collected through a survey

Measure 6Z: Ensure the implementation of regular and extraordinary expert supervision with counseling in 2018 with an emphasis on nursing, midwifery and medicine

Ukrep 5Z:
Implementacija določb glede notranjega nadzora pri izvajalcih zdravstvene dejavnosti.

Ukrep 6Z:
Zagotovitev izvajanja rednih in izrednih strokovnih nadzorov s svetovanjem v letu 2018 s poudarkom na področju zdravstvene in babiške nege ter medicine.



Measure 7Z: Change of rules relating to the implementation of professional supervision with counseling.

The Medical Chamber appointed the working group, which is also a representative of the Ministry of Health, for the preparation of the rules in question.

Measure 8Z: Data collection and analysis (for internal control and expert supervision with advice).

Information will also be collected through the survey.

Ukrep 7Z:
Sprememba
pravilnikov s
področja izvajanja
strokovnih nadzorov
s svetovanjem.

Ukrep 8Z: Pridobitev
in analiza podatkov
(za notranji nadzor in
strokovni nadzor s
svetovanjem).

- **Measure 9Z:** Amendment of Chamber Regulations in the field of (withdrawal) of medical licenses.
- **Measure 10Z:** Preparation of the proposal of Act of the Quality and Safety in Healthcare.

Activities will continue with the new government.

- **Measure 11T:** Reforming the system of reporting and learning from the sentinel and other adverse events in accordance with the agreed action plan.

The update takes place within the project SenSys.

Ukrep 9Z: Sprememba zborničnih pravilnikov s področja (odvzema) zdravniških licenc.

Ukrep 10Z: Priprava predloga Zakona o kakovosti in varnosti v zdravstvu.

Ukrep 11Z: Prenova sistema sporočanja in učenja iz opozorilnih nevarnih in drugih škodljivih dogodkov v skladu s sprejetim akcijskim načrtom.

- **Measure 12Z:** The Ministry of Health ensures the implementation of the Regulation on Public Health Operations

At the Ministry of Health, a draft methodology and a questionnaire are being prepared (it is in the final stage). Both acts will be published on the MoH website.

- **Measure 13Z:** Medical Chamber of Slovenia is again prompted to determining the sum insured for each specialty.

Ukrep 12Z:
Ministrstvo za zdravje zagotovi izvajanje 14. člena Uredbe o poslovanju z uporabniki v javnem zdravstvu:

Ukrep 13Z:
Zdravniško zbornico Slovenije se ponovno pozove k določitvi zavarovalne vsote po posameznih specialnostih.

Measure 14Z: It is proposed to supplement the contents in the field of quality and safety and crisis communication in the curricula (curriculum and curricula) of undergraduate and postgraduate education of professional education and training of health professionals.

Measure 15Z: Complementing the contents of the professional examination for health professionals carried out by the Ministry of Health through the amendment of the Rules on traineeships and professional examinations of health professionals and health professionals in the field of health care.

Ukrep 14Z: Predlaga se dopolnitev vsebin s področja kakovosti in varnosti ter kriznega komuniciranja v kurikulumu (predmetnik in učne načrte) dodiplomskega in podiplomskega izobraževanja, strokovnega izobraževanja in usposabljanja zdravstvenih delavcev.

Ukrep 15Z: Dopolnitev vsebin strokovnega izpita za zdravstvene delavce, ki se opravlja pri Ministrstvu za zdravje, in sicer s spremembo Pravilnika o pripravništvu in strokovnih izpitih zdravstvenih delavcev in zdravstvenih sodelavcev na področju zdravstvene dejavnosti.



The measures of the Ministry of Justice are linked

- by identifying the causes of such a long process and the preparation of improvement measures
- improving the work of medical court experts

Ukrepi Ministrstva za pravosodje so povezani z opredelitvijo vzrokov takega dolgega postopka in s pripravo ukrepov za izboljšanje - izboljšanje dela strokovnjakov za medicinsko sodišče

Razlogi za presojo odškodnine v pravnem postopku so bili:

- ni bila izpolnjena pojasnilna dolžnost (7 primerov),
- nestrokovnost zdravstvenih delavcev – odstop od standarda obravnave zaradi opustitve (16 primerov),
- nestrokovnost zdravstvenih delavcev – napačna odločitev in posledično hujše posledice za pacienta (3 primeri),
- neprimeren odnos zdravstvenih delavcev (2 primera),
- težave na področju dokumentiranja (zdravstvena dokumentacija) (4 primeri).
- Pravdni postopki se zaključili s presojo o upravičenosti do odškodnine, obsodilno ali zavrnilno sodbo.

17.000 eur...najvišje izplačana odškodnina

Bi pa verjetno "odškodninski sistem, ki temelji na nekrivni odgovornosti" olajšal stisko prizadetih in vpletenih zdravstvenih delavcev.



- The first findings of the analysis show that the example of Šilih is an exception not a rule.
- Doing all necessary that such cases are not repeated.

