Razprave o medicini in pravu v Mariboru

Uvod

Področje medicine in prava se v različnih državah obravnava zelo različno, zato so primerjave med posameznimi pravnimi sistemi na interdisciplinarnem področju prava in medicine zapletene (1, 2, 3). Ponekod se to področje zaradi obsežnosti in zapletenosti predava kot poseben predmet na pravnih fakultetah, v Sloveniji pa se je to področje pričelo bolj poglobljeno obravnavati v okviru letnih srečanj med zdravniki in pravniki na rednih mednarodnih srečanjih v Mariboru, ki jih je bilo doslej že dvajset. Tradicionalna mednarodna letna srečanja v Mariboru so namenjena obravnavi tem, v katerih se srečujeta dve stroki: medicinska in pravna. Občasno se njunim pogledom pridružijo še pogledi strokovnjakov drugih strok. Izbor tem sledi aktualnim problemom, ki jih je treba najprej bolje razumeti, da jih je mogoče uspešno reševati. V tem prispevku želimo prikazati, kakšne so bile poglavitne smernice razprav posameznih srečanj in njihov učinek na razvoj medicinskega prava v Sloveniji.

Po dvajsetih letih lahko rečemo, da ne gre zgolj za posvet, temveč za projekt, ki je pomembno vplival na razvoj pravnega urejanja (zakonodaja, teorija in praksa) in družbenega dogajanja na področju zdravstva na sploh. Pred dvajsetimi leti so se v Sloveniji z nekaterimi danes ključnimi vprašanji medicinskega prava poglobljeno ukvarjali le redki (3), pri čemer sta za sodobnimi dogajanji v svetu zaostajala tako zakonodajalec kot teorija. Na voljo ni bilo usmerjene slovenske literature. Zato ne smemo prezreti, da so spoznanja teh srečanj pogosto orala ledino (4).

Poglavitne obravnavane teme

Bolnikova avtonomija

Ves čas je v bil ospredju odnos med zdravnikom in pacientom (4, 5). Pacientova svoboda odločanja o sebi (avtonomija) je bila že spočetka obravnavana kot vrhovni postulat medicinskega prava (4). Vendar je bilo potrebno hkrati razreševati vprašanje, kje so meje bolnikove avto-

Discussing medicine and law in Maribor

Introduction

The combined discipline of medicine and law is dealt with very differently among different countries. As a result, the comparison between individual legal systems in the interdisciplinary area of law and medicine is complicated (1, 2, 3). In some European universities, this subject is taught as a separate course in law departments because of its extensiveness and complexity. In Slovenia, however, this subject was initially discussed in depth in gatherings of medical and legal experts at regular international meetings in Maribor, with this year marking the twentieth such discussion. The annual international medicine-law gatherings in Maribor are intended for discussion of topics where the two fields of knowledge meet. Sometimes the participants' views are joined by views from other fields. The selection of discussion topics is dictated by relevant issues requiring clarification and analysis before successful solutions can be found. In this article, we show what the main guidelines were for discussions at such meetings and their effect on the development of medical law in Slovenia.

After twenty years of such meetings, we can say that it is not just a conference, but rather a project which had an important influence on the development of legal (legislation, theory, and practice) and social events in the area of health care, in general. Twenty years ago, few in Slovenia were dealing in depth with key current questions on medical law (3), where the legislator (as well as legal theory) was falling behind with respect to modern developments. No specific literature dealing with in depth analysis of emerging problems in the filed of medical law in Slovenia was available. This is why we cannot overlook the fact that these meetings have often been breaking the ice on the field of medical law in Slovenia (4).

Main discussed topics

Patient autonomy

The doctor-patient relationship has consistently stood in the foreground of these discussions (4, 5). The patients' freedom to make choices about their health and medical care (auton-

nomije in kakšno naj bo ravnanje v primerih bolnikove nesposobnosti za odločanje, saj pri teh občutljivih vprašanjih obstajajo velike razlike v anglosaškem pravnem prostoru (1) in prav tako tudi znotraj tako imenovanega kontinentalnega prava (2).

Lahko rečemo, da je zasluga prvih posvetov uvajanje in razumevanje pojma privolitve po pojasnilu in pojasnilne dolžnosti v slovenskem prostoru (3, 4). Opozorjeno je bilo na več vrst pojasnil (pojasnilo tveganja, terapevtsko pojasnilo, pojasnilo diagnoze).

Razsežnosti zdravniške dolžnosti informiranja so bile prikazane tudi s pomočjo primerjalno pravnih zgledov, pri čemer je bilo mogoče največ vzporednic potegniti z avstrijskim in nemškim pravnim redom, pač zaradi njune podobnosti s slovenskim. Tako je bil npr. predstavljen zanimiv sodni primer »The Lancet case« (1970)(6). Gospe Buckle je bilo zaradi akutne depresije predpisano zdravilo »Parnate«, ki je absolutno nekompatibilno z uživanjem sira in lahko celo povzroči smrt. Zdravnik jo je posvaril s sledečimi besedami: "Po tem ko boste zaužili zdravilo, ne smete jesti sira. Uživanje zdravila in sira hkrati ima resne posledice." Gospa Buckle je razumela navodilo svojega zdravnika, vendar je kljub temu jedla sir in umrla. Po mnenju sodišča je Dr. Launay zadostil svoji dolžnosti, s tem da jo je posvaril. Sodnik je štel, da toženec ni bil dolžan nakazati konkretne smrtne nevarnosti.

Posebej je bila izpostavljena tudi pravica pacienta do zamolčanja rezultatov diagnoze, če njegova specifična osebna situacija zahteva takšen pristop, kar je bilo kasneje eksplicitno vključeno v slovenski zakon o pacientovih pravicah (7). Pogosto se zdravniku poraja vprašanje, ali naj bolnika obvesti o nastopu smrtne bolezni. Po mnenju nemškega sodišča naj se pojasnilo opusti, če bi privedlo "do resne in nepopravljive škode za bolnikovo zdravje." Poseben pristop je potreben pri umirajočem bolniku, če lahko preprečimo, da bi preostali čas bolnikovega življenja po nepotrebnem otežili s psihičnim trpljenjem zaradi poudarjanja neizbežnosti. Seveda mora zdravnik pri tem še posebej previdno raziskati, kako naj se oceni bolnikovo stališče do umiranja in smrti. Posebej občutljivo poglavje so dogajanja ob terminalni bolezni ali takrat, ko

omy) has been dealt with as the overriding postulate of medical law from the beginning (4). But at the same time, the question that needed to be solved was where the boundaries of patient autonomy lie and what the physicians conduct should be in cases of the patient's inability to express his will or decide on care specifics. There exist significant differences in opinion regarding these delicate legal questions in the Anglo-Saxon region (1) and also inside the so-called Continental Law region (2).

We can say that the major accomplishment of the first conference was the introduction and clarification of the meaning of the term "informed consent" and patient information after adequate explanation is given and criteria for legal explanation duties in Slovenia's medical environment are met (3, 4). Many different kinds of explanations were addressed (explanation risk, therapeutic explanation, explanation of diagnosis).

The extension of the doctors' duty to inform was shown with the help of comparative law examples wherein most parallels were drawn to Austrian and German legal practice, because of their similarities to the Slovene system. Thus, an interesting court case "The Lancet Case" (1970) (6) was presented. For her acute depression, Mrs. Buckle was prescribed the medication "Parnate, which was absolutely incompatible with cheese and consumption with cheese could even cause death. The doctor warned her with these words: "After taking the medication, you are not allowed to eat cheese. Taking the medication and eating cheese at the same time can have serious consequences." Mrs. Buckle understood her doctor's instructions, but ate cheese anyway and died. In the court's opinion, Dr. Launay did his duty by warning the patient. The judge's opinion was that the defendant was not obligated to point out the concrete danger of death.

The right of a patient not to be informed of his diagnosis was also specifically addressed: if the patient or patient's specific personal situation demand the withholding of such information, such withholding is allowed. Such approach was later explicitly included in the Slovene law on patient rights (7). Doctors are often faced with the dilemma whether or not they should inform patient about a lethal disease. According to the German court, the explanation should be left out if it would bring about "serious and irreparable damage to a patient's health." A distinct and sensible approach to a dying patient is needed in cases where we can avoid making the patient's remaining time more difficult. By emphasizing the inevitable the psychological suffering can be deepened.

bolnik zaradi stanja svoje zavesti ni več zmožen odločati o sebi. Razprave na tem področju so prinesle v slovenski prostor obravnavo tako imenovane zdravstvene oporoke in prenosa volje, kar je dobilo svoje mesto tudi v novem zakonu o pacientovih pravicah.

Poseben pristop pri pojasnjevanju je prav tako potreben, če gre za »obotavljanje« bolnika in objektivno nujno potrebne zdravstvene ukrepe. Pravo ne more določati povsem nedvoumnih pravil za vse možne primere, zato mora zdravnik še vedno upoštevati posebnosti vsakega posameznika in njegov položaj ter mu nuditi ustrezno mero informacij. Vnaprej pripravljeni formularji so lahko le pripomoček, ne morejo pa nadomestiti zdravnikovega osebnega angažmaja, da preuči sposobnost razumevanja in druge okoliščine primera.

Opredeljena je bila pravna narava razmerja med zdravnikom in pacientom. Obravnavani posamezni pravni elementi tega razmerja, kot so pogodba o zdravstveni storitvi in obveznosti iz pogodbe in zakona, iz katere sledi dolžnost osebne izvedbe medicinskega posega, pregleda in sestave anamneze, določitve diagnoze, dolžnost zdravljenja, skrbi za pacienta in postopanje na sploh legem artis, so pomembno vplivali na slovensko sodobno zakonodajo o pacientovih pravicah (7).

Razviden je prispevek pri uvajanju instituta varuha bolnikovih pravic.

Ob poudarjanju pacientovih pravic je bilo nujno opozarjati na vzajemnosti razmerja, saj ima pacient poleg pravic tudi dolžnosti: sodelovalno dolžnost in dolžnost zagotoviti plačilo storitve. Poudarjanje pacientovih pravic pa se ne sme spremeniti v svoje nasprotje, ko bi zdravniki zaradi bojazni pred odgovornostjo uporabljali pretirano defenzivne tehnike.

Leta 2008 je bil v Sloveniji sprejet Zakon o pacientovih pravicah, ki je povsem primerljiv s sodobno evropsko zakonodajo na tem področju (2, 7). Zaključki srečanj in objavljeni prispevki sodelujočih niso bili prezrti pri pripravi zakona. Posvet po njegovem sprejetju je bil namenjen kritični oceni in razlagi posameznih zakonskih rešitev. Zakonske norme niso vselej povsem enoznačne, zato je za njihovo uporabo potrebno uporabljati metode

Physician must carefully find out how to assess the patient's viewpoint about dying and death. A sensible chapter is experiencing the time of terminal disease. Patient is often unable to express his will and make decisions for himself because of cognitive changes or severe changes in state of consciousness. Discussions in this area have brought into the Slovene region, the principle of the so-called living will and transfer of patient rights or guardianship to third persons, which topic is also addressed in the new law on patient rights. A special approach is also needed in cases when patient rejects medical treatment or is too subjective and hesitant with respect to objectively urgent health measures. The law cannot determine entirely unambiguous rules for every case, which is why doctors still have to take into account the specific situation of each patient and his personal position. In every situation physicians should choose personal and sensible approach to duty to inform patient. Printed informed consent documents prepared in advance can be an auxiliary tool, but they cannot replace a doctor's personal obligation to consider the patient's level of comprehension and other circumstances of a case.
The legal nature of patient-doctor relationship was defined. The individual legal elements of this relationship, like the contract about health services and contractual obligations, as well as the law regulations from which follows the duty of personal execution of a medical procedure, examination and composition of anamnesis, determination of a diagnosis and duties of treatment and patient care, in general de lege artis, were elaborated and have importantly influenced the modern Slovene legislation on patients' rights (7).

The basis for introduction of the institutes for patient rights ombudsman was established.

When emphasizing the patients' rights, it was also necessary to point out the mutuality of the relationship, because the patient has not only rights, but also obligations: the duty to cooperate and the duty to ensure the payment of services. Emphasizing patient's rights cannot be turned into its own contrariety when the doctor would use overly defensive techniques because of fear of responsibility.
In 2008, the Patients Rights Act was passed in Slovenia, which is comparable in every respect to modern European legislation in this area (2, 7). The conclusions of pertinent discussions and published articles of those cooperating in drafting the act were not overlooked. The conference after the law passage was intended to provide critical assessment

razlage, ki jih posebej razvijata pravna teorija in praksa. Lahko rečemo, da prispevki udeležencev pomembno prispevajo k razumevanju pravnih pravil. Določene pozornosti je vsakokrat deležno razmerje med etičnimi in pravnimi normami.

Prisilno zdravljenje in nujno zdravljenje brez privolitve

Večkrat so bile obravnavane dileme prisilne hospitalizacije. Opozorjeno je bilo na pomanjkljivosti tedanje ureditve s predlogi novih rešitev. Poudarek je bil na iskanju ravnovesja med varstvom pravic osebnosti in varstvom drugih interesov pri prisilnem pridržanju in zdravljenju oseb z duševnimi motnjami ter pri medicinskih posegih v izrednih razmerah s ciljem podpreti oblikovanje nove zakonodaje. Prisilno hospitalizacijo je urejal Zakon o nepravdnem postopku. Ustavno sodišče je njegovo ureditev spoznalo za neustavno zaradi pomanjkljivega varstva pravic pridržanega in je naložilo uvedbo posebnega zagovornika po uradni dolžnosti (8). Lahko rečemo, da je odločitev Ustavnega sodišča vsaj časovno sledila obravnavi teh vprašanj na posvetu. Neskladnosti naj bi bile odpravljene s sprejetjem Zakona o duševnem zdravju. Ta zakon ni izpolnil pričakovanj in je bil tako s strani pravnikov kot predstavnikov medicinske stroke na posvetu močno kritiziran. Poleg tega se je izkazalo, da je ob pripravi tega zakona zakonodajalec izpustil bolnike z organskimi boleznimi, ki imajo pogosto spremljajoče hude kognitivne motnje in v določenih obdobjih svoje bolezni zaradi lastne varnosti prav tako potrebujejo prisilo. To področje sedaj spremlja pravna praznina, kar pri delu s takimi bolniki povzroča velike zagate.

Pri ugotavljanju, kje so meje bolnikove avtonomije, so udeleženci skušali oblikovati pravne okvire izrednih razmer. Na to se navezuje vprašanje nujnega zdravljenja brez pojasnila, vprašanje karantene, kdaj je pravno in etično upravičena zdravnikova odklonitev sodelovanja pri zdravljenju bolezni, ki ogrožajo tudi njegovo zdravje, in vprašanje suspenza prava v izrednih razmerah.

V zvezi s pacientovo avtonomijo so bili obravnavani tudi reformni predlogi za odpravo odvzema poslovne sposobnosti in podaljšanja roditeljske pravice ter za ureditev skrbništva za odrasle, ki spadajo v okvir nove družinske zakonodaje.

and explanation of individual applications of the law. Law norms are not always unambiguous and understandable and this is why methods of explanation which were specially developed by legal theory and practice were analyzed. We can say that the participants provided important contributions to the understanding of new developed legal rules. Every time a specific attention was given to the relationship between ethic and legal norms.

Forced treatment and emergency treatment without consent

The dilemmas about forced hospitalization (hospitalization and treatment without consent) were repeatedly addressed. The deficiencies of the former regulation were noted and suggestions for new solutions were made. The emphasis was on the search for a balance between protecting personal rights versus protecting other personal or social interests with regard to forced commitment and treatment of individuals with mental disorders, and medical procedures given in exceptional circumstances. The objective was to support the formation of new legislation. Forced hospitalization in the field of mental disorders was regulated by the Non-Litigation Civil Procedure Act. The constitutional court recognized that its regulation was unconstitutional. The reason was deficient protection of human rights of the forcedly treated patients. The constitutional court ordered the introduction patients defender. Defender should be ordered to every detainee by official duty (8). We can say that the decision of the constitutional court has followed, by timeline at least, the discussions at the conference. Inconsistencies were to be remedied with the passing of the Mental Health Act. However, this act did not fulfill the expectations and it was severely criticized by lawyers, as well as the representatives of the medical field and civilian associations. Additionally New Mental Health Act fails to address patients with organic diseases which are often accompanied by severe cognitive disorders; in certain phases of their illness, and forced treatment is often required for the patient's own protection. This area is now a legal vacuum, which creates a quandary for medical personnel dealing with these patients.

In determining where the boundaries of patient autonomy lie, the participants attempted to form a legal framework for exceptional circumstances. Questions were raised about the issues of urgent medical treatment without explanation and consent (the question of presumed consent), quaran-

Zaplet in medicinska napaka

Osrednja skupna točka obeh strok je zaplet v medicini. V tej zvezi so potrebni ukrepi za preprečevanje in ukrepi za odpravo posledic zapleta ali strokovne napake. Odškodninska, disciplinska, kazenska odgovornost zdravnika in odgovornost zavoda temeljijo na splošni ureditvi odgovornosti za protipravno ravnanje ali za ravnanje drugega. Potrebno pa je bilo vzpodbuditi preučevanje posebnosti, značilnih za področje medicine. Gre za posebne primere odgovornosti zdravnika in zdravstvene ustanove, kot so odgovornost za napačno diagnozo, odgovornost za škodo pri različnih posegih, zaradi napačne terapije, zaradi okužbe, odgovornost v primeru sodelovanja več različnih specialistov, odgovornost za škodo zaradi uporabe medicinskih naprav in orodij, odgovornost zdravnika, ki opravlja kozmetični poseg itd.

Značilna pri obravnavanju zdravniških napak je velikost tveganja, ki je povezano z opravljanjem tega poklica. Z ene strani je opravljanje zdravstvenih storitev plemenita in zelo humana dejavnost, z druge strani pa praviloma vsaka napaka ogroža največje vrednote človeka, to je njegovo zdravje in življenje. Zato sta predpisana postopek in način, kako usposobiti zdravnika, da opravlja tako pomembno in odgovorno poklicno dejavnost. To pa pomeni, da je pri tem poklicu še posebej poudarjeno načelo strokovno vestnega dela ob uporabi strokovnega znanja in izkušenj. Lahko bi dejali, da je odgovornost zdravnika v sodobni družbi urejena med mejami grozovito strogega Hamurabijevega talionskega načela in Platonovega načela laksizma (9).

Ugotavljanje odškodninske ali druge odgovornosti zdravnika za njegovo ravnanje v konkretni situaciji poteka v enem najtežjih dokaznih postopkov, pri čemer se zavarovalniška zakonodaja v Sloveniji zaenkrat ni prilagodila nekaterim zahtevam po ureditvi, ki bi omogočala izplačilo zavarovalnine brez ugotavljanja krivde, kar je značilno za Švedsko (10). Prav razprave v okviru projekta Medicina in pravo dajejo koristne napotke, katera dejstva je treba šteti za pravno odločilna.

Jasno je bilo izpostavljeno, da pravna teorija škodljiva dejanja in opustitve pri nudenju zdravstvenih storitev razvršča v štiri skupine (3, 11, 12):

tine, when it is legal and ethically justifiable for a doctor to refuse to cooperate in treating a disease which also endangers his health, and the suspension of law in exceptional circumstances. In connection with patient autonomy, the reform suggestions for the legal abolishment of the patient's capacity to contract, the extension of parental rights, and the regulation of the custody of adults, which concepts are a part of the new family legislation, was also discussed.

Complications and medical error

The central common point of both law and medicine is complications in medical treatment. In this regard, preventative steps, as well as measures for eliminating the consequences of complications or practitioner error, must be taken. Damages responsibility, disciplinary responsibility, criminal responsibility of doctors and responsibility of the institute are based on the general regulation of responsibility for unlawful conduct or for conduct of another. It was necessary to encourage the study of peculiar characteristics in this area of medicine and law. There are special cases of doctor and health care institution responsibility, like responsibility for wrong diagnoses, damages from various procedures and incorrect therapy, inadvertent infection, damages resulting from the cooperation of many different specialists, damages due to the improper use of medical devices and tools, the responsibility of a doctor who performs cosmetic procedures causing damages, etc.

Characteristic for medical error is the evaluation of specific risk which is connected to working in this profession. On one hand, the medical profession is a noble and humane one. On the other hand, as a rule, every mistake endangers the most important human values of health and life. This is why there are prescribed processes and methods for training doctors for such an important profession requiring high levels of responsibility. Thus, the principle of expertly performed conscientious work (professional duty), using expert knowledge and experience, is especially emphasized. We could say that a doctor's responsibility in modern society is spread between borders of horribly strict Hammurabi's talionis principle and Plato's principle of laxity (9).

Establishing legal (civil) liability of doctors for their misconduct in a concrete situation is complicated by the fact that the insurance legislation in Slovenia is not yet adjusted to some regulatory requirements enabling the payment of compensation money without specifically looking for guilt, as is the case in Sweden (10). The discussions in the frame

1) kršitev pravil zdravstvene stroke (zdravniška napaka),
2) kršitev osebne pravice na telesni integriteti (zdravljenje brez pristanka pacienta),
3) kršitev obveznosti nudenja nujne medicinske pomoči,
4) kršitev obveznosti sklenitve pogodbe o zdravstveni storitvi.

Na posvetih so se ob tem izoblikovali tudi določeni pogledi na subjektivno in objektivno odgovornost za škodo v medicini. Hkrati so bile predstavljene tudi možnosti, ki jih omogoča škodno zavarovanje (9).

V zvezi z vprašanjem privolitve po pojasnilu se zastavlja vprašanje, ali zdravnik odškodninsko odgovarja tudi, če ni dobil pristanka pacienta za poseg oziroma ga ni pravilno obvestil, pa je zdravljenje bilo uspešno, kar pomeni, da pri tem ni bilo nobene zdravniške napake. V tem primeru naj zdravnik odgovarja, vendar le za škodo, ki je nastala kot posledica posega v osebne pravice človeka do telesne integritete, torej za nematerialno škodo. V pravni teoriji najdemo tudi stališča, da ne bi bilo potrebno priznati niti takšne škode, če je s samovoljnim zdravljenjem rešeno življenje pacienta. Pri tem gre za ocenjevanje znanega načela o sorazmernosti pri varstvu posameznih osebnostnih pravic (6).

Ob pomanjkljivi privolitvi se zastavlja tudi vprašanje kazenske odgovornosti (13). Medicinska stran je posebej vzpodbujala razpravo o vprašanju kaznivega dejanja v zvezi z medicinskim posegom, s katerim se telo najprej poškoduje, da se doseže zdravstveni učinek, privolitve pacienta pa ni ali je vprašljiva (14). Še zlasti je to vprašanje postalo aktualno ob sprejemu novega Kazenskega zakonika (KZ-1). 3. odst. 125. čl. KZ-1 po nemškem zgledu izrecno izključuje protipravnost telesne poškodbe pri zdravljenju ali zdravilski dejavnosti zgolj za primer, ko je bila privolitev dana v obliki in ob pogojih, ki jih določa zakon. Izraženi so bili pomisleki, da posegi v telo, kljub odsotnosti privolitve po ZPacP, ne bi smeli biti inkriminirani kot kaznivo dejanje telesne poškodbe, če so imeli za cilj zdravljenje (14, 15). Predstavniki pravosodja so povedali, da bo pripombe proučila skupina za pripravo novele KZ-1. V avstrijskem kazenskem in civilnem pravu so mnenja glede problematike samovoljnega zdravljenja različna. Nekateri zagovarjajo mnenje, da predpisano in lege artis izvedeno zdravljenje ne more povzročiti delik-

of the project Medicine and Law gave beneficial guidelines for which facts have to be taken into account to be legally decisive in cases of presumed medical errors.

It was clearly pointed out that legal theory arranges acts and omissions in providing medical services, which cause damages, into four groups (3, 11, 12):

1) infringing upon the rules of the medical profession (medical error),
2) infringing upon the personal right of body integrity (treatment without patient consent),
3) infringing upon the obligation to give urgent medical help, and
4) infringing upon the obligation to sign contract for health service.

Certain views on subjective and objective responsibility for damages in medicine were also formed at conferences. At the same time, possibilities were presented which are offered by damage insurance (9).

In connection with the issue of consent after explanation (informed consent, patient information), a numerous considerations arise about doctors civil and criminal liability when no consent is obtained. A special cases are procedures where patient was not properly informed, but the treatment was nonetheless successful. It is general legal view that in such cases, doctors should be responsible, but only for the damages which were a direct consequence of the interference with patients will, which means physician should be liable only for non-material damages. In legal theory, we also find views that even this kind of damage does not have to be conceded, if treatment without consent results in saving the life of a patient. This is an issue about assessing a known principle of proportionality in protecting individual personal rights (6).

If the consent is deficient, the question of criminal responsibility arises (13). The medical side has particularly encouraged the discussion about the question of criminal offence in connection with German legal theory explaining that any medical intervention is considered to contain elements of the legal offense known as physical injury (14). It is an old theoretical discussion as to whether surgical interventions are prima facie legal or illegal under the common law (15). This question was especially accentuated with passing of the new Slovene penal code (KZ-1). Paragraph 3, article 125 of KZ-1 which is based on German example, explicitly excludes physicians legal responsibility for body injury by treatment

ta naklepne telesne poškodbe (6). Zdravniški posegi, ki imajo za cilj izboljšanje zdravstvenega stanja bolnika, so v Avstriji že z vidika dejanskega stanu izvzeti iz področja deliktov glede telesnih poškodb. Drugače je v Nemčiji, kjer je kazenskopravna presoja medicinskega posega odvisna od veljavnosti bolnikove privolitve (13). Tudi de lege artis izveden poseg je po njihovem stališču upravičen šele s privolitvijo bolnika (6, 14).

Reševanje sporov

Pomembno področje razprav je obsegalo ureditev postopkov, v katerih je mogoče uveljavljati pacientove pravice. Poudarek je bil tudi na alternativnih načinih reševanja sporov ter na upravnih in internih postopkih v zvezi s pomanjkljivostmi pri zdravljenju. Prikazana je bila vloga zdravniške zbornice. Govora je bilo o možnih postopkih v primerih, ko zdravstvena storitev ne izpolnjuje bolnikovih pričakovanj. Opozorjeno je bilo na različne cilje, ki jih zasledujejo posamezni postopki: sodni, disciplinski in postopki pred častnim razsodiščem. Pomembna ugotovitev je bila, da ni treba zmeraj zasledovati zdravniške napake, ki je podlaga odškodninske ali celo kazenske odgovornosti, temveč pogosto zadostuje človeška komunikacija za reševanje nesoglasij, zlasti če izvirajo iz premajhne poučenosti bolnika. Če se pri zdravljenju kaj zaplete, bolniki ali svojci večinoma ne želijo odškodnine ali uvedbe disciplinskega postopka, še manj sodnega postopka, temveč bi radi hitro izvedeli, kaj se je v resnici zgodilo. Tudi javnost želi izvedeti, kaj se je v resnici zgodilo in ali je treba sprejeti kakšne ukrepe. Tudi v zvezi s tem je bilo večkrat obravnavano pridobivanje objektivnega izvedenskega mnenja v sodnih in izvesodnih postopkih. Prav pri izvedenstvu se medicinska stroka neposredno povezuje s pravno stroko, zato je bila tudi razprava o tej temi vselej zelo tvorna in je vedno znova opozarjala na nekatere probleme medicinske izvedenske prakse v Sloveniji (16).

Organizacija zdravstva

Predmet posebne pozornosti je bila organizacijska zdravstvena zakonodaja in razmejitev med javnim in zasebnim v zdravstvu. Odločilno vlogo ima, seveda, financiranje, zato so bili predmet razprave vpliv zdravstvenega zavarovanja na izvajanje zdravstvene dejavnosti, pomen programa financiranja in odgovornost za sistemske ukrepe, odnos države do standardov v zdravstvu in proble-

or medical act merely for a cases when consent was given in form and under conditions determined by law. Problems arise when the patient is unable to give a valid consent and the responsibility for consent therefore rests with third parties (14, 15, 16). New penal code is trying to resolve the problem with referring to Patients rights act (PRA). However PRA rules for treating patients without consent (under the presumed consent doctrine) are ambiguus and in cases of urgent medical treatment without proper consent physicians could be incriminated for an act of criminal offence. In Austrian criminal and civil law, which are very similar to Slovene legal regulations, the opinions about the problems of treatment without consent differ. Some Austrian scholars advocate the position that the prescribed medical treatment, when performed in lege artis manner cannot cause a criminal offence of intentional body injury, even when performed without proper consent (6). Medical procedures which aim to improve a patient's health should be, from the point of view of the medical profession, excluded from offences of body injury. This is different in Germany, where the criminal-legal assessment of medical procedure depends upon the validity of patient consent (13). Also a de lege-artis-performed procedure is, in their view, are justifiable only with patient consent (6, 14, 16). Slovene physicians believe that it is necessary for the law to recognize and accommodate three realities in the context of medical interventions. First, medical interventions should not be regarded in practice as prima facie illegal. Second, some non-therapeutic interventions are accepted by modern society. Third and most important, those unable to consent for themselves need increased protection (15). Physicians proposed that the most satisfactory approach to such an accommodation is to regard therapeutic interventions as prima faciei legal and to retain criteria for of prima faciei illegality with respect to non-therapeutic medical procedures (15). Representatives of the jurisdiction have said that the medical profession objections will be studied by a group of experts preparing an amendment to KZ-1.

Resolving disputes between physicians and patients

An important area of discussion contained the regulation and establishment of procedures intended to resolve disputes between physician and patients arising from different interpretations or disrespect of PRA. The emphasis was put on alternative ways of resolving disputes in connection with deficiencies in treatment. Also, the role of the Medical Chamber

matika upravljanja velikega zdravstvenega sistema. Predstavljeni so bili zdravstveni sistemi po svetu in pravno-organizacijske oblike v zdravstvu pri nas, prehajanje iz zasebne prakse v javni zavod in obratno, organiziranost zasebne prakse in pridobitev koncesije, vloga splošnega zdravnika v zdravstvenem sistemu itd.

Vselej je težko vprašanje, kako ugotoviti konkretno upravičenost do medicinskega posega oziroma zdravstvene oskrbe na račun javnih sredstev, ki jo abstraktno ureja norma 12. čl. ZPacP, sestavljena iz pravnih standardov: "Pacient je do medicinskega posega oziroma zdravstvene oskrbe, ki se opravlja na račun javnih sredstev, upravičen, če je ta po pravilih medicinske stroke potrebna in se glede na sodobno medicinsko doktrino upravičeno pričakuje, da bo pacientu koristna in so pričakovane koristi za pacienta večje od tveganj ter obremenitev." Vsebino pravnih standardov je treba iskati v drugih predpisih in praksi.

Posebno poglavje se odpira z novo zdravstveno zakonodajo, ki jo pripravlja Ministrstvo za zdravje in je bila komentirana na lanskem posvetu. V prispevku na lanskoletnem posvetu je bilo izrecno opozorjeno tudi na zahteve, ki jih za ureditev zdravstvenega sistema prinaša Direktiva Evropskega parlamenta in Sveta o uveljavljanju pravic pacientov na področju čezmejnega zdravstvenega varstva (17) in na njene nepredvidljive razsežnosti (18). Pripravljavci zdravstvene zakonodaje se na opozorila za sedaj niso odzvali.

Posebne razprave so bile posvečene trikotniku bolnik, zdravnik, lekarnar. V tem kontekstu so bile upoštevane naslednje razprave: »Original ali generik?«, »Nadzor nad zdravili – vloga republiškega Urada za zdravila po vstopu Slovenije v EU (19)«, »Odgovornost za realizacijo recepta – problematika lekarniške dejavnosti – dialog zdravnik : lekarnar«, »Pravna ureditev patentov, znamk in licenc v zvezi z zdravil«, »Pravica do zdravil iz obveznega zdravstvenega zavarovanja – Reforma na področju predpisovanja zdravil«, »Harmonizacija evropskega prava na področju farmacevtskih produktov – Evropska agencija za zdravila«. Veliko zanimanja je požel sklop, namenjen alternativni medicini ob sprejemu tozadevnega zakona. Predstavljene so bile tudi razvitejše tuje ureditve tega področja.

of Slovenia was clarified. Possible procedures in cases when the medical service does not fulfill patients' expectations were discussed. Different procedural and substantial aspects of civil and criminal court processes, disciplinary processes, and processes before honorable arbitration court were analyzed. An important find was that it is not always necessary for medical error to be followed by a law suit for damages or even criminal responsibility; many times simple human communication to resolve arguments is enough, especially if the dispute originates from patient's lack of knowledge. Regarding a complication in treatment, the patient, or their next of kin, usually do not want to sue for damages or start a disciplinary procedure, much less a criminal procedure, however they want to quickly ascertain the true facts of the situation. The public also wants to know what actually happened and if it is necessary to take any preventative steps in the future. In connection with this, acquiring an objective expert opinion both for in-court and out-of-court procedures has been repeatedly discussed. The expert opinion from medical field has almost in every legal medical case deep impact on legal decision making process, and this is why a discussion about this topic was always very creative and has always pointed out problems of medical expert practice in Slovenia (17).

Organization of health care

The subject of special attention was the organizational health care legislation and the demarcation between public and private health care. The determining factor in this classification is, of course, financing, and because of this, the subjects of discussion were the influence of health insurance companies on the performance of health services, the impact of the national health service regulations on financing and responsibility for systemic measurements, the attitude of the state to standards in health care, and the problems of managing a vast health care system. Various national health care systems from around the world were discussed and compared with legal-organizational forms in health care in Slovenia. Special problems in Slovenia are the transfer of private practices into public institutes and vice versa, the organization of private practice and acquiring concession for public funding, the role of the general practitioner in the health care system, etc. It is always a difficult question how to find out the concrete justification of medical procedure in health care on public expenses when such funding is abstractly regulated by a norm in Article 12 PRA (ZpacP): "The patient is entitled to

Presajanje organov in tkiv ter sodobna biomedicina

Obravnavana so bila tudi vprašanja, povezana s presajanjem organov. O tej temi so najprej spregovorili strokovnjaki, ki so zadolženi za razvoj boljših možnosti dostopa do organov, pravo pa je bilo pozvano k oblikovanju ustreznih varovalk za preprečevanje možnih hudih kršitev in zlorab. Prezrti niso bili niti zavarovalniški vidiki pri presajanju organov, problematika uvoza zarodnih celic, darovanja preko meja in organiziranja bank organov. Predstavljen je bil pravni status delov človeškega telesa.
Posebno dimenzijo ima večkrat obravnavano področje biomedicine. S tem povezane so bile naslednje aktualne teme: »Pravna ureditev v zvezi z izvornimi celicami, z genetiko, z novimi potmi spočetja in oploditve« (20). Izpostavljeni so bili problemi, od kdaj se zagotavlja varstvo pri oploditvi izven telesa matere, ali so zarodki v epruveti lahko deležni pravnega varstva. Poudarjeno je bilo, da ženska, ki sodeluje pri umetni oploditvi v epruveti, ni dolžna omogočiti vnosa in donositi zarodkov, ki so ostali kot višek. Opozorjeno je bilo tudi na pomembnejše mednarodnopravne vire, kot je za področje biomedicine Oviedska konvencija (21), ki jo je Slovenija ratificirala med prvimi evropskimi državami. Dogajanje v projektu Medicina in pravo je imelo določen vpliv na sprejem Zakona o oploditvi z biomedicinsko pomočjo. Udeleženci naslednjih posvetov pa so opozorili tudi na vprašanja, ki jih je zakon neutemeljeno prezrl.

Po odkritju človeškega genoma je bila na dnevni red posveta uvrščena aktualna tema, kakšno nalogo ima pri tem pravo. Gre za velik pomen pravnega varstva človekovih pravic v zvezi z biomedicino (posegi v človekov genom, raziskave na zarodkih, uporaba dosežkov genetike zaradi zdravljenja, pridobivanje zarodkov zaradi zarodnih celic, sprememba spola). Pravo verjetno v danih razmerah utemeljeno omejuje posege v človeški genom, ki se smejo opraviti le iz preventivnih, diagnostičnih ali terapevtskih razlogov, vendar le pod pogojem, da njihov cilj ni povzročiti kakršnih koli sprememb na genomu potomcev.

Družinska zakonodaja

Ob pripravah družinskega zakonika je bila na posvetu izpostavljena pravica otroka, da izve za svoj izvor. Zato je potrebno zakonsko urediti prenatalno priznanje očetovstva v vseh oblikah, če je otrok že spočet, pod pogojem,

medical procedures or health care paid by public funds if the treatment or service is by medical rules necessary and it is, according to modern medical doctrine, justifiably expected to benefit the patient, and that the expected benefits are greater than the risk or burden." Substantial content of legal standards in national health care should be more practice oriented and less abstract.
A special chapter is opening with the new health care legislation, currently being prepared by the Ministry of Health and being brought forward for the health care system by directive of the European Parliament. The directive regulates patients' rights and their access to medical services in the area of European cross-border health care protection (18). The directive will have unforeseen extensions (19). The drafters of the health care legislation have not yet responded to the warnings that Slovene health legislation is not prepared for changes ordered by directive.
Special discussions were dedicated to the triangular patient-doctor-pharmacist relationship. In this context, the following discussions were considered: "Original or generic drug?", "Control over prescribing drugs–the role of the National Agency for Medical Products after Slovenia became a part of the EU (20)," "Responsibility in connection with getting the medication at pharmacy–problems of pharmaceutical work–the dialog doctor-pharmacist," "Legal regulation of patents, trademarks and licenses in connection with medication," "The right to medication from mandatory health insurance–reform in the area of prescribing medication," and "Harmonization of European law in the area of pharmaceutical products–European Medicines Agency." Much interest was shown in the group about alternative medicine at the passing of its law. More-developed foreign regulations for this area were also presented.

Organ and tissue transplantation and modern biomedicine

Questions connected with the transplantation of organs were also addressed. The experts who are committed to the greater availability of organs for transplantation first raised this topic, and the law was called upon to form appropriate safety guidelines for preventing possible severe wrongdoings and abuse. Even insurance issues regarding organ transplantation were considered, as well as the problems of importing embryo cells, donating across borders, and organizing organ banks. The legal status of human body parts was presented. In the area

da se otrok rodi živ. Za otroka, spočetega z donorskimi spolnimi celicami, mora kljub temu veljati izjema, da ne more zahtevati vseh podatkov o dajalcu. Po predlagani ureditvi bo lahko dobil le zdravstveno pomembne podatke o darovalcu/ki in le iz zdravstvenih razlogov, če bo razsoden in star najmanj 15 let. Predmet obravnave so bila etična vprašanja na začetku in koncu življenja, z vzdrževanjem življenja in evtanazijo (21).

Medicinske raziskave

Na področju znanstvenih raziskav se posebna pozornost posveča zaščiti oseb, ki v raziskavah sodelujejo. Slovenija ima to področje urejeno sodobno in vzorno. Vse biomedicinske raziskave, ki se dotikajo vprašanj humane medicine, pregleda Republiška komisija za medicinsko etiko. Slovenija je sodelovala pri nastajanju Oviedske konvencije (22), bila pa je tudi med prvimi, ki jo je ratificirala. Kljub temu se prav v zvezi z medicinskimi raziskavami na ljudeh še vedno odpirajo nova vprašanja. Posebej so bili opredeljeni izjemni primeri, t.j. kdaj in pod kakšnimi pogoji se raziskave lahko izvajajo tudi na osebah, ki zanje niso sposobne dati veljavnega soglasja. Posebej pa je govora o raziskavah na zarodkih in vitro. Ukvarjali smo se tudi s vprašanji posthumne oploditve, surogatnega materinstva, genskega inženiringa. Številna pričakovanja so usmerjena v razvoj genske diagnostike in terapevtskih možnosti, naloga prava pa pri teh težkih etičnih vprašanjih še ni povsem definirana.

Sklep

Eno izmed bistvenih sporočil, ki izhaja iz dolgoletnega povezovanja medicine in prava, je ugotovitev, da odnosa med pacientom in zdravnikom zaradi življenjske pestrosti ni mogoče preprosto ujeti v toge pravne okvire. Bistvo tega odnosa predstavlja na eni strani pacientovo zaupanje, da bo zdravnik storil skladno s pravili medicinske stroke vse, kar je potrebno, da se mu zdravje izboljša ali da mu celo reši življenje, na drugi strani pa pripravljenost zdravnika, da takšnim pričakovanjem zadosti in hkrati s tem tudi zahtevam svoje stroke. Prav takšno zaupanje in pričakovanje sta tisto, kar zdravnika obvezuje tako moralno in strokovno ter naposled tudi pravno. Pri tem pa je potreben ustrezen posluh za slabosti, ki izvirajo iz nepopolnosti človeške narave. Tej namreč ni vselej dano, da zadosti določenim željam, pričakovanjem

of biomedicine, new and emerging technologies have been discussed many times. Connected to this were the topics of legal and ethical problems of stem cell research, genetics, and new ways of fertilization" (21). The problems arising from when the protection at fertilization outside a mother's body is ensured were exposed, and if the embryos in a test glass can get legal guardianship. It was emphasized that a woman who takes part in vitro fertilization is not obligated to allow the insertion and bringing to term embryos that are redundant. A number of important sources from international law were also noted, like the Oviedo Convention (22) in the area of biomedicine, which was ratified by Slovenia, (among the first European countries to do so). The events in the project Medicine and Law had a certain influence on the passage of the law on fertilization with biomedical assistance. Participants in the subsequent conferences also pointed out the questions and problems which were not included in present Slovene law regulations covering new biomedical technologies.

After discovery of the human genome, the topic of what role the law has in relation to it was put on the agenda. This issue is of great importance for legal protection of human rights in connection with biomedicine (interfering with the human genome, embryo research, use of accomplishments in genetics due to treatment, acquiring embryos for stem cells, and gender change). In given circumstances, the law probably justifiably restricts interference with the human genome, which interference can only be made for preventive, diagnostic, or therapeutic reasons, and only on the condition that its aim is not to alter the genome of offspring in any way.

Family legislation

In the light of the preparation of the family code, the problem of children's right to know their origin was specifically raised at the conference. The problem should be approached in very sensible way and that is why it is necessary to legally regulate extent of prenatal recognition of fatherhood in all forms for all live-born children. A child conceived with donor gametes cannot demand all donor information; the family code does not allow this exception. According to the suggested regulations, they will be able to obtain only medically relevant information of the donor, only for prudent medical reasons, and if they are at least 15 years old. The subjects of discussion were ethical questions regarding the beginning of life, and the end of life, specifically, concerning artificial life support and euthanasia (22).

in zahtevam. Napaka na tem področju je že sama po sebi tragična in to toliko bolj, kolikor večje je nesorazmerje med njeno subjektivno platjo in težo njenih posledic. Zato impresija o posledicah, nastalih ob zdravljenju, na racionalno presojo ne sme imeti vpliva. Zdravstvenih delavcev, glede na delikatnost njihovega poklica, seveda ni potrebno privilegirati, temveč od njih zahtevati le tisto previdnost in skrbnost, ki sta bili glede na njihova strokovna merila v konkretnem primeru objektivno potrebni in subjektivno mogoči (23).

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Medical research

In the area of medical research, special attention was given to the protection of study participants. Slovenia's regulation of this area is modern and exemplary. All biomedical research which mentions the questions of humane medicine is reviewed by the National Medical Ethics Committee. Slovenia took part in the creation of the Oviedo Convention (23), and it was also among the first countries to ratify it. Despite this, many questions still arise in connection with medical research on humans. Exceptional cases were discussed, for example, when and under what conditions research can be done on individuals who are not able to give valid consent. Research on in vitro embryos was also discussed, as well as questions of posthumous fertilization, surrogate maternity, stem cells and genetic engineering. The legal parameters for these difficult ethical questions have not yet been defined.

Conclusion

One of the key messages from many years of connecting medicine and law is the realization that the doctor-patient relationship cannot simply be controlled by a rigid legal framework, because of its necessarily flexible nature. The essence of this relationship represents, on one hand, the patient's trust that the doctor will, according to the rules of the medical profession, do everything that is necessary to improve the patient's health or even save his life, and on the other hand, the preparedness of the doctor to fulfill such expectations, as well as the demands of his profession. This degree of trust and expectation is what obligates the doctor morally, professionally, and lastly, also legally. At this, sensitivity for deficiencies stemming from the imperfections of human nature is needed. Medical error is tragic by itself and even more so when there exists a dis proportionality between its subjective side and the weight of its objective consequences. Therefore, the emotional experience accompanying medical errors and their consequences should not influence rational legal judgment. However, health workers, even when considering the delicacy of their profession, do not have to be privileged. They have to perform their profession with necessary caution, care and professional duty which should have been, according to their expert experience in a concrete case, objectively needed and subjectively possible (24).

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