

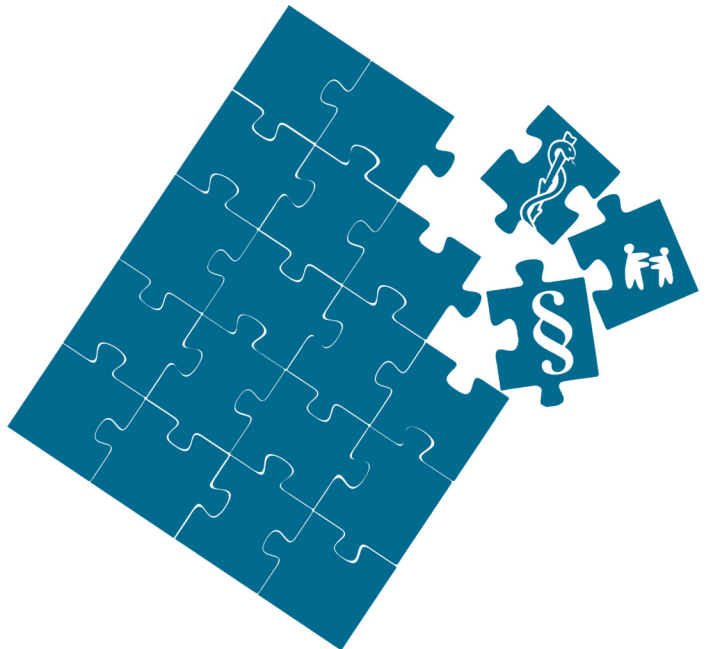


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PUBLIC ATTITUDES AND LEGAL AMBIGUITY: RESULTS FROM A SURVEY ON MEDICAL CANNABIS IN SLOVENIA

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Abstract Public attitudes toward medical cannabis play an important role in shaping regulatory practice and integrating new therapies into health systems. This online survey of Slovenian adults (n = 226) examined perceptions of medical cannabis within a context of legal ambiguity and limited institutional guidance. Support for legalization was high, but respondents commonly reported unclear understanding of what current law permits and limited trust in the accuracy of information received from healthcare professionals. Participants relied heavily on informal and online sources, highlighting gaps in regulatory clarity and professional readiness. These findings underscore the need for clear legal frameworks, improved clinical guidance, and more transparent communication to align public expectations with medical and legal practice in Slovenia.

1 Introduction

Public attitudes toward medical cannabis have become a central focus for health policymakers worldwide. As legal reforms accelerate, many jurisdictions face challenges integrating cannabis into clinical practice, where regulatory permissiveness is not always matched by public understanding or institutional readiness (Hossain & Chae, 2024, pp. 2-6; Webb & Mansfield, 2020, pp. 124-128). In both liberal and conservative systems, social perception has emerged as a key determinant of whether legalization translates into safe, equitable access (Sznitman & Bretteville-Jensen, 2015, pp. 2-7). At the same time, regulating medical cannabis increasingly raises socio-legal questions about how law is understood, interpreted, and enacted in everyday life. In this field, “legal ambiguity” does not simply mean the absence of rules; it can describe a condition in which legal change occurs without sufficiently clear procedures, institutional responsibilities, or public communication, leaving patients, professionals, and regulators uncertain about what is permitted in practice. Such ambiguity is well documented in early medical cannabis regimes, where statutory frameworks were sometimes broadly permissive yet vague regarding practical access pathways, production models, and enforcement boundaries -creating confusion among patients, caregivers, and authorities (Pacula, 2017, pp. 8-16).

Slovenia offers a particularly illustrative case within this evolving policy landscape. In 2016, the country formally reclassified cannabis from Group I to Group II of controlled substances, allowing for restricted medical use under specific conditions. Despite this regulatory shift, cannabis remains marginal within Slovenian healthcare. Physicians frequently report inadequate training and inconsistent prescribing guidance (Hossain & Chae, 2024, pp. 3-6), pharmacists encounter supply barriers, and patients face confusion over eligibility, products, and legal procedures. Media coverage is often superficial or sensationalized, and public health campaigns are largely absent. Taken together, these features position Slovenia as a case of partial legalization with incomplete implementation: formal legal permissibility exists, but the institutional infrastructure needed for consistent clinical integration and public comprehension remains underdeveloped. Comparative research on medical cannabis regulation shows that “medical cannabis law” is not a single intervention but a variable set of statutory and regulatory components (e.g., patient eligibility, product safety, supply channels, and prescriber roles), and differences in these

components can strongly shape real-world access and governance outcomes (Klieger et al., 2017, pp. 4-6).

These limitations are not unique to Slovenia. A recent survey of Polish physicians published in *Cannabis and Cannabinoid Research* found that over 70% felt unprepared to advise patients on cannabis use, and 93% supported developing structured clinical guidelines and professional education (Hordowicz et al., 2021, p. 2). This underscores a broader regional pattern of legal reform outpacing institutional support and physician readiness. At the EU level, reports by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA, 2018) similarly highlight a fragmented policy landscape, where public awareness and access to medical cannabis vary dramatically across countries, further complicating harmonized implementation. More generally, analysis of national medical cannabis programs emphasizes that effective governance depends not only on formal legalization but on coordinated regulation, clinical guidance, and community-facing implementation strategies (Ruheel et al., 2021, pp. 13-16).

These challenges echo findings from other jurisdictions. In the United Kingdom, despite formally introducing medical cannabis in 2018, clinical uptake remains slow due to physician hesitancy and ambiguous guidelines (Waldron et al., 2023, pp. 1-5). In Germany, public enthusiasm for cannabis often surpasses clinical conservatism, reflecting a broader disjuncture between consumer optimism and institutional caution (Meyerding & Groninga, 2025, pp. 2-12). In Mexico and Ukraine, public education and institutional reform have played critical roles in bridging perception and policy (Camberos-Barraza et al., 2023; Aliekperova et al., 2020, pp. 2-10). International surveys also reveal that legalization alone does not resolve uncertainty. In New Zealand, longitudinal studies show consistently high public support for medical cannabis, yet persistent concerns over dependency and misuse, especially among older adults (Boden et al., 2020, pp. 80-85). In Canada, enthusiasm initially surged following recreational legalization, but perceptions of medical efficacy became more cautious over time as the public was exposed to regulatory inconsistencies and evolving media narratives (Doggett et al., 2025). In the United States, public knowledge remains fragmented despite broad legalization, with attitudes shaped by political affiliation, race, age, and access to trustworthy information (Pew Research Center, 2024; Montgomery et al., 2024, pp. 2-14).

Importantly, public perception matters legally, not only politically, in settings characterized by regulatory ambiguity. When formal rules are unclear or poorly translated into clinical routines, individuals must interpret legality as a practical guide for health behavior: whether to disclose cannabis use, whether to seek medical authorization, and which information sources to trust. These perceptions can influence the “law-in-action” by shaping compliance, disclosure, and patterns of access—especially where the clinical encounter becomes a key site of governance. Yet empirical work shows that patient–provider communication about medical cannabis can remain limited even where medical cannabis is legally available, reinforcing reliance on non-institutional information channels (Turner et al., 2024, pp. 298-301).

From a systems perspective, successfully integrating medical cannabis requires more than legal change. It depends on training healthcare professionals, engaging patients in policy design, and developing accurate public information systems (Webb & Mansfield, 2020, pp. 124-128; Aliekperova et al., 2020, pp. 2-8). In contexts with limited institutional clarity, such as the situation in Slovenia, public opinion can serve as both a barometer and a catalyst for reform. Despite strong anecdotal support, empirical data on Slovenian public attitudes remains scarce. Prior surveys conducted by public health institutions and oncology centers have suggested high support among both the general public and patients with chronic illness. However, these datasets have not been comprehensively analyzed in peer-reviewed literature, nor compared to international findings.

To address this gap, this study analyzes original data from an online survey conducted by the Medca Association. The survey sampled respondents across Slovenia using a snowball distribution method and included questions on attitudes toward medical cannabis, perceived risks and benefits, trust in information sources, and personal experience. While the sample of 226 respondents is not probabilistic, it provides broad geographic and demographic diversity and offers valuable insight into general population attitudes. This paper situates Slovenia’s cannabis perception in an international comparative framework and contributes new empirical evidence from a Central European country with formal legalization but incomplete implementation. In doing so, it aims to inform policy, medical training, and public communication efforts that align with both the legal framework and public expectation.

2 Methods

This cross-sectional descriptive study investigated public attitudes toward medical cannabis among adult residents of Slovenia. The survey was conducted online between June 11 and September 21, 2024, by the Medca Association in collaboration with the Institute ICANNA. Eligible participants were Slovenian residents aged 18 years or older. Recruitment followed a snowball sampling approach using digital channels including social media, email invitations, and institutional mailing lists. Participation was voluntary, anonymous, and self-selected. A total of 226 respondents completed the questionnaire in full. Because the study aimed to capture a broad range of perspectives, no exclusion criteria were applied.

2.1 Survey Instrument

The online questionnaire was developed by adapting items from four internationally recognized and validated instruments, as presented in table 1. The final questionnaire consisted of 33 items grouped into three thematic sections.

Table 1: Validated instruments used to develop the MEDCA Survey

Instrument	Institution	Purpose / Key Measures
Cannabis Supplement Core Measures Questionnaire	U.S. National Cancer Institute (NCI), USA	Provides standardized epidemiological items for assessing cannabis use, frequency, and context to enable international comparability.
Cannabis Community Attitudes Survey (CCAS)	National Drug Research Institute, Curtin University, Australia	Measures public attitudes, beliefs, and stigma related to cannabis use and policy.
Cannabis Abuse Screening Test (CAST)	French Monitoring Centre for Drugs and Drug Addiction (OFDT), Europe	Brief six-item screening tool identifying potentially problematic or high-risk cannabis use among adolescents and adults.
National Cannabis Survey (NCS)	Statistics Canada	Collects national data on cannabis consumption frequency, product types, and access channels.

Items were translated into Slovene and culturally adapted for national context. The survey captured sociodemographic data, cannabis-related behaviors, perceived benefits and risks, and trust in information sources. Data were collected via the 1KA online survey platform. Participation was anonymous, and no personal identifiers were collected. In accordance with Slovenian regulations, ethical approval was not

required for this non-interventional public survey. All data collection complied with the General Data Protection Regulation (GDPR) and national privacy standards.

2.2 Data Collection and Analysis

In this study, we focused on describing how participants perceive and use cannabis. Data were collected through an online questionnaire (www.1ka.si) and analyzed using Microsoft Excel software (Microsoft Corporation, Redmond, WA, USA). Only valid responses were included in the final dataset. For questions using Likert-type scales such as “Strongly disagree” to “Strongly agree” or “Never” to “Very often”, the full distribution of responses was presented. To illustrate broader trends, categories were occasionally grouped (e.g., reporting the percentage of participants who selected “agree” or “strongly agree”, or those who reported a behavior “sometimes or more often”). Demographic variables (e.g., gender, age, education level, employment status) were summarized using frequencies, percentages, means, and interquartile ranges. Descriptive summaries were used for all outcome variables, including perceived benefits and risks, information sources, and policy attitudes. Given the exploratory nature of this cross-sectional study, the analysis was purely descriptive, and no inferential or hypothesis-testing statistics were conducted. Where appropriate, 95% confidence intervals (CIs) for key proportions (e.g., support for legalization, perceived benefits) were estimated to provide an indication of variability and precision. To minimize potential reporting bias, only complete cases were included, and data consistency checks were performed prior to analysis. The purpose of this study was primarily descriptive and exploratory, aimed at improving understanding of how medical cannabis is perceived and used within the Slovenian adult population.

3 Results

3.1 Demographic of Study Participants

The sample consisted of adult citizens of the Republic of Slovenia, ranging in age from 18 to 89 years ($n = 226$). Of the respondents, 44% ($n = 100$) identified as male and 56% ($n = 126$) as female. The mean age was 48.73 years ($SD = 14.83$). The majority of participants reported having completed secondary or higher education.

In terms of employment status, 57% of respondents were employed, 9% unemployed, 24% retired, and 5% were students.

Table 2: Demographics of study participants

Demographic	% (n)
Sex	
Female	56 (126/226)
Male	44 (100/226)
Age (years)	
Mean (range)	48.7 (18–89)
Highest level of education	
Primary school or lower	3,54% (8/226)
Secondary school 2 or 3 years	19,50% (43/226)
High school or other secondary 4 years schools	26,55 % (60/226)
Bachelor's degree Level VI/I	12,83% (29/226)
Bachelor's degree Level VI/II	15,49% (34/226)
Master's degree Level VII	13,27% (30/226)
Post graduate University	6,19% (14/226)
Doctorate (PhD)	3,54% (8/226)
Employment Status	
Employed	56,64 % (128/226)
Unemployed	9,29 % (21/226)
Retired	23,89% (54/226)
Student	4,87% (11/226)
Prefer not to answer	5,31% (12/226)

3.2 Perceived Benefits of Medical Cannabis

From the participants of this survey 81% have previously used cannabis and of those 53% use it for medical purposes and 47% for personal/recreational purposes. When asked if they perceive that there are benefits to using cannabis 94% answered yes. Participants reported a wide range of perceived benefits associated with medical cannabis use (Figure 1). The most frequently endorsed effects included pain management (89%), improved sleep (87%), and relief of stress and anxiety (85%). A majority also noted its usefulness to manage cancer treatment side effects (64%), to reduce the use of other medications (62%), and to treat or help relieve other medical conditions such as epilepsy or chronic pain (61%). Roughly half of respondents identified medical cannabis as beneficial for increasing appetite (49%), enhancing relaxation and pleasure (48%), and reducing fatigue (47%). Fewer participants

selected effects such as relief of neuropathy (39%), reducing nausea and vomiting (38%), and decreased use of substances like alcohol and tobacco (36%). The least commonly reported benefits were increased libido and sexual function (31%) and relief of sweating symptoms (30%). In our survey 90% of participants know one or more people who are using cannabis for medical purposes.

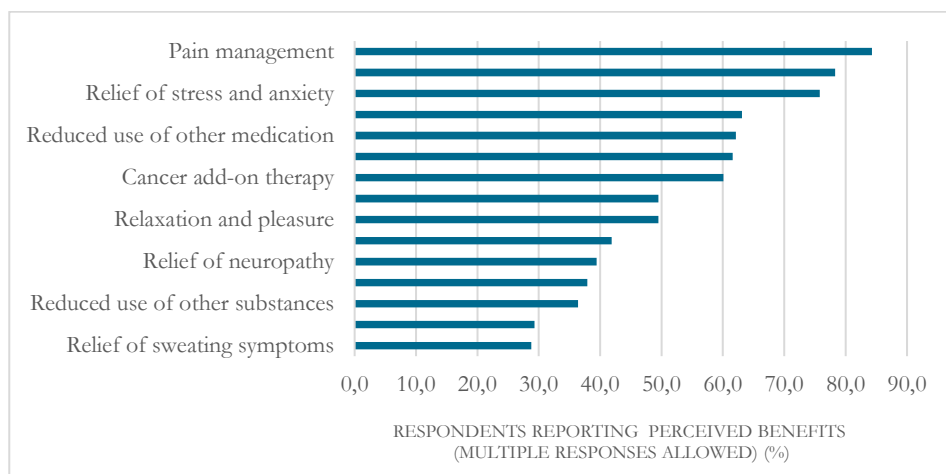


Figure 1: Perceived Benefits of Medical Cannabis

3.3 Perceived Risks and Concerns

When participants were asked if they perceive that there are risks and concerns for using cannabis 49% answered yes. Participants identified a variety of concerns associated with medical cannabis use (Figure 2). The most frequently reported were legal problems (46%), inability to operate vehicles or machinery (44%), and cannabis dependence (43%). Other common concerns included difficulty concentrating (38%), negative reactions from family or friends (36%), and job loss or negative career impact (35%). Issues such as daytime drowsiness (34%), memory problems (33%), and dizziness or increased risk of falls (26%) were also noted.

Less frequently reported concerns involved increased appetite or weight gain (25%), stress or anxiety (22%), and lung damage (20%). Only a small minority of participants expressed concern about sleep disturbances, headaches, or the increased

use of other substances or medications. Fewer than 10% noted concerns about an increased risk of cancer or other illnesses.

The most frequently reported concern is legal problems, that is further corroborated by the fact that 62% of participants know at least one person to have legal problems due to cannabis use. These findings suggest that perceived risks are primarily related to cognitive or functional impairment, social stigma, and legal or occupational consequences, rather than severe health effects.

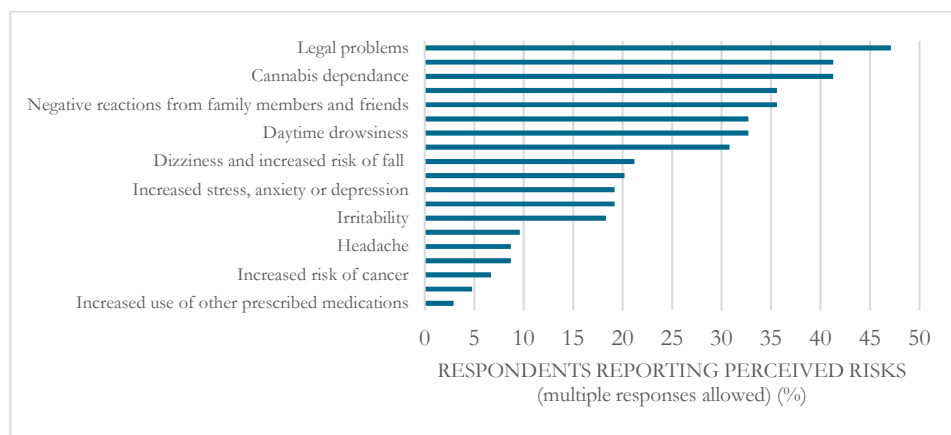


Figure 2: Perceived Risks and Concerns of cannabis

A substantial majority (97%) of participants supported legal reforms permitting the cultivation and possession of cannabis for medical purposes, while 87% endorsed similar changes for limited personal use. Additionally, 66% indicated a willingness to cultivate cannabis at home if legally permitted. Notably, 67% of respondents stated that legalizing cannabis in Slovenia would not lead to increased use among young people. Among participants who used cannabis for recreational or personal reasons, most reported minimal adverse effects (Figure 3). They largely did not engage in problematic behaviors, experienced little difficulty reducing their cannabis use when desired, and noted that family or friends had not expressed concern about their consumption.

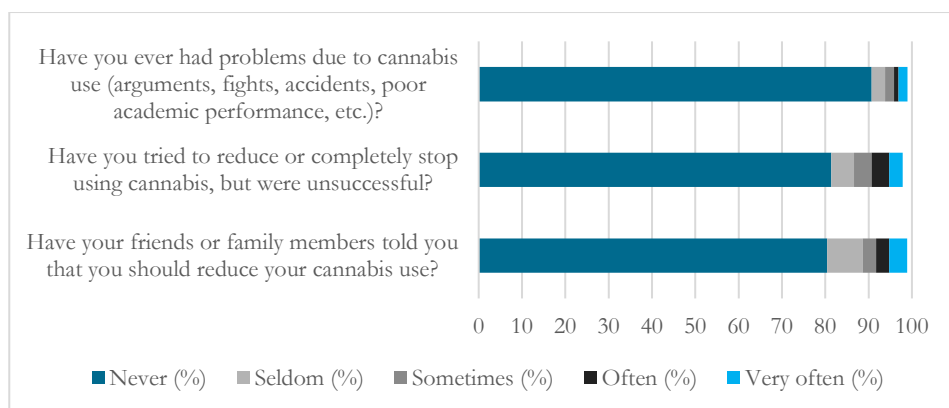


Figure 3: Self-reported problems using cannabis.

3.4 Sources of Information and Trust Regarding Medical Use of Cannabis

Only 44% of participants reported initiating a conversation with a medical doctor regarding the potential use of cannabis for medical purposes. Among those who did engage in such discussions, the majority described the experience as either pleasant or neutral, while 25% found the interaction unpleasant (Figure 4). Half of the respondents (50%) perceived the healthcare professional as being well-informed about medical cannabis. In terms of informational outcomes, 27% stated that they received all the necessary information, 25% felt the conversation was satisfactory but incomplete, and 48% reported receiving either no information or information they believed to be inaccurate.

Participants reported relying on a variety of sources for information related to the medical use of cannabis (Figure 4). The most frequently cited source was expert literature, such as books and research papers (19%), followed by consultations with medical specialists (e.g., oncologists, neurologists) and web pages of non-governmental organizations (NGOs) involved in cannabis-related activities (both 13%). Other commonly referenced sources included patients being treated for similar conditions (10%), cannabis shops including online vendors (10%), search engines (10%), and miscellaneous sources (10%). Fewer respondents indicated receiving information from primary care physicians (6%), friends or family members (5%), or social platforms such as forums and blogs (4%). Reliance on nurses or other

healthcare practitioners, black market sellers, and official government or public health institution websites was notably low (2% or less).

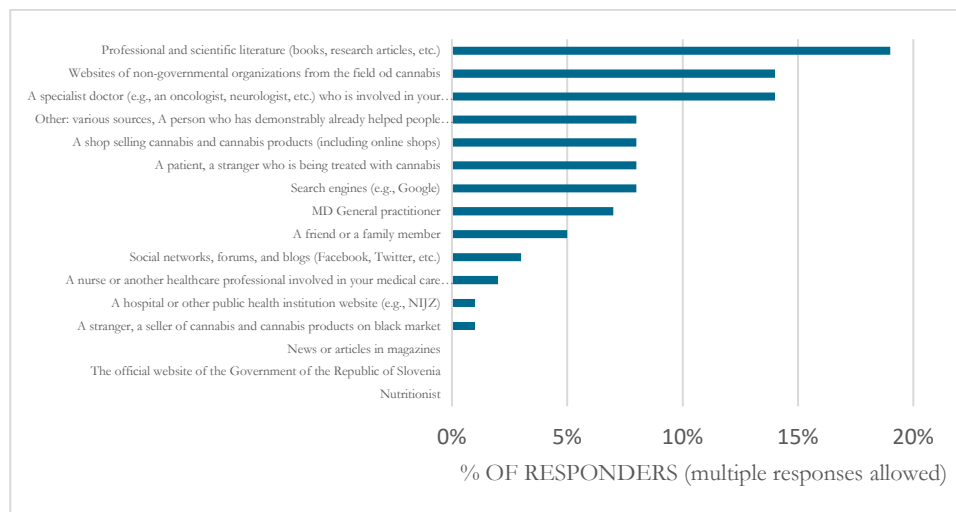


Figure 4: Reported sources of information about medical cannabis among survey participants.

3.5 Medical Versus Non-medical Cannabis Users

Further descriptive analysis revealed meaningful differences between respondents who reported using cannabis primarily for medical purposes and those who reported non-medical or recreational use. Medical users were more likely to endorse therapeutic benefits across multiple domains, particularly pain management, sleep improvement, and anxiety relief. They also reported stronger agreement with normative statements supporting the legitimacy of cannabis as a medical therapy for chronic and treatment-resistant conditions. In contrast, non-medical users were somewhat more likely to frame cannabis use in terms of general well-being and relaxation, though support for medical access remained high across both groups. Medical users were also more likely to perceive legal ambiguity as a significant concern. Despite using cannabis for health-related reasons, many reported uncertainties regarding legal protections, eligibility criteria, and acceptable modes of access. This suggests that medical motivation alone does not mitigate legal anxiety in the absence of clear institutional guidance. At the same time, medical users were

more inclined to seek information from expert literature, NGOs, and medical specialists, reflecting greater engagement with formal knowledge sources even when clinical support was perceived as limited. In terms of disclosure, respondents using cannabis for medical purposes were more likely than non-medical users to initiate conversations with healthcare professionals. However, they also reported higher dissatisfaction with the outcomes of these interactions, frequently describing the information received as incomplete or unreliable (Table 3). This pattern underscores a paradox in which those most motivated to engage with formal healthcare structures encounter the greatest informational barriers.

Table 3: Interaction with healthcare professionals regarding medical cannabis.

	Category	n	%
Communication experience (n = 173)	Extremely unpleasant	17	10
	Somewhat unpleasant	26	15
	Neutral	65	38
	Somewhat pleasant	27	16
	Extremely pleasant	38	22
Discussed with healthcare professional (n = 214)	Yes	94	44
	No	120	56
Satisfaction with information (n = 93)	Received all necessary information	25	27
	Received partial information	23	25
	Received some information but dissatisfied	16	17
	Received no useful information	29	31
Perceived healthcare professional knowledge (n = 92)	Yes (well-informed)	46	50
	No (not well-informed)	46	50

3.6 Legal Uncertainty, Disclosure, and Information-Seeking Behavior

Across the sample, legal uncertainty emerged as a central organizing factor shaping disclosure behavior and information-seeking practices. Nearly half of respondents identified legal problems as a major concern related to cannabis use, and a substantial majority reported knowing at least one person who had experienced legal consequences due to cannabis. This indirect exposure to legal enforcement appears to contribute to heightened risk perception, even among individuals who support legalization and perceive medical benefits. Only 44% of respondents reported

discussing medical cannabis with a physician. Among those who did not initiate such discussions, common implicit barriers included fear of negative judgment, uncertainty about legality, and doubts regarding physicians' knowledge. Respondents who described previous clinical interactions as unpleasant or uninformative were markedly more likely to rely on non-institutional information sources, including search engines, peer networks, NGOs, and cannabis retailers. Official government or public health websites were among the least frequently cited sources of information. These patterns indicate that legal ambiguity and limited professional guidance may indirectly redirect patients toward informal knowledge systems. Rather than functioning as a gateway to regulated medical access, the healthcare encounter appears, for some respondents, to reinforce reliance on alternative sources perceived as more practical or responsive. Taken together, these findings illustrate how uncertainty in legal and clinical frameworks can shape not only attitudes toward cannabis, but also concrete behavioral strategies for managing health, risk, and information.

4 Discussion

This study presents findings from the MEDCA survey, a public-focused sample of Slovenian adults with interest in or experience with medical cannabis. The results provide new insights into how medical cannabis is perceived in Slovenia, including perceived benefits and risks, trust in information sources, and public readiness for policy reform. Where relevant, the MEDCA findings were contextualized by comparison with prior national surveys and oncology-focused studies conducted in Slovenia. Support for medical cannabis was exceptionally strong among MEDCA respondents, with 97% endorsing legal reform to allow cultivation and possession for medical use and 87% supporting limited personal use. These levels of support exceed those reported in earlier Slovenian studies, including an oncology patient sample (84%) (Červek & Červek, 2023) and a national public opinion survey conducted in 2020, in which approximately 80% of respondents supported medical cannabis either conditionally or in general terms (Centre for Public Opinion and Mass Communications, 2021). Results from the 2024 national referendum, in which 66.7% of voters supported legalization of cultivation for medical purposes (State Election Commission, 2024), further suggest a broader societal shift toward acceptance. The higher support observed in the MEDCA sample may reflect continued evolution of public attitudes, but also likely indicates greater cannabis-

related familiarity and engagement among respondents. This interpretation is reinforced by the finding that 66% of participants would cultivate cannabis at home if legally permitted and that 81% reported prior or current cannabis use, suggesting a more empowered and self-directed stance than that observed in general population samples.

Across the survey, symptom relief emerged as the dominant narrative shaping perceptions of medical cannabis. Respondents primarily framed cannabis as a means of managing chronic pain, sleep disturbances, and anxiety or stress, rather than as a curative therapy. This pragmatic orientation aligns closely with international evidence indicating that patients most commonly seek cannabis to improve quality of life during chronic or serious illness (Waldron et al., 2023, pp. 1-5; Camberos-Barraza et al., 2023). This symptom-focused framing may also help explain why most respondents reported few adverse consequences of use, minimal difficulty regulating consumption, and little concern expressed by family or peers. Similar associations between therapeutic motivation, perceived legitimacy, and reduced stigma have been documented in studies from Mexico, New Zealand, and the United States (Camberos-Barraza et al., 2023; Boden et al., 2020, pp. 80-84; Spilka et al., 2013; Dowd et al., 2023, pp. 3-12).

At the same time, the MEDCA findings highlight how legal ambiguity surrounding medical cannabis in Slovenia is experienced as a social and clinical condition rather than merely a regulatory technicality. Although cannabis is formally permitted for restricted medical use, respondents continued to report uncertainty regarding legality, access pathways, and professional endorsement. Nearly half identified legal concerns as a primary risk, a proportion exceeding those who expressed concern about serious health effects. This suggests that perceived risk is shaped less by biomedical harm than by uncertainty about enforcement, stigma, and professional or occupational consequences. In this sense, legalization appears to function symbolically rather than operationally, signaling permissibility without providing sufficient clarity for consistent practice.

The study also reveals a pronounced trust-knowledge gap between patients and healthcare professionals. Although physicians and pharmacists were identified as the most trusted sources of information, only one-third of respondents felt that their doctors were well informed about medical cannabis. Among those who initiated

clinical conversations, nearly half reported receiving no useful or reliable information, and one-quarter described the interaction as unpleasant. These findings mirror patterns reported in other countries where legalization has outpaced professional education and institutional guidance (Hordowicz et al., 2021, pp. 2-8; Ziemianski et al., 2020, pp. 1-10; Hossain & Chae, 2024, pp. 2-6). Importantly, the gap does not necessarily indicate professional opposition, but rather reflects structural constraints, including limited training, unclear liability frameworks, and the absence of authoritative national guidelines.

As a consequence, informational authority appears to shift away from formal institutions toward informal networks and digital sources. Respondents reported greater reliance on search engines, peer networks, NGOs, and even informal market actors than on official government or public health websites. This misalignment between institutional authority and perceived informational relevance signals a broader credibility challenge for public health institutions. Similar erosion of trust in official sources has been observed in jurisdictions where regulatory ambiguity leaves patients and caregivers searching for accessible, experience-based guidance (Waldron et al., 2023, pp. 2-4; Camberos-Barraza et al., 2023; Boden et al., 2020, pp. 79-24). Over time, such dynamics risk normalizing medical cannabis use outside formal healthcare systems, potentially undermining both patient safety and regulatory oversight.

The examined differences between medical and non-medical cannabis users further illuminate how legal ambiguity and institutional readiness shape lived experience. Respondents who used cannabis for medical purposes demonstrated higher engagement with formal knowledge sources and were more likely to seek interaction with healthcare professionals. Paradoxically, they also reported greater dissatisfaction with clinical encounters and heightened concern regarding legal uncertainty. This suggests that medical motivation does not translate into greater regulatory security; instead, it may increase exposure to institutional gaps, as medically motivated users actively seek guidance that the healthcare system is not yet equipped to provide. In this sense, the group most aligned with formal medicalization appears to bear the greatest burden of ambiguity.

Patterns of disclosure and information-seeking behavior further underscore the socio-legal consequences of incomplete implementation. Fear of legal repercussions, combined with uncertainty about professional competence, appears to discourage open communication with healthcare providers and redirects patients toward informal or semi-formal sources of information. Rather than functioning as a gateway to regulated medical access, the clinical encounter may operate as a filtering point where patients reassess the practical value of institutional authority and adapt their strategies accordingly.

Importantly, the prominence of legal anxiety, even among respondents who support legalization and perceive substantial medical benefit, highlights the distinction between symbolic legality and operational security. Legal reform without clear procedural translation may normalize cannabis use socially while simultaneously maintaining a climate of uncertainty and self-regulation. The MEDCA findings thus suggest that public support and personal experience alone are insufficient to stabilize medical cannabis governance.

Overall, Slovenia's medical cannabis framework appears characterized by high public readiness but limited institutional integration. Strong support for legalization should therefore not be interpreted solely as social approval, but also as an expression of unmet demand for coherent governance, professional engagement, and trustworthy communication. Addressing these gaps will require aligning legal frameworks with clinical education, clear prescribing and dispensing guidance, and credible public information strategies. Without such alignment, legalization risks remaining aspirational rather than translating into equitable and well-regulated medical practice.

5 Policy Implications

Although Slovenia reclassified cannabis from Schedule I to Schedule II controlled substances in 2016, the findings of this study suggest that policy reform remains poorly integrated into clinical systems and public understanding. Despite widespread societal support for medical cannabis and growing familiarity among citizens, participants continued to encounter barriers in accessing accurate, evidence-based information and navigating legally sanctioned medical pathways. Even within the MEDCA sample, which likely represents a relatively motivated and health-literate subset of the population, respondents reported fragmented guidance, limited

physician engagement, and persistent uncertainty regarding legal responsibilities and clinical eligibility. These patterns point to a structural trust–knowledge gap that extends beyond individual attitudes and reflects broader systemic challenges within Slovenia’s healthcare and regulatory frameworks.

From a policy perspective, addressing this gap requires a shift from symbolic legalization toward active institutional implementation. Professional education in cannabinoid science should be systematically incorporated into medical, nursing, and pharmacy training, enabling healthcare providers to engage confidently with patients and to interpret legal provisions consistently within clinical practice. In parallel, developing clear national guidance on prescribing, dispensing, and patient counseling would reduce professional hesitation and variability in care. Public-facing communication strategies should also be strengthened, prioritizing accessible, digital, and evidence-based platforms that reflect contemporary health information-seeking behavior and reinforce the credibility of official institutions. Finally, patient perspectives - particularly those of individuals living with chronic or treatment-resistant conditions - should be formally embedded in policy design, implementation, and evaluation processes. Such participatory approaches can enhance transparency, rebuild institutional trust, and ensure that evolving medical cannabis frameworks align legal intent with clinical practice and societal expectation. Aligning these measures with broader European policy initiatives would further support Slovenia’s transition toward an evidence-based, patient-centered model of medical cannabis governance.

6 Limitations

This study is based on a non-probabilistic, self-selected sample obtained via online snowball distribution. The MEDCA cohort may overrepresent individuals with favorable attitudes toward cannabis. Online recruitment may underrepresent older adults or individuals with limited digital access, which should be considered when interpreting population-level implications. All data are self-reported and may be influenced by recall or social desirability bias. Importantly, comparisons with oncology and national survey data are used for contextual reference only, as those data were obtained from independent studies and not collected within the scope of this research. Despite these limitations, the MEDCA results meaningfully contribute

to understanding cannabis perception in Slovenia and reveal substantial public readiness for more transparent, inclusive cannabis policy and education.

7 Conclusion

This study offers the first comprehensive insight into Slovenian public attitudes toward medical cannabis, based on original data from the MEDCA survey. Participants demonstrated exceptionally high support for legalization (97%), a strong belief in the therapeutic value of cannabis (94%), and primarily symptom-driven motivations for its use, particularly for chronic pain (89%), sleep disturbances (87%), and mental health concerns such as stress and anxiety (85%). Despite this overwhelming support, participants frequently encountered informational and institutional barriers, including unclear legal pathways, limited physician engagement, and a reliance on informal or non-institutional sources of information. Compared with prior Slovenian oncology and national surveys, individuals with higher familiarity with cannabis, whether through personal experience or clinical exposure, were significantly more likely to view it as effective, safe, and deserving of policy reform. However, the persistence of a trust, knowledge gap between patients and healthcare providers, coupled with low public confidence in government information sources, underscores the urgent need for coordinated efforts in professional education, clear public health communication, and patient inclusion in policymaking. As Slovenia enters a pivotal phase of revising its cannabis legislation, aligning legal frameworks with institutional readiness and public expectations will be critical. These findings can inform targeted educational campaigns, clinical training programs, and regulatory reforms, not only in Slovenia, but also in other transitional jurisdictions navigating the complex shift from prohibition toward therapeutic integration.

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Povzetek v slovenskem jeziku

Odnos javnosti do medicinske konoplje igra pomembno vlogo pri oblikovanju regulativne prakse in vključevanju novih terapij v zdravstvene sisteme. Spletna raziskava med slovenskimi odraslimi (n = 226) je preučevala dožemanje medicinske konoplje v okviru pravne nejasnosti in omejenih institucionalnih smernic. Podpora legalizaciji je bila visoka, vendar so anketiranci pogosto poročali o nejasnem razumevanju, kaj trenutna zakonodaja dovoljuje, ter o omejenem zaupanju v točnost informacij, ki so jih prejeli od zdravstvenih delavcev. Udeleženci so se v veliki meri zanašali na neuradne in spletne vire, kar poudarja vrzeli v jasnosti predpisov in strokovni pripravljenosti. Izsledki poudarjajo potrebo po jasnih pravnih okvirih, izboljšani klinični usmeritvi in preglednejši komunikaciji, kar bi prispevalo k usklajenosti pričakovanj javnosti z medicinsko in pravno prakso v Sloveniji.

THE NEW EUROPEAN UNION LEGAL FRAMEWORK ON DEFECTIVE DIGITAL MEDICAL DEVICES: ALLEVIATING THE PATIENT'S BURDEN OF PROOF

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Abstract Digitalisation has changed the medical sector, introducing sophisticated digital medical devices (such as software as a medical device and devices assisted by Artificial Intelligence systems). Innovations in medicine present potential for improving diagnosis and treatment. Simultaneously, they raise certain questions about civil liability and the legal position of the patient who has suffered harm caused by a defective digital product. This paper examines whether the modernized EU liability rules for defective digital medical devices can alleviate the evidentiary burden patients face in civil litigation, thus strengthening their position. The author focuses on the adequacy of the new rules on disclosure of evidence and burden of proof. The key findings show that the new rules strengthen patients' position by alleviating the burden of proof and imposing an obligation to disclose relevant evidence. The author proposes drafting guidelines to resolve existing ambiguities, ensuring the new evidentiary framework is applied consistently and effectively.

Keywords

burden of proof,
defective digital medical
device,
Directive (EU)
2024/2853 on liability
for defective products,
disclosure of evidence,
patient

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1 Introduction

The application of digital technologies in medicine offers many benefits. At the same time the use of digital medical devices can present risks to life, health, or property. Digitalization is perceived as the main factor in the global transition from traditionally industrial to digital, based on technology model (Zhao, Wallis & Singh, 2015, p. 734). It has been noted that the COVID-19 pandemic further accelerated the digital transformation of healthcare (Wickramasinghe, 2024, p. 2). AI systems are often believed to be able to make decisions faster and more accurately than human practitioners. This has led to their widespread implementation across the medical field (Devenney & Howells, 2025, p. 118). AI applications and other digital technologies are often recognized to be able to significantly improve healthcare, making delivery more efficient, accurate, and personalized (Steinhauser, 2025, p. 87). However, like any powerful technological change, digitalisation introduces significant risks and perils associated with the use of defective digital medical products. One such risk is the risk of harm a patient may suffer due to a defective digital medical product. Under such circumstances, the existing product liability system was increasingly struggling to keep pace with rapid technological development. This has created significant legal inconsistencies and uncertainty in this specific legal area (Gsell & Mayrhofer, 2025, p. 205).

The European legislator identified the need for reform, given recent tech advances, new circular economy business models and new global supply chains. Therefore, the European Union has recently established a comprehensive regulatory framework consisting of the Medical Devices Regulation,¹ Regulation (EU) 2024/1689,² Product Liability Directive³ and Regulation (EU) 2024/2847 on cybersecurity for products with digital elements⁴ and AI Act to govern the safety and accountability

¹ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC OJ L 117 (hereinafter: MDR).

² Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) OJ L, 2024/1689 (hereinafter: AI Act).

³ Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products and repealing Council Directive 85/374/EEC OJ L, 2024/2853 (hereinafter: PLD).

⁴ Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act) OJ L, 2024/2847 (hereinafter: CRA).

of digital medical devices. The new PLD came into force in 2024. The Member States must implement the new PLD rules into their national laws by December 2026. Patients currently face significant hurdles when claiming compensation for defective medical devices. These difficulties stem from restrictive rules and the complexity of proving liability, especially new technologies (Recital 3, PLD). To address this, the PLD introduces major reforms. Among its key changes are mechanisms of disclosure of evidence and rebuttable presumptions regarding defect and causation. The new measures are aimed at adjusting the standard of proof to be less demanding for the patient as a claimant.

There is a significant existing literature on defective product liability in the EU. The aim of the paper is to complement the field by employing both normative dogmatic and comparative methods. This paper examines whether modernized EU rules on liability for defective digital medical devices can ease the evidentiary burden patients face in civil litigation. It provides a critical assessment of the former and current regulatory frameworks for defective digital medical devices. By comparative analysis of the European Union and Croatian case law, the paper also examines judicial standards of interpretation concerning the patient's evidentiary burden and the legal definition of product defectiveness. The central part of the paper examines the newly enacted mechanisms for the disclosure of evidence and rebuttable presumptions, providing a comparative analysis of the standard of proof under the previous and new PLD regimes. Implementation challenges and potential legal uncertainties surrounding these mechanisms are also being addressed. Finally, the concluding section of the paper synthesizes the key findings of this research.

2 Legal Framework for Medical Digital Products

2.1 Digital Medical Devices Under the MDR

A regulatory framework in the European Union was developed to guarantee that medical devices meet safety and performance standards before being placed on the market. In the European Union, the governance of medical products is primarily managed by MDR. This regulation established stringent new rules focusing on enhancing the safety, traceability, and overall compliance of medical devices throughout Europe. These regulations are typically structured around the risk a device poses to the patient. The framework is designed to guarantee patients access

to high quality, safe, and effective devices. In the European Union, this is achieved through an integrated system of premarket safety requirements and post market monitoring and reporting duties, whereby the responsibility for safety and reporting is shared among manufacturers, certification organizations, and competent national authorities (Cappelli, 2024, p. 531). The MDR defines a medical device as any instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer to be used for medical purposes such as diagnosis, prevention, monitoring, treatment, or alleviation of disease (MDR, Article 2(1)). It requires that all medical devices meet the general safety and performance requirements detailed in Annex I.⁵ Devices must be designed and made to perform as intended without jeopardizing the safety of patients or users. Furthermore, the regulation enhances transparency and traceability through provisions like the mandatory Unique Device Identification (UDI) system (Article 27), ensuring authorities and the public have better access to vital device information and post-market surveillance data.

Regulation (EU) 2017/746,⁶ or the In Vitro Diagnostic Medical Device Regulation (hereinafter: the IVDR), represents a revision of the European Union's legal framework of in vitro diagnostic products that imposes stricter requirements for the safety and efficacy of those products. The legislation requires specified person that would be responsible for compliance. Compliance is a prerequisite for institutional accountability. The IVDR introduces the Unique Device Identification (UDI) marking system to enhance transparency and traceability throughout the whole healthcare sector. It also mandates registration within the European Database on Medical Devices (EUDAMED),⁷ and the adoption of common specifications. What is more, manufacturers are liable to higher standards of maintaining clinical evidence and post market surveillance under the new rules of the IVDR.

⁵ MDR, Annex I, Section 3.

⁶ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance) OJ L 117.

⁷ EUDAMED is, under Article 30 IVDR, a centralized secure IT system designed to improve transparency, traceability, and coordination of information regarding medical devices, including in vitro diagnostics on the European Union market.

In 2025, the European Commission introduced a new regulatory proposal aimed at simplification of the existing MDR and IVDR. This initiative, which represents the most significant reform since the original adoption of these regulations, is designed to make the regulatory environment more efficient, agile, and digital-first while maintaining a high level of patient safety. As a core component of the broader Choose Europe for Life Sciences⁸ strategy, the reform seeks to bolster the European Union's global standing. For the pharmaceutical and biotech sectors, this transition promises a substantial reduction in administrative hurdles, particularly for the development of companion diagnostics and combination products. Moving forward, the proposal will enter the ordinary legislative procedure, where it will undergo review and potential amendment by the European Parliament and the Council. The European Union has established a comprehensive and symbiotic regulatory framework consisting of the PLD, the CRA, and the AI Act to govern the safety and accountability of high-risk AI systems and other digital medical devices. The AI Act sets a foundational standard for safety and quality, while the revised PLD ensures that failures to meet this standard result in effective compensation for injured patients. The PLD and the AI Act complement the MDR, as discussed in the next section.

3 The MDR'S Interplay with Other European Union Regulations

3.1 New Liability Rules for Defective Products Under the PLD

The New PLD represents a fundamental overhaul of European product liability rules, replacing the outdated Directive 85/374/EEC (hereinafter: PLD 1985).⁹ The PLD aims to address the shortcomings of PLD 1985 and to modernize the European Union's product liability law. That way the rules would become relevant for the digital age, circular economy practices, and suitable to complex global supply chains (De Luca, 2023, p. 1). It is suggested that the new PLD modernizes and broadens the liability framework but retains the core principle of strict producer defective product liability (Masnada et al., 2024). The new PLD addresses several

⁸ Choose Europe for Life Science is a flagship strategy launched by the European Commission in July 2025. It serves as a comprehensive roadmap to restore Europe as a global leader in health, biotechnology, and medical technology by the year 2030. Retrieved from: https://research-and-innovation.ec.europa.eu/strategy/strategy-research-and-innovation/jobs-and-economy/strategy-european-life-sciences_en (accessed: December 30, 2025).

⁹ Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ L 210.

key questions. The questions include the classification of software as a product, liability distribution within complex supply chains, and the mitigation of procedural hurdles for patients (Devetzis, 2025, p. 112). The new legislation expands the definitions of both product and product defectiveness to better adjust to product digitalisation. The new PLD, therefore, allows to hold manufacturers liable for damages caused by an AI based defective product (Asensio, 2024, p. 89). Under the PLD 1985 product was defined unfairly narrow, essentially as movable goods and electricity (Lee & Schutte, 2023, p. 592). The new PLD's expanded product definition now captures many digital features of the product. It encompasses software (from standalone mobile apps to embedded operating systems) and an AI system, independently or as integrated components. The definition further encompasses digital production files, provided they contain the functional information required to manufacture a physical item. It also covers digital connected services that are so integral to a product that it would lose its core functions without them.

PLD integrates cybersecurity failures directly into the definition of defectiveness. A product is, therefore, considered defective if it does not provide the safety level a person is entitled to expect, considering, among other factors,¹⁰ the cybersecurity requirements and features of the product (Article 7(2)(f)). This liability is not limited to the point of sale. Manufacturers are also liable if the defect is caused by a failure to provide necessary software updates or upgrades, including addressing cybersecurity vulnerabilities, where they retain control over such updates (Article 7(2)(e)). This aligns with the obligations established in The MDR Annex I establishes obligation for manufacturers to manage information security to prevent any unauthorized access. While the core definition of defectiveness remains somewhat vague (Howells, Spindler & Wilhelmsson, 2020, p. 150), others argue that the product definition is just as ambiguous. Such ambiguity is unavoidable because judges must assess each situation on an individual basis (Machnikowski, 2024, p. 42).

The PLD expands manufacturer liability for defective digital products. Manufacturers can now be held accountable for damage resulting from a product defect caused by insufficient cybersecurity, thereby encompassing the risks of the

¹⁰ Article 7 of the PLD also defines other criteria for determining whether a product is defective. These criteria include an assessment of its design, labeling, foreseeable use, and any post-market updates or interconnections with other products. A product is not considered defective because a newer or superior version has been released.

contemporary digital environment. Furthermore, liability is no longer limited to the moment the product is placed on the market, it also extends to failures in issuing software updates or upgrades if these failures subsequently cause a defect. Regarding compensation, the PLD, for the first time, ensures that the destruction or corruption of data used for private purposes caused by a defective digital product is now recoverable damage. In this way, the PLD ensures the application of the principle of strict liability across the entire supply chain, consistently integrating digital elements which are an integral part of nearly every modern product into the legal liability framework. Additionally, the minimum financial threshold of €500 for property damage is abolished, making it easier to pursue damages, including potential mass actions. Simultaneously, the list of entities strictly liable for damages has been substantially expanded; in addition to manufacturers and importers, it now includes fulfillment service providers and online platforms in cases where they mislead consumers about the identity of the actual supplier. This expanded liability aims to hold all relevant economic operators accountable, especially given the continuous nature of digital products, where manufacturers retain control even after the initial placement on the market through updates. The PLD also introduces a significant change that, in our opinion, weakens the development risk defense for manufacturers (Article 11(e) of the PLD). The development risk defense, or the unknown risk exception is the manufacturer's argument that the defect was unknowable at the time the product was placed on the market, given the state of scientific and technical knowledge. The new PLD still lists the development risk defense as one of the circumstances where a manufacturer is exonerated from liability. However, the new PLD explicitly allows Member States to decide whether to retain or abolish this defense when transposing the PLD into national law. If a Member State chooses to abolish it, a manufacturer operating in that country would be subject to absolute strict liability, removing this key defense completely (Article 18 of the PLD). This optionality presents a significant issue, as it leads to legal fragmentation across the EU, potentially subjecting manufacturers to different liability standards depending on the Member State. Ultimately, the construction of Article 18 of the PLD can be interpreted as a compromise between individual protection and the need for scientific innovation. It principally preserves the development risk defense, but its optional nature might result in unnecessary legal fragmentation. This lack of full harmonization is a deficiency that needs to be addressed. In our opinion, such fragmentation undermines the goal of an internal single market and creates uncertainty for both consumers and producers.

The PDL operates in parallel with existing national contractual and non-contractual liability rules as it is not intended to replace them. Consequently, individuals harmed by defective medical devices may choose to seek compensation through national legal system. Because of this, we expect that the actual legal outcome will, in the future, still vary considerably, depending on which country the claim was filed in.

3.2 Cybersecurity as an Essential Digital Medical Devices Safety Requirement

The CRA makes cybersecurity an essential part of product safety for all digital devices. This new requirement works in tandem with the expanded definition of a defective product found in the PLD. Once the CRA has full effect, manufacturers must guarantee that every product with a digital element is protected against cyber threats. Some experts argue that under the CRA manufacturers now must incorporate strong cyber protection onto digital products. This should be based on potential risk assessment. Crucially, they must also provide regular updates to those cyber protections to maintain continuous product cyber security (Schoo, 2024, p. 245). The digital transformation in medicine resulted in a complex system of interconnected digital devices. While such digital medical product connectivity offers enhanced precision, it simultaneously introduces new risks of physical harm to patients' health and life. In this context, the CRA mandates are not just another technical feature. They are crucial for the patient's safety. Under Article 6 of the CRA and Annex I, product safety now includes security by design, the elimination of exploitable vulnerabilities and the preservation of data integrity. Furthermore, the CRA requires that manufacturer manages said vulnerabilities and provide continuous security updates. Otherwise, the CRA enforces heavy fines to ensure the product's cybersecurity requirements are met.

3.3 Compliance Standards for Digital Medical Devices under the AI Act

Incorporating AI systems into medical devices promises personalized and improved healthcare for patients (Braun & Harasimiuk, 2023, p. 1). However, its integration in medical devices raises significant ethical questions that need to be addressed (Bertarini, 2023, p. 82). The AI Act supplements the MDR and introduces an additional set of standards necessary for the secure use of digital medical devices with integrated AI systems. Under the AI Act, medical devices with integrated AI

system require third-party conformity assessment (as regulated under the MDR). Such medical devices are classified as high risk, which triggers strict compliance obligations. Therefore, manufacturers must maintain a continuous product risk management system, as mandated by Article 9 of the AI Act. Failure to comply with these provisions can be directly interpreted as evidence of a defect under the new PLD. Under Article 10, the AI Act imposes strict data governance requirements. These provisions mandate high standards for training, validation, and testing datasets. Poor-quality data leads to flawed analytics, such as misdiagnosis. This can form a basis for a liability claim. Furthermore, human oversight obligations for high-risk artificial intelligence systems (Article 14 of the AI Act) as well as an obligation to maintain detailed technical documentation (Article 11 of the AI Act), record keeping (Article 12 of the AI Act) and logging capabilities (Article 19 of the AI Act) are not merely compliance paperwork for manufacturers. These provisions could represent essential pieces of evidence for plaintiffs pursuing legal action. The new PLD rules on liability supplement, but do not replace the strict safety requirements established by the MDR. The MDR ensures the *ex ante* compliance of digital medical devices with quality, safety, and performance requirements before they are even placed on the market. Failures to comply with the MDR and the CRA, therefore, will be a strong indicator of product defectiveness under the PLD. Violations of a manufacturer's obligations under the AI Act may facilitate the proof of defectiveness and causation in court, as explored further in this paper.

4 Patients' Standard of Proof Under the European Union Legal Framework on Liability for Defective Digital Medical Devices

After nearly 40 years the European Union updated its product liability framework in 2024. The new PLD aims to ease the evidentiary burden for patients when establishing manufacturer liability in compensation claims. Prior to examining how the patient's standard of proof has changed under the new PLD rules, we will provide an overview of the patient's position in court proceedings under the PLD 1985., Croatian Obligations Act¹¹ and relevant European and national case law.

¹¹ Obligations Act, Official Gazette, no. 35/2005, 41/2008, 125/2011, 78/2015, 29/2018, 126/2021, 114/2022, 156/2022, 145/2023, 155/2023.

4.1 Patients' Standard of Proof Under the PLD 1985

Moving away from traditional medical litigation that required proof of negligence, the PLD 1985 introduced a strict liability framework under Article 1, holding manufacturers accountable for damages regardless of whether intent or fault can be proven. According to some scholars, the application of the concept of manufacturer's strict liability for damage caused by a defective product, independent of fault, is the most significant innovation introduced by PLD 1985 (Misita, 2019, p. 369). This protection is supported by Article 2 of the PLD 1985, which classifies products as all movables, including those incorporated into other movable or immovable properties. The definition specifically extends to electricity.¹² Under Article 4 of the PLD 1985, the burden of proof rested on the injured patient, who had to successfully demonstrate the existence of a defect, the resulting damage, and a clear causal link between the two. However, once these elements were established, the manufacturer was held liable by default, removing the nearly impossible requirement for an individual to prove specific intent or negligence. The main practical evidentiary challenges for the injured patient were the defendant's practice of retaining technical documentation and design specifications. The patient often lacked specialized knowledge and resources to prove the defect. In the case of technically complex products or pharmaceuticals, it was virtually impossible to isolate the exact defect that caused harm. Furthermore, scientific uncertainty magnified the patient's difficult position, as it was rather challenging to prove that a specific product had caused the sustained damage in situations when there was no scientific consensus on the matter.

In several judgments, the Court of Justice of the European Union (hereinafter: the CJEU) established the use of indirect evidence and a rebuttable presumption of defect, bypassing the rigid PLD 1985 requirements associated with the burden of proof. In the *Boston Scientific case*¹³ the CJEU, exploring ways to ease the burden of proof in complex product cases, ruled that if a specific batch or model of a product

¹² In *VT v KRONE-Verlag case*, the CJEU rejected the idea that inaccurate health advice in a newspaper constitutes a "defective product" under the PLD 1985. The case concerned a physical newspaper that published inaccurate health advice regarding a herbal treatment, which subsequently caused physical injury to a reader. The CJEU reasoned that the defect must be inherent to the physical characteristics of the product itself (such as the paper or ink) rather than the intellectual content or service provided within it. Judgment of 10 June 2021, C-65/20, *VT v KRONE-Verlag Gesellschaft mbH & Co. KG*, ECLI:EU:C:2021:471, paras. 34–36.

¹³ Judgment of 5 March 2015, Joined Cases C-503/13 and C-504/13, *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt*, ECLI:EU:C:2015:148.

(such as a pacemaker) has a significantly high failure rate, every individual unit in that group can be legally classified as defective. Consequently, a patient does not need to prove that their specific device was actually broken or malfunctioning, the potential risk inherent to the product group is enough to establish a defect under the law.¹⁴

One of the most significant cases regarding the patient's burden of proof (under the PLD 1985) is the *W and Others v Sanofi Pasteur case*¹⁵ (C-621/15), which centered on the alleged link between a hepatitis B vaccine and the onset of multiple sclerosis. The central legal challenge arose from the lack of a definitive scientific consensus regarding the connection between the vaccine and the disease. In its ruling, the CJEU held that national courts may accept evidence based on serious, specific, and consistent indicia to establish causation. The CJEU held that if the link between the administration of a vaccine and a suspected side effect is neither proven nor disproven as a matter of medical science, then no inferences can be drawn about its existence for the purposes of adjudication.¹⁶ A requirement of scientific proof would be contrary to the objective of the PLD to apportion risks fairly between the injured person and the producer.¹⁷

European case law, as is evident from examples above, has made it considerably easier for the injured person to demonstrate a causal link between the product defect and the damage. The condition outlined by the CJEU is that such alleviation does not undermine the PLD 1985 provision that places the burden of proof on the injured person and that the free assessment of evidence by the courts must be preserved.¹⁸

The rules on liability for defective products from PLD 1985 have been transposed into the Croatian Obligations Act. Under the provision of Article 1073(1) of Obligations Act a manufacturer who places a product on the market is liable for damage caused by a defect in that product, regardless of fault. The burden of proof is regulated according to the provision of Article 1073(8) of Obligations Act, which rests with the injured patient. To be entitled to compensation for damages, the

¹⁴ *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt*, paras. 39-41.

¹⁵ Judgment of 21 June 2017, C-621/15, *N. W and Others v Sanofi Pasteur MSD and Others*, ECLI:EU:C:2017:484.

¹⁶ *N. W and Others v Sanofi Pasteur MSD and Others*, para. 55.

¹⁷ *N. W and Others v Sanofi Pasteur MSD and Others*, para. 32.

¹⁸ *N. W and Others v Sanofi Pasteur MSD and Others*, para. 54.

patient is required to prove the defect in the product, the damage incurred, and the causal link between the product's defect and the damage. Croatian judicial practice further affirms these requirements through established interpretive standards. For instance, The County Court in Zagreb held that a patient is not required to prove the fault of the physician or the manufacturer if the damage resulted from a defective medical device. The Court accepted the existence of a causal link based on the entirety of the medical documentation and the expert witness findings. Evidence also included official correspondence and registries. The Court maintained that any challenges to the causal link that lack firm evidence do not affect the legality of the judgment. Also, the Court stated that the manufacturer's liability is based on the principle of strict liability, without the need to prove fault.¹⁹ In another case, the Supreme Court of the Republic of Croatia emphasized that the injured patient must prove the product defect, the damage, and the causal link. However, in this particular case, the claimant failed to prove that the endoprosthesis she used to be defective, nor did she prove a causal link between the defect and the resulting damage. The lack of evidence regarding the defect and the product's withdrawal from the market led to the dismissal of the claim. The Court also highlighted the importance of precisely determining the safety of the specific product in relation to its characteristics and the individual patient.²⁰

The new PLD introduces new rules regarding the disclosure of evidence in technically demanding cases and sets out rebuttable presumptions. The application of these presumptions is intended to alleviate the burden of proof for the injured patient, as it is further discussed below.

4.2 Patients' Standard of Proof Under the New PLD

The new PLD aims to place the patient in more favorable evidentiary position than under the PLD 1985 regime. While the fundamental principle of strict liability remains, the PLD introduces several mechanisms designed to overcome the difficulties patients historically faced in proving the defect, harm and the causal link. The most critical change to the patient's position is the introduction of rebuttable

¹⁹ Judgement of 3.6.2025, The County Court in Zagreb, case no. *Gž-133/2025-2*. Retrieved from: <https://www.iusinfo.hr/sudska-praksa/ZSRH2025ZgGzB133A2> (accessed: March 15, 2026).

²⁰ Judgement of 1.2.2023., The Supreme Court of the Republic of Croatia, case no. *Rev 1785/2019-2*. Retrieved from: <https://www.iusinfo.hr/sudska-praksa/VSRH2019RevB1785A2> (accessed: March 15, 2026).

presumptions regarding the defect and causation, as well as a disclosure mechanism. They are perceived as a shift in doctrine towards facilitating private enforcement of product liability-based claims (Jacquemin, 2024, p. 130). The presumption of defect (Article 10(2) of the PLD) is triggered if and when the defendant fails to comply with a court ordered disclosure obligation, or the damage results from an obvious malfunction during reasonably foreseeable use. The presumption of causation is triggered when the product is established to be defective, and the damage is of a kind typically consistent with that defect (Article 10(3) of the PLD). The patient's burden of proof is simplified in technically complex cases (Casarosa, Gennari & Rossi, 2025, p. 3). A court can presume defectiveness, causal link, or both in situations where the patient faces excessive difficulty in proving the defect or causation, (due to technical or scientific complexity of the product) and has demonstrated that the defect or causal link is likely (Article 10(4) of the PLD). The most debatable aspect of this presumption, in our opinion, is the lack of a clear definition of what constitutes excessive difficulty. Recital 48 of the new PLD does not provide closer guidelines on how this term should be interpreted. It only states that the assessment of the excessive difficulties should be made by national courts individually. This could, in our view, potentially undermine legal certainty. Similarly, some maintain that the rules on rebuttable presumptions explicitly rely on national courts to evaluate circumstances and apply presumptions discretionarily and case-by-case (Buiten, 2024, p. 241). Therefore, we believe that the issuance of interpretative guidelines regarding these vaguely defined terms would be highly beneficial. Such guidance would prevent divergent interpretations in similar cases.

The new PLD also introduces a disclosure mechanism (Article 9 of the PLD) aimed at facilitating patients' access to evidence. If a patient makes a sufficiently plausible claim for compensation, the national court can now oblige the defendant (the manufacturer) to disclose relevant and necessary evidence concerning the product's function, design, or production process. This, indeed, represents a major advantage for the patient as it forces the manufacturer to provide documents necessary to establish the defect or causation. We find these provisions particularly important for the medical digital devices sector. It is often very difficult for patients to understand or prove defects in complex digital systems, especially when technical documentation is often exclusively available to the manufacturer. The refusal to disclose evidence allows the court to presume the manufacturer's liability, serving as an effective mechanism to compel defendants to comply with disclosure orders. At

the same time, the manufacturer's obligation is limited to what is necessary and proportionate (Article 9(6) of the PLD). The legislator does not further specify the criteria for necessity and proportionality. Instead, access is limited to prevent non relevant searches and to ensure the protection of confidential data. There is, again, significant uncertainty regarding the effectiveness and the practical application of this provision. In the author's view, the lack of precision and the absence of a clear definition as to when a measure is deemed necessary and proportionate represent a significant deficiency. This ambiguity creates a risk of arbitrary interpretation and ultimately undermines legal certainty.

5 Conclusion

The use of digital medical devices enhances the accuracy of medical diagnoses and treatments by meeting the specific needs of individual patients. Thus, medicine becomes significantly more precise (Amaral et al., 2024, p. 20). However, all of this, simultaneously, exposes patients to novel risks that can result in damage. The European Union's response to the obsolescence of the product liability 1985 system was a comprehensive overhaul of its defective product liability framework. The new PLD structure is believed to permit adjustments to the new appearing risks (Steindl, 2024, p. 8). The findings of this research suggest that the new PLD, in conjunction with the MDR and the CRA strengthens the legal position of the injured patient. This is accomplished by broadening the definition of a product and its defectiveness, as well as establishing cybersecurity as a core product's safety requirement. Furthermore, the process is aided by simplifying the burden of proof in technically complex cases (Casarosa, Gennari & Rossi, 2025, p. 3). This paper examined the extent to which the modernized European Union liability regime alleviates the evidentiary burden faced by patients in civil litigation. The study showed that these updated rules effectively strengthen the patient's position by lowering the evidentiary threshold. By introducing evidence disclosure and easing the burden of proof with new rebuttable presumptions, the new PLD provides mechanisms that enhance procedural parity. Furthermore, practical implementation of these mechanisms could simplify the path for patients seeking compensation for damage caused by defective digital medical devices. Conversely, the certain ambiguity surrounding the presumptions of the burden of proof in technically complex cases may result in legal uncertainty and disparity in interpretations across national case laws. Therefore, we advocate for the introduction of guidelines on how to interpret the ambiguities

identified in certain provisions. The goal is to establish a framework that, by addressing these deficiencies, ensures the uniform interpretation of provisions and the full functionality of the new evidentiary mechanisms.

Legal Acts, Case-law

- Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products and repealing Council Directive 85/374/EEC OJ L 2024/2853.
- Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ L 210.
- Judgement of 1 February 2023, The Supreme Court of the Republic of Croatia, *Rev 1785/2019-2*.
- Judgement of 3 June 2025, The County Court in Zagreb, *Gž-133/2025-2*.
- Judgment of 10 June 2021, C-65/20, *VI v KRONE-Verlag Gesellschaft mbH & Co. KG*, ECLI:EU:C:2021:471.
- Judgment of 21 June 2017, C-621/15, *N. W and Others v Sanofi Pasteur MSD and Others*, ECLI:EU:C:2017:484.
- Judgment of 5 March 2015, Joined Cases C-503/13 and C-504/13, *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt*, ECLI:EU:C:2015:148.
- Obligations Act, Official Gazette, no. 35/2005, 41/2008, 125/2011, 78/2015, 29/2018, 126/2021, 114/2022, 156/2022, 145/2023, 155/2023.
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC OJ L 117.
- Regulation (EU) 2017/745 on medical devices, European Parliament and Council (2017) amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117/1.
- Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) OJ L 2024/1689.
- Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act) OJ L 2024/2847.

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Povzetek v slovenskem jeziku

Digitalizacija je spremenila zdravstveni sektor z uvedbo naprednih digitalnih medicinskih pripomočkov (kot so npr. programska oprema, medicinski pripomočki in pripomočki, ki jih podpirajo sistemi umetne inteligence). Inovacije v medicini ponujajo potencial za izboljšanje diagnoze in zdravljenja. Hkrati pa sprožajo določena vprašanja o civilni odgovornosti in pravnem položaju pacienta, ki je utrpel škodo zaradi okvarjenega digitalnega izdelka. Članek preučuje, ali lahko posodobljena pravila EU o odgovornosti za okvarjene digitalne medicinske pripomočke olajšajo dokazno breme, s katerim se pacienti soočajo v civilnih sporih, in s tem okrepijo njihov položaj. Avtor se osredotoča na ustreznost novih pravil o razkritju dokazov in dokaznem bremenu. Ključne ugotovitve kažejo, da nova pravila krepijo položaj pacientov z zmanjšanjem dokaznega bremena in uvedbo obveznosti razkritja relevantnih dokazov. Avtor predlaga pripravo smernic za rešitev obstoječih nejasnosti, s čimer bi se zagotovila dosledna in učinkovita uporaba novega dokaznega okvira.

INFORMATION AND COMMUNICATION ACCESSIBILITY FOR SENIORS IN POLISH HEALTH CARE

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Abstract The study focuses on information and communication accessibility in Polish health care, with particular emphasis on geriatric patients. We aimed to identify and analyze legal barriers and institutional mechanisms that determine interaction effectiveness between older adults and public administration. The core of the research problem lies within the paradigm of demographic population aging, which creates the need to implement systemic communication solutions. Communication accessibility constitutes both a formal legal requirement and a key determinant behind the quality of the therapeutic process and the health safety of older patients. We employed two research methods: doctrinal and empirical.

Keywords

health care,
right to health
information, information
accessibility,
communication
accessibility,
seniors

1 Introduction

Population aging constitutes a significant challenge for states in many fields of social life. Although most prominent in Western Europe, this issue also encompasses Poland. According to 2024 Eurostat data, the share of older adults – namely persons aged at least 65 years – in the EU population reached 21.6% (Eurostat, n.d.). This figure indicates a continuous increase: by 0.3 percentage points (pp) compared with 2023 and by 2.9 pp compared with 2014. Demographic projections suggest a substantial rise in the proportion of the oldest age group, namely 80 years and over. Researchers expect that the share of this group in the EU population will increase 2.5-fold between 2024 and 2100, from the current 6.1% to 15.3%. Simultaneously, the rate of population aging varies across Central and Eastern European countries: Bulgaria, Latvia, and Croatia are among the most demographically advanced, Poland is aging rapidly, and Slovakia remains one of the youngest societies in the region. Meanwhile, in Poland, population aging displays a particularly rapid increase in the number of people in the oldest age groups. Population aging varies in intensity across regions of Poland. Most individuals aged 60 and older live in urban areas (63.7%). Data from Statistics Poland (2024) show that the Świętokrzyskie Voivodeship had the highest share of older adults (29.8%), whereas the Małopolskie Voivodeship had the lowest (24.5%). By the end of 2024, 576.9 thousand retirees aged 60 and over remained employed, which represents a 1.4% increase compared with the previous year. At the same time, 84.8% of older adults remained economically inactive (Wyszkowska, Gabińska & Romańska, 2025, pp. 15–18). Polish seniors do not constitute a homogeneous group in terms of their activities and lifestyles. Researchers distinguish three categories: broadly active seniors (average age 69), seniors active mainly in the private sphere (average age 71), and withdrawn seniors (average age 76). Age and health status largely shape their behaviors. The youngest cohort (ages 60–64) shows the highest level of activity; they also have the highest levels of education and material well-being and predominantly live in urban areas. In contrast, withdrawn seniors tend to have lower levels of education, poorer financial conditions, and more significant health problems. Seniors active in the private sphere most often live in rural areas, and their levels of education, health, and material status fall between those of the first and second groups (Omyła-Rudzka, 2025, pp. 12–14). According to the PolSenior2 study and other data, a substantial majority of older adults report long-term health problems or chronic diseases. For example, in 2023, 63.2% of people aged 60 and over reported such issues. Moreover,

multimorbidity (polypathology) occurs frequently among this group. The increasing pace of population growth for 75+ and 80+ groups, referred to as ‘double aging,’ requires the Polish State to undertake appropriate measures – including, and perhaps above all, in the health care sector. However, some of these initiatives demand systemic solutions, such as the need to integrate the activities of all institutions responsible for senior policy, creating a coordinated senior policy that aligns social and health policies for older adults, legally defining long-term care, and the need to introduce social facilitation measures and innovations in health care. Other initiatives include the need to provide information and the use of existing accessibility instruments, such as communicating relevant preventive programs and promoting healthy aging, physical activity, and wholesome lifestyles to extend healthy life expectancy.

2 Communication in Health Care

As a patient, an older adult interacts with multiple entities within the health care system, including those that provide health services operating within primary care (PC), outpatient specialist care (OSC), emergency departments (ER), hospitals, and, in the final stage of life, long-term care facilities and hospices. From primary care, through specialist care, to long-term or terminal care, it is essential for there to be effective communication between medical staff and the patient, or a person authorized by the patient. However, in practice, such communication often proves inadequate due to various limitations in the health care system and barriers arising in the day-to-day functioning of health care institutions. Irrespective of these challenges, communication plays a fundamental role in realizing patients’ rights, particularly those of older adults, in safeguarding patient dignity and autonomy (Bernatek-Zagula, 2008, p. 95), and in ensuring treatment safety. In order to ensure that patients are able to provide informed consent for the treatment they receive, staff must convey information in a manner adapted to the patient’s age, health status, and cognitive abilities, using plain language and avoiding medical jargon. Furthermore, proper communication with older patients fosters trust and reduces anxiety among older adults, who often feel isolated or overlooked. Such an approach helps to prevent ageism and the perception of the older person as a ‘difficult’ patient (Bujny, 2007, p. 138). Achieving an appropriate communication standard requires a shift from a service-oriented model of doctor–patient interaction to a relational model. In a theoretical framework, one can develop this model by applying Jürgen

Habermas's theory of communicative action. In the context of healthcare, the Habermasian ideal speech situation refers to a relationship in which the patient and the clinician jointly develop a treatment plan based on well-founded arguments and mutual understanding, while excluding coercion and paternalism. This approach enables patients to fully articulate their needs and provides an ethical justification for therapeutic decisions, framing the healing process as the outcome of a collaborative dialogue rather than by imposing decisions unilaterally (Wonicki, 2012). Within this framework, the asymmetry of knowledge between the professional and the patient remains a fact. However, clinicians bracket it as a source of authority so that therapeutic actions emerge from ethical consensus, mutual understanding, and shared responsibility for the course of treatment (Maślanka, 2011).

3 Legal Framework in Communication and Information Accessibility

The obligation to inform patients about their health status stems from two spheres: first, from law, including both national and international acts, such as Article 8 of the European Convention on Human Rights and Fundamental Freedoms; and second, from ethics, in particular Article 16 of the Polish Code of Medical Ethics, annexed to Resolution No. 5 of the Extraordinary 16th National Medical Congress of May 18, 2024. Legal acts defining the right to medical information, specifically access to information about one's health, include: the Act on Patient Rights and the Patient Ombudsman of November 6, 2008 (Ustawa o prawach pacjenta i Rzeczniku Praw Pacjenta), Articles 9–12; the Act on the Collection, Storage, and Transplantation of Cells, Tissues, and Organs of July 1, 2005 (Ustawa o pobieraniu, przechowywaniu i przeszczepianiu komórek, tkanek i narządów), Article 5; the Act on Laboratory Medicine of September 15, 2022 (Ustawa o medycynie laboratoryjnej), Article 24; the Act on Mental Health Protection of August 19, 1994 (Ustawa o ochronie zdrowia psychicznego), Articles 23(3) and 33(2); the Act on the Prevention and Control of Infections and Infectious Diseases in Humans of December 5, 2008 (Ustawa o zapobieganiu oraz zwalczaniu zakażeń i chorób zakaźnych u ludzi), Articles 17(9), 26, and 28; and the Act on Medical Activity of April 15, 2011 (Ustawa o działalności leczniczej), Article 29(4).

In certain situations, the law allows these legal obligations to provide information to patients to be fulfilled by imparting the requisite information to persons other than the patient, such as close relatives. Article 31(4) of the Act on the Professions of

Physician and Dentist of December 5, 1996 (Ustawa o zawodach lekarza i lekarza dentystry), sets regulations in this regard. These provisions concern specific patient groups, which may include older adults, such as persons who remain legally incapacitated, unconscious, or unable to comprehend the significance of the information. Either the law itself or the patient's consent can serve as the legal basis for providing information to a person other than the patient (Ziółkowska, 2015, p. 154).

Satisfying the obligation to inform patients requires adherence to the principles of accessibility as defined in: the Act on Sign Language and Other Means of Communication of August 19, 2011 (Ustawa o języku migowym i innych środkach komunikowania się); the Act on Ensuring Accessibility for Persons with Special Needs of July 19, 2019 (Ustawa o zapewnianiu dostępności osobom ze szczególnymi potrzebami); and, indirectly, the Act on Digital Accessibility of Public Entity Websites and Mobile Applications of April 4, 2019 (Ustawa o dostępności cyfrowej stron internetowych i aplikacji mobilnych podmiotów publicznych). These obligations are particularly important for older adults, who typically have special needs, including specific communication needs. With age, the natural decline in vision and hearing poses serious barriers to standard medical communication. Geriatric challenges, both sensory and cognitive, oblige health care professionals to actively adapt communication to the patient's individual needs, which directly affects fulfilling patient rights, ensuring that treatment is effective, and protecting seniors' safety.

Consequently, one effectively realizes a patient's right to information only when one adapts that information to the patient's sensory and cognitive abilities (see Lewaszkiewicz-Petrykowska, 1994, p. 49). Moreover, only then can the information serve as the basis for informed consent to medical procedures (Safjan, 2005, p. 19; Drozdowska & Wojtal, 2010, pp. 44–45). Broadly speaking, the Polish health care system has a long-standing tradition of noncompliance with patients' information rights, which can lead to extreme situations. On the one hand, health information provided by the Ministry of Health or the National Health Fund (NFZ) often appears unclear (Charzyńska, 2017, p. 247), while information on patients' rights, such as prehabilitation, frequently remains missing (Hnat, 2025). On the other hand, medical communication sometimes becomes oversimplified and reduced solely to forms – seldom individualized and frequently replacing or diminishing doctor-

patient contact (Szudejko, 2023, pp. 40–41). In this context, fulfilling the information obligation toward seniors, particularly those with special needs requiring additional communication support, proves highly challenging.

4 Communications and Accessibility Barriers in Health Care

4.1 The Barrier of Specialized Language: Medical Jargon

The problem of effective communication with seniors becomes particularly important for the doctor-patient interaction. The risk involves communication disruptions, such as difficulties in asking and answering questions accurately, lapses in concentration during conversations, and problems with summarizing information (Ostrowska, 2018, pp. 9–12). Seniors might repeat information several times to ensure that they both heard and understood the message correctly. Key disruptive factors on the part of physicians include reliance on stereotypes in perceiving seniors, expressing reluctance toward this age group, providing limited or overly concise responses, and excessive use of specialized language, or medical jargon (Park & Song, 2005, pp. 155–160). Other barriers include the inability to convey information clearly, speaking too quickly, failing to respond when patients show difficulty understanding information, inappropriate volume – speaking either too loudly or too softly, neglecting patients' sensory impairments (Sulkowska, et al., 2018, p. 40), the use of baby talk, infrahumanization (Barański, 2021, pp. 60–62), as well as heightened authoritarianism, reduced patience, and lower engagement (Stefaniak, 2011, p. 209).

The use of specialized terminology constitutes a significant communication barrier, particularly for seniors. Notably, the outcomes of medical education include the ability to communicate with patients and their families in a trusting atmosphere, considering the patient's needs, delivering unfavorable information according to professional communication principles, and conducting medical interviews with adults, including seniors, using skills related to the communication content, process, and perception, while considering both biomedical and patient perspectives. Therefore, communication forms part of the curriculum for at least one semester (Wrocław Medical University, 2025), for several semesters (Warsaw Medical University, 2025), or even from the first to the fifth year of study (Łódź Medical University, 2025). Moreover, descriptions of a medical graduate emphasize the need

to adapt verbal communication to the patient's needs, express oneself clearly, and avoid medical jargon. Similarly, the nursing education standards include the ability to identify errors and barriers in the communication process and to use verbal and nonverbal communication techniques in nursing care, adapting verbal communication to the patient's needs, expressing oneself clearly, and avoiding medical jargon. Paramedics must additionally know the principles of communicating with visually impaired, blind, hard-of-hearing, and deaf patients, as stated in the Regulation of the Minister for Science and Higher Education on the Standards of Education Preparing for the Professions of Physician, Dentist, Pharmacist, Nurse, Midwife, Laboratory Diagnostician, Physiotherapist, and Paramedic of July 26, 2019 (Rozporządzenie Ministra Nauki i Szkolnictwa Wyższego w sprawie standardów kształcenia przygotowującego do wykonywania zawodu lekarza, lekarza dentystry, farmaceuty, pielęgniarki, położnej, diagnosty laboratoryjnego, fizjoterapeuty i ratownika medycznego).

Unfortunately, the functioning of health care institutions shows that the knowledge and skills acquired in communication courses fail to translate into actual practice, or do so only to a limited extent. Physicians and other health care professionals themselves recognize that they lack solid communication knowledge, even though the latter remains essential for efficient work and for effectively obtaining informed consent from patients. For this reason, Polish universities, led by Jagiellonian University, have introduced mandatory courses on patient communication for future physicians and nurses (Polityka Zdrowotna, 2023).

Importantly, the use of specialized jargon runs counter to the plain language approach promoted within the accessibility framework, as outlined in Resolution of the Council of Ministers No. 102/2018 of July 17, 2018: Accessibility Plus Government Program 2018–2025 (Uchwała Rady Ministrów nr 102/2018: Program Rządowy Dostępność Plus 2018–2025). Moreover, the use of medical jargon reinforces paternalism in doctor-patient communication, as it deepens communicative asymmetry and prevents patients from consciously and actively participating in the discourse (Rutkowski, 2016, pp. 93–94). Therefore, training for medical profession candidates should include plain language communication, enabling those persons to perform intralingual translation in doctor-patient interactions. In other words, medical staff should be able to translate from specialized terminology into plain language, since this proves both possible and

desirable (for more see Łomzik, 2021, pp. 264–273). Moreover, candidates should receive training in the functioning of individuals with complex communication needs, who require special consideration in the context of information delivery.

4.2 Accessibility and Information Barriers

Accessibility and information barriers relate to the way institutions convey required information about patient rights, particularly to seniors with special needs. We may refer to the method of providing information to individuals with special needs as a special type of informing, or ‘informing plus,’ because, in addition to the standard obligation to communicate patient rights, it also includes the delivery form. This may involve making information available through Polish Sign Language (PSL), signed language systems (SLS), or the communication system for blind individuals (CSBI), as well as through other communication-supporting measures under the Act on Sign Language and Other Means of Communication (Article 6(3)), the Act on Ensuring Accessibility for Persons with Special Needs (Articles 4 and 6(3)), and the Act on Patient Rights and the Patient Ombudsman (Article 12(2)). Among the main problems in the area of accessibility and information barriers, we may identify the following:

1. lack of procedures for serving individuals with special needs in various health care facilities: PC units, OSC units, and hospitals, including ERs;
2. insufficient knowledge of patient rights, including information rights, among patients with special needs (Chmielowiec et al., 2025, pp. 551–552, 556–557);
3. the absence of sign language interpreters, including online interpreters, required in health care facilities (Radio Kraków, 2022; see also Sobańska-Laskowska, 2023, p. 108);
4. failure to use appropriate tools and organize work effectively so as to enable service delivery, including providing information to older adults with special needs (for more on such tools see Sahaj, 2021, pp. 33–35).

These problems stem from years of inadequate management within the broadly understood healthcare system and from the lack of knowledge and soft skills among both administrative and medical staff. The absence of procedures for serving individuals with special needs means that health care facilities have failed to adopt standards for serving such patients. The standards in question should specify how a

facility should interact with older adults who are deaf or blind, have communication difficulties, or display cognitive impairments. Under the adopted standards, all facility staff should receive training in the functioning of individuals with special needs and on relevant communication methods. Furthermore, each facility should designate a person to coordinate the needs of such patients and to organize communication-supporting equipment, either through internal funding or using European funds. For example, the project *Accessibility Plus for OSC* currently conducts recruitment (Gov.pl, n.d. (a)).

The lack of PSL interpreters and appropriate equipment in health care facilities largely results from missing NFZ funding. The Act on Health Care Services Financed from Public Funds of August 27, 2004 (Ustawa o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych), does not oblige the NFZ to finance health care providers' tasks arising from the Act on Ensuring Accessibility. However, support may come from the Accessibility Fund. Facilities can use real-time video interpreter services provided by certain organizations for deaf persons, or the support of a designated assistant, who has the right to participate in communication under Article 7 of the Act on Sign Language and Other Means of Communication.

Regarding equipment in facilities, the limitations concern both finances and, perhaps primarily, awareness. Consequently, patients encounter a lack of procedures and knowledge regarding interaction with individuals with special needs. The latter require appropriate support through the use of text readers, tactile maps, communication cards for deaf individuals, tablets equipped with real-time communication software with PSL or SLS interpreters, signature frames, written communication tools, and personal alternative communication devices such as GoTalk or Mówik.

Communication with individuals with sensory impairments can sometimes approximate standard communication owing to tools such as audio induction loops, FM systems, infrared (IR) devices, or Bluetooth. Unfortunately, their implementation in healthcare facilities has not become widespread yet. Although health care institutions have made progress in recent years, they mostly remain insufficiently prepared to provide information and communication services to individuals with special needs, as evidenced by patient complaints filled with both

the Patient Ombudsman and the Citizen Ombudsman (Imiolczyk, 2020, pp. 20–22). The Citizen Ombudsman highlights these issues in the address to the President of the State Fund for the Rehabilitation of Persons with Disabilities (PFRON) (Biuro Rzecznika Praw Obywatelskich, 2024a) and to the Patient Ombudsman (Biuro Rzecznika Praw Obywatelskich, 2024b). More recently, patients direct their complaints also to the President of the PFRON (PFRON, 2025). In summary, health care institutions continue to fail to treat patients with special communication needs as full participants.

4.3 Digital Barriers

In recent years, Poland has experienced intensified digitization of public administration (Ziółkowska, 2022, p. 2023), including a significant growth in telemedicine and the range of related services (for more on telemedicine see Wrzesińska-Wal & Hajdukiewicz, 2020, pp. 509–524). Although this development represents a positive solution, it can also pose a barrier, particularly for digitally excluded older adults or seniors with disabilities, when the information provided through these channels proves insufficiently accessible.

Key solutions in this area include:

- electronic medical records (EMRs) – Article 13a of the Act on the Health Information System of April 28, 2011 (Ustawa o systemie informacji w ochronie zdrowia), and the Regulation of the Minister for Health of May 8, 2018, on the types of electronic medical records (Rozporządzenie Ministra Zdrowia w sprawie rodzajów elektronicznej dokumentacji medycznej), according to which EMRs include information on the diagnosis of a disease, health problem, or injury, examination results, reasons for refusal of hospital admission, provided health services including recommendations, hospital discharge summaries, laboratory test results with descriptions, diagnostic test reports, and Individual Medical Care Plans (Szewczyk, 2024, pp. 63–73; Maj, 2022, pp. 165–174);
- e-prescriptions – Article 56 of the Act on the Health Information System. They require a PIN code and the ability to read SMS messages (see more in Owczarczyk, 2023, pp. 13–30);
- Internet Patient Account (IKP) – Article 7a of the Act on the Health Information System.

The IKP allows patients to:

- submit statements authorizing individuals to access medical records, as referred to in Article 26(1) of the Act on Patient Rights and the Patient Ombudsman of November 6, 2008 (Journal of Laws 2024, item 581);
- provide consent for data sharing, as referred to in Article 35(1a) of the Act, and to withdraw such consent;
- submit statements of consent for the provision of information, as referred to in Article 9(3), and to withdraw such consent;
- submit statements of consent for the provision of specific health services, as referred to in Articles 16–18;
- access information on disease prevention and healthy lifestyles based on individual patient data;
- respond to surveys on health care quality;
- access information on issued prescriptions, as referred to in Article 38(4a) of the Act on the Reimbursement of Medicines, Foodstuffs for Particular Nutritional Uses, and Medical Products of May 12, 2011 (Ustawa o refundacji leków, środków spożywczych specjalnego przeznaczenia żywieniowego oraz wyrobów medycznych) (see Kowalska et al., 2023, pp. 35–46).

Among other ways, medical records can be available through on-site review at the health care facility, the preparation of copies, printouts, transcripts, or extracts, issue on an electronic data carrier, and transmission via electronic communication channels (see Klimas, 2018, pp. 91–105; Klich, 2017, pp. 351–360).

The digitalization of medical services and medical records makes it relevant to ask how authorities implement the right to information under Article 23(1) of the Act on Patient Rights and the Patient Ombudsman, particularly with regard to older adults. The Patient Ombudsman has repeatedly emphasized the obligation of health care providers to make medical documentation available in digital form and in a machine-readable format, such as a PDF-accessible file. This obligation stems directly from digital accessibility requirements and conditions the comprehensibility of information for this group of patients. Accordingly, activities undertaken within telemedicine can and should complement direct doctor-patient interactions. Telemedicine tools remain useful for information purposes insofar as both

physicians and patients, including older patients, use them appropriately, which is not always obvious or feasible. Physicians also highlight this concern, emphasizing that health care facilities should integrate telemedicine into a hybrid model of health service provision (Paprocka-Lipińska, 2022, p. 148).

A separate yet equally important issue concerns the digital exclusion of seniors: limited access to smartphones and other internet-enabled devices, as well as cognitive barriers, such as the need to remember passwords imposed by digital interfaces. In conjunction with the digitalization of medical services, this situation poses a risk to ensuring equal access to health care (Ziółkowska & Gronkiewicz, 2023, pp. 537–548). For this reason, digitalization cannot eliminate traditional forms of access, such as in-person registration at health care facilities or direct doctor-patient contact.

4.4 Organizational and Administrative Barriers

Medical services in Poland display a deeply entrenched bureaucratization, which constitutes a significant barrier to change. Medical workforce aging also poses a considerable issue. Projections regarding the number of nurses and midwives prove pessimistic, which generates staffing shortages and organizational challenges, particularly with respect to the length of visits. Apart from clinical examination and diagnosis, a consultation involves completing EMR, and that requires digital competencies. Although the use of medical assistants has become more common among private health care providers, this practice remains less evident in public health care facilities due to organizational constraints and financial limitations. Nevertheless, a widespread introduction of medical coordinators and a broader presence of medical assistants or medical secretaries within the health care system appears justified given the limited number of strictly medical staff and their ongoing aging.

Within the scope of their statutory powers, medical assistants may provide patients with information on test results and administer medications prescribed by a physician. Moreover, when authorized by a physician, they may issue electronic documents such as prescriptions, referrals, and medical leave certificates. As of October 1, 2022, PC physicians can also introduce a new model for the provision of health services in their facilities – coordinated care, as defined in the Notice of the

Minister for Health of February 15, 2021, on Publishing the Consolidated Text of the Regulation of the Minister for Health on Guaranteed Services within Primary Health Care (Obwieszczenie Ministra Zdrowia z dnia 15 lutego 2021 r. w sprawie ogłoszenia jednolitego tekstu Rozporządzenia Ministra Zdrowia w sprawie świadczeń gwarantowanych z zakresu podstawowej opieki zdrowotnej).

A medical coordinator ensures communication and cooperation between the patient and the medical team. The coordinator's key responsibilities include scheduling visits and diagnostic tests, informing the patient about the course of treatment, managing medical documentation, and ensuring effective communication with the patient on therapeutic matters. Although the coordination model remains well-founded, its effectiveness is often impaired due to myriad factors including work overload, lack of systemic integration, and inadequate staffing and financial resources to fully perform such broad and important duties. Therefore, the introduction of medical coordinators appears highly desirable and, in fact, necessary, particularly in large medical institutions such as hospitals, among other facilities. Authorities are already introducing similar measures within the health care system by appointing various coordinators whose tasks involve organizing the patient's treatment pathway, primarily in its informational dimension. In this sense, their role resembles that of accessibility coordinators. Alongside formally established oncology coordinators (Osowiecka et al., 2025, pp. 3–10), we also see stroke coordinators and cardiology coordinators. However, these solutions frequently lack legal regulation and a systemic character, as is the case with oncology coordinators. Moreover, medical coordinators do not currently constitute a separate, formally recognized professional group. At the legislative stage of adopting the Act on Ensuring Accessibility for Persons with Special Needs, the legislator did not consider it necessary to establish accessibility coordinators in medical institutions, unlike in public administration bodies or courts.

Notably, the explanatory memorandum to the draft Act on Ensuring Accessibility for Persons with Special Needs states that the Act will not require the appointment of accessibility coordinators in certain entities: 'therefore, it will not be necessary to designate such a person, for example, in a police unit, a cultural institution, or a hospital, but rather at the level of offices serving the competent ministers, in regional and local self-government bodies, and in the judicial authorities' (Sejm of the Republic of Poland, 2019, p. 18). We should regard this approach as a mistake, given

the generally low level of implementing patient rights, including the right to information. The Supreme Audit Office (NIK) also highlights this deficiency in its post-audit statement – *Information on Audit Results: Compliance with Patient Rights in the Health Care System* (Najwyższa Izba Kontroli, 2024, pp. 13–14, 17, 31–32). The introduction of an accessibility coordinator appears all the more justified in light of the difficulties that seniors and persons with special needs experience within health care institutions.

5 Conclusions and Recommendations

The law formally protects senior patients under the Act on Patient Rights and the Patient Ombudsman, which sets the principle of comprehensibility. Poland has also passed accessibility laws, such as the Act on Sign Language and Other Means of Communication and the Act on Ensuring Accessibility for Persons with Special Needs. Nonetheless, administrative practice still creates barriers. Authorities fail to enforce this law due to financial reasons and because of organizational, administrative, and, above all, mental barriers. In light of the above, one may conclude that the system of structures organizing society, in this case, the healthcare system, effectively colonizes the lifeworld in the Habermasian sense. As a result, power and money displace understanding and dialogue, reducing them to secondary values. This dynamic leads to the erosion of a shared public sphere in the domain of health. Moreover, in the context of a ‘fatigue’ or ‘exhaustion’ society, characterized by egotism and social isolation (Han, 2022, pp. 53–58), high-quality public services increasingly become a luxury rather than the State’s foundation. Over time, the absence of adequate institutional solutions will further undermine social cohesion by weakening generalized social trust. At the same time, this organizational and professional arrangement generates risks from which certain groups, often those that have partially produced them, can benefit by expanding their activities into the private sphere (Beck, 2004, p. 314). This process further accelerates the erosion of community and, in effect, increases dependence on the market across all areas of life (Han, 2024, pp. 21, 91). Because contemporary societies are more interdependent than commonly assumed, the State should pursue structural reform. Restoring a balance between public and market-based services appears necessary, even if doing so requires challenging the interests of specific groups, including those who benefit from the risks produced. At the same time, the medicalization of communication cannot serve as the sole ideological foundation of the doctor–patient relationship.

Following Habermas, one must recognize that not every use of language constitutes communicative action. Neglect of older adults in healthcare, including the failure to comply with existing regulations, leads to the disregard of standards concerning older persons developed by international bodies (Wedel-Domaradzka, 2023, *passim*) and may directly violate the rights of persons with disabilities as enshrined in the Convention on the Rights of Persons with Disabilities (e.g., Articles 9, 25, and 26). Addressing this situation requires a range of measures, including both immediate, practice-oriented initiatives and legal reforms formulated as *de lege ferenda* proposals.

Any effective reform must begin with increased funding for the Polish health care system, which the report '*10 nowych źródeł finansowania NFZ*' (*10 New Sources of NFZ Funding*) indicates as feasible (Owczarek et al., 2025, pp. 3–43). Another way to secure additional funds for health care could involve introducing income thresholds in the '800+' benefit program, which operates under the Act on State Support in Raising Children of February 11, 2016 (Ustawa o pomocy państwa w wychowywaniu dzieci). This program effectively initiated a wave of public service privatization in Poland (see Pawłowski, 2020, *passim*). Due to the deterioration of public service quality, this phenomenon increased the inequalities in Polish society (Bukowski et al., 2024, *passim*), including disparities in healthcare access, which particularly affected senior citizens.

Among the practical actions, authorities should take appropriate organizational and administrative measures both at the level of health care system units and with regard to the medical and paramedical staff. The first proposal should entail launching formally designated units, such as geriatric centers for patients aged 75 and over. Although specified in the Act on Special Geriatric Care of August 17, 2023 (Ustawa o szczególnej opiece geriatrycznej), such centers have not yet opened due to the lack of implementing regulations required by the law. Naturally, the organization of such centers may require reconsideration. Nevertheless, the concept itself, abandoned mainly due to insufficient funding in the health care system, appears important and promising. Around these centers, authorities could aim to integrate medical services with social services, forming a model of organized community geriatrics. Coordinated care represents one attempt to address these issues (Badora-Musiał, 2025, *passim*), although practice shows that it still requires refinement (Stawicka, 2025).

Some health care managers and physicians publicly propose appointing geriatric coordinators or establishing a fast-track geriatric pathway for seniors, modeled after oncology pathways. Furthermore, physicians recognize the need to develop solutions in the field of community geriatrics. Currently, primary care in Poland partially fulfills this role, but in the context of an aging population, this coverage appears insufficient. Notably, Poland lacks hospitals dedicated to patients with cognitive impairments such as dementia or Alzheimer's disease or with sensory limitations. In addition to performing standard medical work, such hospitals would be able to provide appropriate communicative care for these patients. Consequently, the health care system generally redirects seniors to conservative treatment, even though they could undergo certain medical procedures – including operations – and potentially enjoy longer and healthier lives.

A separate issue that requires reform concerns training. The lack of service standards for persons with special needs, including seniors, in many health care facilities appears to reflect low awareness across all levels, from management staff to medical and paramedical personnel. This lack of standards proves unjustified, especially given the availability of numerous publicly accessible materials and brochures (e.g., Zespół Rzecznika Praw Pacjenta, 2022a), including ready-to-use standards freely available for adaptation in various health care units, such as primary care (Gov.pl, n.d. (b)), outpatient care (Ministerstwo Zdrowia, n.d.), and hospital care (Zespół Rzecznika Praw Pacjenta, 2022b). Existing training initiatives on accessibility also demonstrate available frameworks. The project *Patient First: Activities of the Patient Ombudsman to Improve the Quality of Health Services* (Po pierwsze pacjent – działania Rzecznika Praw Pacjenta na rzecz poprawy jakości usług zdrowotnych) took place between 2020 and 2023 (Gov.pl, n.d. (c)). In turn, the ongoing project *Safe Patient: Activities for Patient Rights in the Health Care System* (Bezpieczny pacjent – działania na rzecz praw pacjenta w systemie ochrony zdrowia) is scheduled for 2024–2027 (Gov.pl, n.d. (d)).

The medical professions acts do impose a duty of continuous education and professional development on all medical personnel. These include, for example, the Act on the Professions of Nurses and Midwives of July 15, 2011 (Ustawa o zawodach pielęgniarstwa i położnictwa), the Act on the Professions of Physician and Dentist, and the Act on Certain Medical Professions of August 17, 2023 (Ustawa o niektórych zawodach medycznych). Still, these programs should entail training in

communication with seniors on a much larger and mandatory scale. Such training would adapt language to patients with hearing, vision, or memory impairments, as well as to those with dementia. This adjusted language would ensure accurate and empathetic communication regarding diagnosis, prognosis, and treatment plans, while fully respecting the senior patient's right to make informed decisions.

Given the partial or limited knowledge of patient rights, including information rights, literature suggests that medical education should place greater emphasis on teaching about patient rights. A gap exists between medical personnel's perception that they demonstrate familiarity with patient rights and their actual knowledge of and adherence to these rights (Chmielowiec et al., 2025, p. 556). Furthermore, every newly hired employee, whether medical or non-medical, should undergo mandatory onboarding training on accessibility, including the standards adopted at the specific facility, particularly those relating to information and communication accessibility. Accessibility coordinators or medical coordinators appointed by the unit manager should bear responsibility for the organization of ongoing training after employment in a health care unit. A necessary condition is that these coordinators operate exclusively in this capacity, without additional roles.

Properly conducted training, both during medical studies and throughout employment in health care facilities, should aim at a comprehensive improvement in quality, observable in three spheres: the clinical aspects, such as safety and effectiveness; the organizational aspects, namely efficiency and accessibility; and the consumer aspects – that is, patient experience and satisfaction. Furthermore, formalizing and implementing standards for serving persons with special needs should address certain NIK recommendations stemming from the 2024 post-audit report, directed at health care unit managers. These include ensuring that patients receive all information required by law, providing personalized consent forms for specific procedures that include all relevant details, and enabling electronic patient registration. Such registration should incorporate communication supporting tools, such as SMS, MMS, email, or audiovisual-enabled messaging platforms.

Among the legal proposals, in addition to the need to legally define long-term care, authorities could introduce detailed standards for geriatric communication – for example, in the Act on Patient Rights or its implementing regulations – and include the profession of medical coordinators in the Act on Medical Professions. Such

measures would certainly benefit both senior patients and the remaining patient groups. An alternative option in this regard involves adding hospitals and large outpatient clinics to the group of entities required to appoint accessibility coordinators, in accordance with Article 14 of the Act on Ensuring Accessibility. Finally, we deem it essential to formally strengthen the role of the Patient Ombudsman and the supervisory bodies overseeing medical facilities in intervening when the information right suffers a violation. This need also applies to information aimed specifically for senior patients, as highlighted in NIK's 2024 post-audit report.

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Legal Acts

Konwencja o prawach osób niepełnosprawnych, sporządzona w Nowym Jorku dnia 13 grudnia 2006 r. (Dz. U. 2012, poz. 1169).

Ustawa z dnia 1 lipca 2005 r. o pobieraniu, przechowywaniu i przeszczepianiu komórek, tkanek i narządów (Dz. U. 2005 poz. 1411).

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Ustawa z dnia 12 maja 2011 r. o refundacji leków, środków spożywczych specjalnego przeznaczenia żywieniowego oraz wyrobów medycznych (Dz. U. 2011 nr 122 poz. 696).

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Povzetek v slovenskem jeziku

Študija se osredotoča na dostopnost informacij in komunikacije v poljskem zdravstvenem sistemu, s posebnim poudarkom na geriatričnih bolnikih. Cilj avtorjev je identificirati in analizirati pravne ovire ter institucionalne mehanizme, ki določajo učinkovitost interakcije med starejšimi odraslimi in javno administracijo. Srž raziskovalnega problema leži v paradigmi demografskega staranja prebivalstva, ki ustvarja potrebo po upoštevanju sistemskih komunikacijskih rešitev. Dostopnost komunikacije predstavlja tako formalno pravno zahtevo kot tudi ključni dejavnik, ki vpliva na kakovost terapevtskega procesa in zdravstveno varnost starejših pacientov. Uporabljeni sta dve raziskovalni metodi: doktrinarna in empirična.

MATERNAL CARE ACROSS THE CONTINUUM OF PREGNANCY, LABOUR AND POSTPARTUM: A REGULATORY ANALYSIS AND IMPLEMENTATION IN PRACTICE – SERBIAN EXAMPLE

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Abstract This paper examines maternal care across the continuum of pregnancy, labour, and the postpartum period through a regulatory and policy lens. It analyzes international legal frameworks and clinical standards alongside documented experiences of women in practice, both globally and in Serbia. By comparing normative commitments and how they are implemented in Serbia, the paper identifies key gaps between formal regulations and lived experiences. It further explores structural, institutional and legal factors contributing to these discrepancies and concludes with policy and regulatory recommendations designed to improve compliance, accountability, and the quality of maternal care.

1 Introduction

The issue of mistreatment of women during pregnancy, childbirth, and the postpartum period has received increasing media attention in Serbia in recent years. A public testimony by one woman describing her negative experience in a maternity ward encouraged many others to come forward and share similar experiences. This paper provides a comparative analysis of maternal care in high-, middle-, and low-income countries (hereinafter: HICs and LMICs), with a particular focus on Serbia. The paper first analyzes the international legal framework and standards governing maternal care and examines women's experiences in practice through examples from selected HICs and LMICs. It then explores the Serbian legal framework to assess whether women during pregnancy, childbirth, and the postpartum period are subject to specific legal regulations or protected primarily under general legal norms. The subsequent section examines women's rights in practice, relevant case law, and judicial attitudes toward obstetric violence. Finally, the paper analyzes the structural and systemic factors influencing the (un)satisfactory level of maternal care in Serbia and offers recommendations for achieving adequate standards of maternal care. The research will be conducted using primarily the normative method, via analysing existing national and international legislation; the comparative method when assessing the level of harmonization of Serbian with the international framework; as well as an empirical analysis of collected case law and statistical information on how the existing framework is implemented in practice. The significance of this paper lies in its comparative analysis of maternal care and the gap between normative standards and lived experiences. The paper aims to encourage reflection on and reform of existing practices, potentially mitigating negative experiences related to family planning and childbirth, and to support policymakers, health care providers, and the judiciary in fostering a positive and rights-respecting environment for women during and after pregnancy.

2 International Regulation and General Contemporary Standards Related to Maternal Care

People have the right to be involved in discussions and make informed decisions about their health care (NICE, 2025), in line with WMA Declaration of Lisbon on the Rights of the Patient (WMA, 1981-2015), European Charter of Patients' Rights

(EC, 2002), the European Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (ETS No. 164) of 1997 (CE, 1997), as well as other international and European Acts, and with many Patients' Rights Acts around the world (German Gesetz zur Verbesserung der Rechte von Patientinnen und Patienten (2013); AMA Code of Medical Ethics (1847-2001); French Law No. 2002-303-The Kouchner Law (2002); Spanish Law 41/2002 Regulating Patient Autonomy and Health Documentation and Information-Related Rights and Obligations; Italian law 219/2017; Slovenian Law about Patient Rights (ZPacP), (2008-2022)).

The double vulnerability of women-child in this period increases the possibility for mistreatment. Therefore, different international and national acts and guidelines provide legally binding or soft regulations to ensure quality health care service and to prevent mistreatment, neglect or abuse. Some of the good examples are standards elaborated by the World Health Organization (hereinafter: WHO) (WHO, 2018) and the National Institute for Health and Care Excellence (hereinafter: NICE) (NICE, 2025).

Globally, women's and providers' perspectives on what constitutes respectful maternity care are consistent: being free from harm and mistreatment; having privacy and confidentiality; dignified care; receiving information and giving informed consent; continuous access to family and community support; high-quality physical environments and resources; equitable maternity care; effective communication; having choices and the right to make decisions; competent and motivated human resources; efficient, effective and continuous care (WHO, 2018, p. 21). These components are largely affected by the social determinants of health (Centers for Disease Control and Prevention - CDC, 2024) as well as the systems implemented to deal with illness. Therefore, as specific as they can be, standards have maintained a certain breadth or degree of flexibility in order to satisfactorily respond to different social circumstances.

Communication: The research results show that providing all pertinent information in a clear manner coupled with the staff's interest in addressing women's needs and fears are of key importance (Baranowska et al., 2021, p. 2). Feeling informed significantly enhances the woman's birth experience (Baranowska et al., 2021, p. 7).

Research findings indicate that women, especially those giving birth for the first time, appreciate health care staff's support. Where interventions are required, 'most women would like to receive relevant information from technically competent health care providers in a manner they can understand' (WHO, 2018, p. 26, p. 63). Also, women wish to be in control of their birth process and to be involved in the decision-making process (WHO, 2018, p. 65).

A woman with an experience of trauma should be spoken to 'about the future mode of birth, encompassing: current urgency or incontinence symptoms; the degree of previous trauma; risk of recurrence; the success of the repair undertaken; the psychological effect of the previous trauma; management of her labour'. These discussions provide the basis for her to make truly informed consent (NICE, 2025: Principles 1.9.17, 1.9.19.). Clear, plain language should be used in communication to confirm that women have understood the information (NICE, 2025: Principles 1.4.8. and 1.4.9.).

During 'natural childbirth', because womens' cognitive processes are somewhat blocked and their behavior is influenced by hormones, they tend to rely more on instinct. Then, a 'non-verbal form of communication' is more appropriate. In the 'postpartum period', the woman's attention is focused on the child and information relevant to child care, and accordingly, verbal communication is key. In case of instrumental birth or caesarean section (hereinafter CS), different communication skills are needed (Baranowska et al., 2021, p. 2).

Pregnant women should be counseled to 'drink during labour when they are thirsty, that isotonic drinks may be more beneficial than water, and that overconsumption may be harmful. Information should be given that they can eat a light diet in established labour if they wish, unless they have received opioids or they develop risk factors that make a caesarean birth more likely' (NICE, 2025, Principles 1.8.17, 1.8.18.).

Position and moving: Women should be 'encouraged and helped to move and adopt whatever positions they find most comfortable throughout labour, except lying flat on her back' (NICE, 2025, Principle 1.4.12.).

Pain relief: Women requesting pain relief medications should be informed of their effects and be supported to participate in the decision-making processes (WHO, 2018, p. 104). ‘*Epidural analgesia* (as well as parenteral opioids) are recommended for healthy pregnant women, depending on preferences’ (WHO, 2018, p. 83). NICE provides a list of information women with (NICE, 2025, Principle 1.9.5.) and without an epidural in place should be given during the second stage of labour. If there is delay or excessive distress in the second stage of labour, ‘support and sensitive encouragement should be provided and she should be asked if she needs analgesia or anesthesia’ (NICE, 2025, Principle 1.9.29.). Health care staff should consider that ‘every woman’s experience of pain is unique and may be expressed in different ways, both verbally and non-verbally’ (NICE, 2025, Principle 1.6.2.).

Companionship: Findings from a WHO review of qualitative studies indicate that women from both HIC LMIC countries value the non-pharmacological pain relief measures enabled by the companions, including a soothing touch, breathing, relaxation techniques and adopting alternative positions to ease pain (WHO, 2018, p. 31).

Use of oxytocin: An obstetrician should offer a full assessment for all women with confirmed delay in the established first stage of labour. The use of oxytocin should be discussed and a decision made in collaboration with her. It is especially important that the woman be informed that although its use will hasten the time of birth it will not influence its mode or outcomes, and it will increase the frequency and strength of contractions and can cause hyperstimulation. The woman should be offered an epidural before oxytocin is started or if she requests it later (NICE, 2025, Principles 1.8.50 to 1.8.52.). WHO guidelines do not recommend the use of amniotomy alone, with early oxytocin augmentation and the use of antispasmodic agents, for prevention of delay in labour. They also do not recommend the use of oxytocin for prevention of delay in labour in women receiving epidural analgesia, or the use of intravenous fluids with the aim of shortening the duration of labour (WHO, 2025, pp. 117-119).

Use of Cardiotocography (CTG): CTG is a continuous electronic monitor used during pregnancy and labor both to track a baby’s heart rate and the mother’s uterine contractions. Though very useful in assessing the baby’s well-being, detecting

potential distress, and managing risk during childbirth, continuous CTG during labour can have negative effects on a woman's sense of autonomy, by increasing discomfort and reducing mobility and pain relief options (WHO, 2025, p. 71). Periodical auscultation of the fetal heart rate 'with either a Doppler ultrasound device or a Pinard fetal stethoscope is recommended for healthy pregnant women in labour' (WHO, 2025, p. 74), as well as the new wireless methods of CTG, as they allow mobility during labour (WHO, 2025, p. 79).

Episiotomy and intrapartum interventions to reduce perineal trauma: Health staff should discuss with the woman her wishes for techniques to reduce perineal trauma and support her in it. An episiotomy should not be performed routinely during spontaneous vaginal birth nor after previous third- or fourth-degree trauma (NICE, 2025, Principles 1.9.16, 1.9.18; WHO, 2025, p. 150). Rather, it should be performed only 'if there is a clinical need and in the recommended manner with analgesia provided beforehand' (NICE, 2025, Principles 1.9.12.-1.9.23).

Manual fundal pressure (Kristeller maneuver): Application of manual fundal pressure to facilitate childbirth during the second stage of labour is not recommended and evidence suggests it leads to more pain after birth (WHO, 2025, p. 155).

Expediting birth: Birth with forceps or ventouse (vacuum extractor used to assist with vaginal birth by applying suction to the baby's head) should be offered if there is concern about the baby's well-being, a prolonged second stage or if the woman wants assistance. In this case, pain relief options should be explained to her. If a woman rejects such birth methods, options should be explained to her; she should be advised that her choice may be limited by safety or urgency; she should be supported in her decision (NICE, 2025, Principles 1.9.35-1.9.41.).

Cesarean birth: When CS is undertaken, there is a set of standards, all of which encompass woman's participation in decision making (NICE, 2013).

Management of the third stage: Antenatally, during the initial assessment, women should be advised of the different options for managing the third stage of labour and the benefits and risks associated with active and physiological management of

the third stage. She should be advised that it is linked with the risk of a postpartum haemorrhage, and consequently, need for blood transfusion. Women should be advised ‘to change from physiological to active management in case of haemorrhage, placenta not being delivered or her wish to shorten the third stage’ (NICE, 2025, Principles 1.10.5. - 1.10.18).

Retained placenta: If the placenta is retained, a vaginal examination should be offered to assess the need to undertake manual removal of the placenta. The woman should be advised that assessment can be painful and analgesia recommended, and the uterine exploration or manual removal of the placenta should not be performed without an anesthetic (NICE, 2025, Principles 1.10.25 - 1.10.28.).

Risk factors and management of postpartum haemorrhage: If a woman has risk factors for postpartum haemorrhage, that should be emphasized in her record. Health staff should, together with the woman, develop a care plan covering the third stage of labour and immediate clinical treatment should be given (NICE, 2025, Principles 1.10.32, 1.10.33.).

Perineal care: ‘Before assessing genital trauma, the process should be explained and analgesia offered. The initial examination should be performed gently. All relevant health care professionals should attend training in perineal/genital assessment. Repair of the perineum should be undertaken as soon as possible to minimize the risk of infection and blood loss. If the woman reports inadequate pain relief at any point, it should be addressed immediately. Women should be given information about the extent of the trauma, pain relief, diet, hygiene and the importance of pelvic floor exercises, expectations in recovery and information on psychological support’ (NICE, 2025, Principles 1.12.4. - 1.12.23.).

3 Global Experiences of Women During Delivery and in the Postnatal Period

In many, particularly limited-resource settings, women continue to give birth in facilities while denied the option of having a labour companion present, without access to adequate pain relief, or possibility to mobilize or adopt a chosen birth position. Interventions such as early amniotomy, oxytocin for augmentation and

continuous fetal monitoring are often routinely overused (Volgel et al., 2023, p. 2).

Practice and attitude towards women in labour, both in HIC and LMIC, sometimes result in various forms of abuse. In the obstetric setting, abusive behavior is often referred to as 'obstetric violence', which WHO (although without using the exact term) recognizes as professional abuse, disrespect, and mistreatment of women during childbirth, which often consists of physical and verbal abuse, lack of confidentiality, and neglect (WHO, 2015, p. 1).

Bowser and Hill identified seven categories of disrespectful and abusive behavior reported during childbirth: i) physical abuse, ii) non-consented care, iii) non-confidential care, iv) non-dignified care, v) discrimination based on specific patient attributes, vi) abandonment of care, and vii) detention in facilities (Sando et al., 2017, p. 2). Results of literature review show that the attitude towards women in labour depends not only on the level of country development, but also on: cultural differences, first labour experience, extraordinary circumstances (f.e. COVID-19, Ebola), women's or health care providers' viewpoint. Despite the circumstances that raise feelings of neglect, disrespect or abuse being subjective, this does not diminish their importance.

Concerning LMIC, research conducted, for example in Ethiopia, shows that although access to health care facilities in general has dramatically improved over the past two decades, maternal care has remained considerably low (Baranowska et al., 2021, p. 10). Three in four women reported experiencing at least one form of disrespect and abuse (hereinafter: D&A) during labour. Other studies from sub-Saharan African countries similarly have reported high levels of D&A maternity care during childbirth (Baranowska et al., 2021, p. 10). Women giving birth to their first child were about two times more likely to report experiencing D&A compared to women who had three or more children, since the former are unfamiliar with how healthcare services are commonly provided. Women who gave birth at a higher-level health facility had a greater likelihood of experiencing D&A. While this seems intuitively illogical, as one might expect higher rates of D&A at lower-level facilities, these findings could be the result of understaffing and a high volume of patients, making it difficult to adequately provide care (Baranowska et al., 2021, p. 10). D&A continues to be a serious concern in public health facilities in other parts of Africa,

as well (Mapumulo et al., 2021, p. 2; Adu-Bonsaffoh et al., 2022, p. 1). One study identified numerous systemic barriers to provision of quality, person-centred care for pre-eclampsia in hospitals in rural Ethiopia (Robbins et al., 2023, p. 1).

A common predictor for D&A was the absence of a companion in the labouring room. Providers are more cautious when a companion is present, suggesting that they are aware their behaviour is inappropriate, indicating that companions serve an important role as advocates for women in labour (Baranowska et al., 2021, p. 11).

Concerning Argentina as an example of MIC, research discovered that health care providers feel that they have been losing control over decision-making on birth modes and feel irritated by women's wishes to make autonomous decisions. Communication with patients, regarding the risks and benefits of vaginal birth and CS, seems difficult for them. Concurrently, providers perform an increasing number of CS without medical indication when it is convenient for them, which suggests that paternalistic practices still exist (Vila Ortiz et al., 2023, p. 2).

In Switzerland (HIC), an evaluation of patient satisfaction conducted at the maternity unit highlighted key areas for improvement – the lack of information, their homogeneity, and the multiplicity of intervening stakeholders (Maillefer et al., 2015, p. 3). However, in general, patients spoke positively about the welcoming environment and the staffs', especially midwives', competence (Maillefer et al., 2015, p. 5).

Research shows that, in Sweden, as a HIC, in the case of a woman's refusal 'to undergo an emergency CS for fetal reasons, most midwives (89%) thought that the obstetrician should try to persuade her.' Concerning a woman's request for a CS without any current medical indications, most midwives thought that the obstetrician should agree if the woman had previous maternal or fetal complications. The midwives at six university hospitals were less willing to accept the woman's autonomy in this situation (Danerek et al., 2011, p. 71).

Irish authors observed women-centered care through five major themes representing women's and clinicians' views, experiences and perspectives: protecting normality, education and decision making, continuity, empowerment for women-

centred care and building capacity for women-centred care, and as perceived by participants in the study, women centred-care is not routinely provided in Ireland (Hunter et al., 2017, p. 1).

While reviewing literature, we noticed that most of the articles about abuse and neglect of pregnant women come from LMIC. Articles from HIC mainly focus on changing management in hospitals during COVID-19, or the relationships between midwifery staff and obstetricians, but almost always with the emphasis on the benefit of women in birth (Burau & Overgaard, 2015; Sheil & McAuliffe, 2021; Danerek et al., 2011). Our research results show that the frequency of D&A is prevalent in LMIC, but is not necessarily limited to them and does occur in HIC as well.

4 The Legal Framework for Maternal Health Care in Serbia

In this part of our research, we will examine the legal framework for maternal health in the Republic of Serbia (hereinafter: RS), seeking to identify the norms which protect women during pregnancy, labour and the postpartum period. Our goal is to assess whether the existing framework recognizes the specific status of women in this period and, if it does, whether that framework adequately safeguards their rights.

The Constitution of the RS guarantees human and minority rights arising from ‘generally accepted rules of international law, ratified international treaties and laws’ (Constitution of RS, 2006, Article 18), so the international agreements previously mentioned apply. Although the WMA Declaration of Lisbon on the Rights of the Patient is not a legally binding Act, the Serbian Medical Society is a WMA member and accepts its fundamental principles within its ethical codes and the basic principles embedded in the European Charter of Patients’ Rights, which have found their way into the Serbian Law on Patients’ Rights. Serbia has ratified the Convention on Human Rights and Biomedicine.

In Serbia, the equality of all persons before the law is guaranteed and any form of (in)direct discrimination is prohibited, which includes women during pregnancy, childbirth and postpartum. ‘Special measures that the Republic of Serbia may introduce in order to achieve full equality of persons or groups of persons who are

essentially in an unequal position with other citizens are not considered discrimination' (Constitution of RS, 2006, Article 21). This provision lays ground to the introduction of special forms of maternal health care. The right to life, the right to dignity which is inviolable, the inviolability of physical and psychological integrity, the right to liberty and security, guaranteeing the protection of personal data, guaranteeing the freedom of decision-making about childbirth (Constitution of RS, Articles 24, 25, 27, 42, 63) are all rights that should be protected in this period. The Constitution recognizes the special need to protect the family, mother, single parent and child, while special support and protection must be provided before and after childbirth (Constitution of RS, Article 66). Special attention within the Constitution is devoted to the 'healthcare of children, pregnant women, mothers during maternity leave, single parents with children up to the age of seven who receive health care from public revenues, if they do not receive it in another way, in accordance with the law' (Constitution of RS, Article 68). These constitutionally protected rights are enforced through appropriate legislative measures.

The health care system in Serbia is regulated by the Health Care Law from 2019, which, among other things, regulates the social care for the population's health care and explicitly states that it includes 'persons planning family, women during pregnancy, childbirth, and in maternity period up to 12 months after childbirth' (Health Care Law, 2019, Article 11). Health care in this period should be provided by mandatory health insurance, but if not, funds should be provided in the state budget (Article 11). This law promotes several principles of health care - respect for human rights and values and the rights of the child in health care, equity, comprehensiveness, affordability, continuity, efficiency and continuous improvement of quality and safety of health care (Articles 20-26). All of these apply to women during pregnancy and postpartum, but this is specifically emphasized within the first principle stating that pregnant women and women in postpartum have the 'right to the highest attainable standard of health and health care' (Article 20). From our analysis, we can conclude that the Health Care Law recognizes the special position and vulnerability of women during pregnancy and after childbirth.

The Health Insurance Law (2019) regulates the area of health insurance within which pregnant and postpartum women exercise their rights. This law provides that the right to health care includes 'examinations and treatment related to family planning,

during pregnancy, childbirth and up to 12 months after childbirth' (Health Insurance Law, 2019, see Articles 52, 54). We came to the same conclusion that special attention is provided for women in the period of planning the pregnancy, during and after it.

The Law on the Exercise of the Right to Health Care for Children, Pregnant Women and Mothers was adopted in 2013. This law regulates the right to health care and reimbursement of transportation costs related to the use of health care for children, pregnant women and mothers, if these rights cannot be exercised on the basis of mandatory health insurance (Law on the Exercise of the Right to Health Care for Children, Pregnant Women and Mothers, 2013, Article 1). Additional protection is provided by having access to health care based on a health insurance document issued by the Republic Fund, even if not certified, with precondition to have a report from a specialist in gynecology and obstetrics on the pregnancy or a discharge list from a health institution on the finalized labour (Article 4).

We also analyzed the Law on Patients' Rights (LPR) from 2013, which governs patients' rights in the context of health care provision, the mechanisms for exercising and protecting those rights, and other matters relating to patients' rights and obligations (LPR, 2013, Article 1). Implementing patients' rights in general applies to pregnant women as well as to those in labour and in the postpartum period. Importantly, according to law, patients have the right to affordable and quality health care, information related to their health status, service and the name and surname of the health care worker involved in their treatment (Articles 6, 7). Patients also have the right to 'appropriate health services for the preservation and improvement of health, prevention, suppression and early detection of diseases and other health disorders', as well as to timely and high-quality health care, which implies a 'humane attitude towards the patient' (Articles 8, 9). For women during pregnancy, labour and postpartum, the right to safety in the implementation of health care 'with the aim of achieving the most favorable treatment outcome and reducing the risk of unwanted consequences for the patient's health to the lowest possible extent' is especially important. Therefore, the 'health institution is obliged to take care of safety in the provision of health care, as well as to continuously monitor risk factors and take measures to reduce them, so the patient cannot suffer damage caused by inadequate functioning of the health service' (Article 10). This provision is very

important, as sometimes the lack of health care staff or organizational issues can pose a problem with multiple labours happening simultaneously, leading to the possibility that adequate care might not be provided for all women.

Although the right to receive information is explicitly regulated by the law (Article 11), our research findings reveal that the failure to provide women with pertinent information during and after childbirth is in fact one of the biggest problems in maternity hospitals. These failures can include, among others, not advising the woman about the medical staff's intention to take certain measures, and the failure to ask for, or explain consequences of their (non-)application.

The law grants patients the right to freely choose proposed medical measures and to seek a second expert opinion from a doctor not directly involved in their treatment (Article 12, 13). This freedom is particularly important regarding measures applied during the labour. According to law 'no medical measure may be taken against the patient without consent,' except in exceptional cases established by law, in accordance with medical ethics (Article 15). The law regulates in detail how the consent is given and withdrawn (Articles 16-18). If the notification is not given in such manner it shall be deemed that the consent is not given and consequently the health professional bears the risk of adverse consequences (Article 16). A factor that exacerbates a medical procedure without consent is the presence or active participation of several people in such internal procedure without the woman's consent. These are most often students of schools and higher education institutions of the health profession, present for the purpose of conducting practical classes, as well as health workers and health associates, during their internships and professional development (Simić, 2025, p. 62). Importantly, the law forbids their presence at the procedure if the woman requests their absence (Article 14).

The law also provides for other rights, such as the access to medical documentation, confidentiality of data, respect of patient's time, the right to object, and damage compensation. It stipulates the right to relief from suffering and pain, including pain therapy (Article 28). This right is of particular importance for women enduring the painful childbirth process and is one of the most often complained of problems during childbirth, as not all women are able to receive adequate pain relief therapy during and after labour.

Based on our research, we can conclude that although the Law on Patients' Rights does not distinguish pregnant women and women in childbirth as a special category of patients, the general provisions nevertheless still do apply to them. However, it may not be necessary to separate them into a special category, since adequate implementation of the existing provisions in practice would be sufficient to protect their rights and special position.

Our research results show that the legal framework in Serbia adequately protects women's rights before, during and after childbirth, and is harmonized with relevant international legislation. The problem, unfortunately, is not with the legal framework, but rather with how the regulations are implemented in practice. The deficiencies in how the regulations are implemented is a problem faced by a large number of women, and is the focus of the next sections.

5 Enforcement of Regulatory Framework in Judicial Practice - Case-Law Analysis

The existing case law on obstetric violence in Serbia is rudimentary, and the number of (publicly available) judgments is sparse. This phenomenon ties to the fact that most of the women who have had negative experiences during and after childbirth opt not to seek legal remedies. However, in the last few years Serbia has seen a rise in the media coverage of this issue with women coming forward and sharing their experiences.

When analyzing the limited case law in Serbia, it seems that courts are not necessarily creating a space that would encourage women to pursue legal remedies for rights breached during childbirth. As with any other, these legal proceedings are lengthy and costly. Moreover, as our research results show, the number of rulings in favor of plaintiffs is concerningly low. One of the main reasons lies in the way the courts interpret and apply existing regulations. The courts tend to focus on the so-called medical error,¹ which the case law commonly defines as a culpable deviation from the medical standard.

¹ 'In the retrial, the second-instance court will determine whether medical error occurred, as well as the causal link between the alleged error and the resulting harm.' Judgment of the Supreme Court of Cassation of 22 December 2022, *Rev* 8926/2021.

Plaintiffs often are unable to prove the existence of a medical error.² Thus, the case law allows for the defendants to be exonerated from liability if the plaintiff fails to prove the deviation from the standard. Considering the fact that the medical standard is not uniform and is oftentimes non-existent for every possible situation, women are put in an unfavorable position and discouraged from seeking legal remedies. Similarly, some harmful procedures, such as the Kristeller maneuver, are still ‘commonly used’ and thus present a medical standard, despite the WHO’s opinion that it is harmful.

In relation to the unfavorable position of women as plaintiffs in these proceedings, even the Appellate Court in Novi Sad recognized it, stating: ‘In this regard, the appeal reasonably points to a violation of the principle of equality of parties in the proceedings, since on one side there is the defendant – a healthcare institution and a professional medical expert – and on the other side there are parties who are laypersons.’³

The requirement for expert testimony in such cases in order to render a favorable judgment for the woman often presents an insurmountable hurdle. This is due to the unfortunate fact that such experts often render the opinion that there is no breach of the standard of care without detailed reasoning, out of professional solidarity among medical professionals.

For example, the expert opinion cited in the judgment of the Appellate Court in Niš states: ‘*According to the commission’s findings, it cannot be denied that there was an oversight in the antenatal and intrapartum assessment of the fetal body weight*’, however, the team of senior on-call physicians acted in a timely manner and in accordance with established procedures, doing everything necessary once shoulder dystocia was identified and when there was no other option for completing the delivery. *According to the conclusions*

² See f.e.: ‘The plaintiff was admitted to the hospital in a timely manner, during the plaintiff’s spontaneous labour the Kristeller maneuver was applied as a method commonly used in cases of arrest of fetal descent, but due to impending fetal asphyxia, the delivery was completed by cesarean section, during which a uterine rupture was observed and sutured, thereby being remedied. In such circumstances, even if the uterine rupture had occurred as a result of an inadequate, that is, excessively forceful Kristeller maneuver, as the plaintiff maintains, it was remedied in a timely manner and the causal chain was thereby interrupted. *The subsequent bleeding that led to reoperation and removal of the uterus was caused by the plaintiff’s health condition, namely the condition of her reproductive organs, and cannot be linked to the actions of the defendant’s employees*’. Judgment of the Appellate Court in Novi Sad of 20 April 2016, Gž. 1372/16.

³ Judgment of the Appellate Court in Novi Sad of 16 December 2015, Gž. 3066/15.

*of the said commission, the physicians' conduct represented the only possible medical solution under the given circumstances.*⁴

It is clear that the medical personnel failed to adequately and diligently measure the fetus's weight, thereby failing to conduct the necessary intervention. Yet the expert witnesses nevertheless concluded the standard of care had not been breached.

When analyzing the criminal case law, it is important to note that obstetric violence is not recognized as a separate criminal offense in Serbia. Our case law research results show that obstetric violence is most commonly classified as a serious offense against human health (Criminal Code of the Republic of Serbia, Article 259(2)), which presupposes the occurrence of a human death. However, the courts generally absolve defendants from liability primarily on the grounds that the fetus or stillborn child is not legally recognized as a person and protected under this provision since 'birth is the legally relevant moment when the newborn becomes a "person" within the meaning of said provision'.⁵

Our previous analysis attests to the need for the courts to act as a catalyst to develop the case law on obstetric violence, by adequately interpreting the existing framework and by not further burdening plaintiffs' procedural position. The courts should also insist that expert witnesses deliver unequivocal and impartial opinions and create a safe environment for women to share their experiences. Importantly, however, there are some examples of good judicial practice, where the courts have adequately interpreted existing regulations so as to better protect the rights of women giving birth.

In the Judgement of the Supreme Court of Cassation Rev 3034/2021, the court correctly established the conditions of liability, such as the damage, harmful act, causation and fault, by determining: 'that the doctors who completed the delivery did not objectively assess the specific clinical situation, because they performed the delivery of an unexpectedly large fetus by vacuum extraction, which led to serious injuries to the newborn; doctors did not comply with the rules of the medical practice, primarily due to deficiencies in shift work, information exchange and

⁴ Judgment of the Appellate Court in Niš of 3 December 2015, *11Gž-1270/15*.

⁵ Judgment of the Court of Appeals in Kragujevac of 15 August 2022, *Kž1456/22*.

deficiencies in medical documentation; that the timely surgical removal of the fetus would have led to the birth of the baby without damage or with far less damage; that an ultrasound examination nor continuous CTG monitoring wasn't performed; and that there is a direct cause-and-effect relationship between the injuries and the methods and means used during childbirth'.⁶ These decisions provide a good roadmap for future courts to rule in ways that will promote justice for women giving birth and help to ensure adequate maternal care.

6 Analysis of Maternal Care in Serbia in Practice - Women's Experiences

The problem of women receiving inadequate treatment both during and after childbirth was not widely discussed in the public sphere in Serbia until recently. Public awareness was heightened by the statements of two women who described their negative experiences in a maternity hospital in Belgrade in 2022. Since then, the issue of treatment during and after childbirth has become increasingly prominent in public discourse. Several studies have been conducted on this topic, including women's testimonies and the transmission of their experiences from various state hospitals. During 2022, three lawyers conducted an 'Analysis on the treatment of women in gynecological and obstetric institutions in Serbia' (Mijatović et al., 2022). The research included testimony from approximately 200 women about their experiences in maternity hospitals, out of which 110 gave consent for their statements to be quoted, considering their experience to be a form of obstetric violence (Mijatović et al., 2022, p. 4). Within these testimonies, 16 forms of violence and abuse, i.e., inhumane treatment of female patients, were identified. The largest number of reports analyzed in this research, 76.36%, related to verbal violence and poor communication (Mijatović et al., 2022, p. 22). Women complained about the frequent use of the Kristeller procedure and vacuum extraction, despite their numerous risks (Mijatović et al., 2022, p. 27). Even though the Law on Patients' Rights prescribes both the right to freely choose proposed medical measures and the need for informed consent, testimonies indicate that these provisions are unevenly applied. For example, medical staff often fail to inform women about their intention to apply a certain procedure and their rights to decline certain procedures. Women

⁶ See f.e. Judgment of the Supreme Court of Cassation of 12 August 2021, *Rev. 3034/2021*, Judgment of the Court of Appeals in Belgrade of 28 August 2024, *Kž1 663/24*.

complained about forced episiotomy, physical injuries as a result of abuse during treatments, unwanted induction, not receiving anesthesia, and inhumane and degrading treatment (Mijatović et al., 2022). The complaints regarding consent emphasize that women were required to sign extensive documentation agreeing to various procedures in order to even be admitted to the hospital (Mijatović et al., 2022, pp. 36-37). The conclusion of the presented research is that the ‘treatment of women in gynecological and obstetric institutions in the Republic of Serbia is not in accordance with international regulations and standards, nor with domestic norms’ (Mijatović et al., 2022, p. 22).

According to the results of the research conducted by the Center for Investigative Journalism of Serbia (CINS), over 50% of women complained about verbal abuse (CINS, 2025). They also reported neglect during childbirth and receiving labour induction without adequate prior information. Denial of pain relief was reported by approximately one-third of the women. Violations of privacy were reported by approximately one-third of women, while physical abuse was reported by approximately one-quarter (CINS, 2025).

Of particular concern, and indicative of the historical neglect and taboo surrounding this issue, is that 97% of these women never reported the events they experienced. Some of the main reasons given for not reporting negative experiences included: awareness of future labour in the same institution (and fear of retribution), powerlessness, childcare as priority, lack of awareness and education on the issue (CINS, 2025). Among over one thousand surveyed women, only 33 reported their experiences to the authorities. Unfortunately, most of these reports resulted in no outcome or were still under investigation at the time of reporting; only one case led to the perpetrator being punished (CINS, 2025).

The results from research conducted by the United Nations sexual and reproductive health agency (UNFPA) in Serbia in 2024 are aligned with previously explored surveys. Women complained about being discharged without gynecological examination, the practice of accelerating labour through induction, routine oxytocin use and labour acceleration without previous explanation and disagreements among medical staff regarding interventions (Pantović et al., 2025, pp. 28-31). The degrading treatment of women during childbirth is emphasized with suturing often

performed without anesthesia, women being unable to change positions during labour as they were attached to a CTG monitor, and not being allowed to eat or drink anything during labour despite feeling thirsty or hungry (Pantović et al., 2025, pp. 35, 61, 62).

The use of epidural analgesia during labour in Serbia is concerningly low, considering its benefits and importance and as emphasized by WHO. None of the women in the survey who gave birth in Novi Sad or Novi Pazar received it, despite 22.5% of respondents who gave birth in Novi Sad explicitly requesting it. It appears that epidural analgesia is most widely available in Belgrade and mostly in the tertiary healthcare institutions (Pantović et al., 2025, p. 37). One potential reason for this may lie in the unavailability of resources and health care workers in provincial cities, especially in rural areas.

As did the previous ones, this survey showed that the right to information and informed consent is often ignored, as none of the respondents were able to have a discussion about the planned course of labour, or a birth plan, prior to delivery, except when a cesarean section was scheduled (Pantović et al., 2025, p. 51).

Significantly, the UNFPA survey found that before participating in the discussion, the respondents rated their communication with health care professionals as very satisfactory (26.4%) or completely satisfactory (33%) and more than half of the respondents reported being completely satisfied with the received care (Pantović et al., 2025, pp. 19-20). These findings indicate that the mistreatment of women during labour is so frequent that it has become common and expected.

Notably, the scope of the first two surveys is limited, as they were conducted online and focused on negative experiences. Despite these limitations, these studies are consequential as they raised public awareness about this crucial issue, gave women a space to talk and presented serious problems in practice to decision-makers.

The results of our analysis show that the human rights guaranteed by previously analyzed legal documents often exist only theoretically. Research results find that the most frequently violated rights are the right to information, privacy, dignity, quality health care and the right to freely choose proposed medical measures. Concerningly,

almost none of the WHO standards are adequately implemented in Serbia. Communication is poor, women are discouraged from choosing their preferred positions and moving, adequate pain relief is often not provided, both CTG and episiotomy are used excessively, unnecessarily expediting birth, while the Kristeller maneuver is often used injudiciously without adequate medical indications.

We believe that one of the main factors explaining these human rights violations is that maternal wards are understaffed, especially in light of their huge workload. In 2022, health care services for women's health were provided by 509 physicians. On average, one gynecologist was responsible for the reproductive health of 5,812 women aged over 15 (Beker et al., 2024, p. 81). Similarly, the lack of resources leads to inadequate maternal care, especially with providing pain relief options. The taboo surrounding this issue has led women into silence, which only perpetuates the cycle and leads to normalization of mistreatment during childbirth. On the other side, we believe that the reasons why women shun legal remedies lie in the courts' negative (dismissive) attitude towards these proceedings, fear of mistreatment during future childbirth especially in cities with only one maternal ward, emotional exhaustion, secondary victimization etc.

7 Alignment of the National Guide to Good Clinical Practice for Physiological Vaginal Birth with Contemporary Clinical Standards

Serbia has numerous legal Acts containing standards for maternal care.⁷ The last enacted is the National Guide to Good Clinical Practice physiological vaginal birth from 2025.⁸ This section of our paper will be devoted to analyzing and comparing this Act with international standards previously explored.

⁷ See f.e Radunović, 2005; Ministry of Health of the Republic of Serbia, 2009a, *General Principles of Communication with Pregnant Women, Women in Childbirth and Their Families: A Guide for Midwives and Physicians*, Lozanović-Miladinović, D. (ed.). Belgrade; Ministry of Health of the Republic of Serbia, 2009b, *General Principles of Care and Treatment in Maternity Hospitals: A Guide for Midwives and Physicians*, Lozanović-Miladinović, D. (ed.). Belgrade; National Programme for the Promotion of Breastfeeding and Family and Developmental Care of the Newborn, Official Gazette of the Republic of Serbia, No. 53/2018; National Programme for the Healthcare Protection of Women, Children and Youth, Official Gazette of the Republic of Serbia, No. 28/2009; Strategy for Encouraging Childbearing 2018–2025, Government of the Republic of Serbia, Official Gazette of the Republic of Serbia, No. 56/2018.

⁸ Ministry of Health of the Republic of Serbia, Academy of Medical Sciences of the Serbian Medical Society, Republican Expert Commission for Gynecology and Obstetrics (2025). *National Guide to Good Clinical Practice: Physiological Vaginal Birth*. Belgrade.

Communication: Every pregnant woman should be given information on the use of different methods of labour analgesia, complications during labour that may occur and communicated with in a dignified, kind, and respectful way and in clear, understandable language. They should be informed that they can take fluids and light meals during labour except if they have received opioids.⁹

Position and moving: Women should be encouraged to choose positions that suits them best during labour. However, the recommended position remains lithotomy, and other positions are allowed 'if conditions allow'.¹⁰

Pain relief: Opioid analgesia is recommended for healthy pregnant women but its use is dependent on their availability in the health care institution. If women opt for opioid analgesia they should be informed of possible side effects. Use of epidural analgesia is recommended and women who receive it should be encouraged to move if they can and discouraged from lying solely on their backs.¹¹

Companionship: Women should be able to make a decision about the presence of a close person during labour, who should also be informed about the course of labour and all medical procedures to be undertaken.¹²

Use of Oxytocin: Routine rupture of membranes or combination of early amniotomy with oxytocin administration is not recommended. Use of oxytocin is recommended only with slow progress of labour in the active phase of the first stage and after amniotomy. Women should be able to make an informed decision and be advised about the side effects of oxytocin use. Epidural analgesia is recommended if a woman has received oxytocin.¹³

Use of CTG: Continuous CTG use during the second stage of labour can increase the rate of operative deliveries and is not recommended.¹⁴

⁹ Ibid, Recommendations 1.2, 4.1, 4.4, 7.21, 7.22.

¹⁰ Ibid, Recommendations 3.1, 7.23, 7.11, 8.8, 8.9.

¹¹ Ibid, Recommendations 5.1, 5.9, 5.12, 5.13, 5.24, 5.19, 5.18.

¹² Ibid, Recommendations 3.2, 3.6, 3.8.

¹³ Ibid, Recommendations 7.33, 7.34, 7.42, 7.43, 7.44.

¹⁴ Ibid, Recommendation 8.5.

Episiotomy and intrapartum interventions to reduce perineal trauma: The risk of perineal trauma can be reduced by using water-soluble lubricants in the second stage, perineal massage, and manual perineal protection. Routine episiotomy is not recommended, and it should only be done if needed, especially for suspected fetal distress or instrumental delivery and only after the informed consent of a woman.¹⁵

Manual fundal pressure: Fundal pressure to facilitate or accelerate the labour is not recommended and may only be applied during the completion of delivery assisted by vacuum extraction, using controlled pressure on the uterine fundus.¹⁶

Expediting birth: Active management of labour is not recommended as a routine procedure and should be avoided if pregnancy is not high-risk. Women should be encouraged to make informed decisions on the course of labour.¹⁷

Our analysis of these recommendations shows that they are for the most part harmonized with the previously explored international ones, as guides contain almost identical provisions. Therefore, it seems logical to conclude that the various problems we have discussed that exist in practice are not caused by the lack of written standards or a deficient legal framework, but rather the way they are implemented in practice.

8 Recommendations and Concluding Remarks

This research was conducted with an aim to assess the state of the legal framework regulating women's rights during pregnancy, childbirth and in the postpartum period in Serbia, and how effective that framework is in practice. Moreover, we compared these findings with the international framework and its implementation in LMICs and HICs. On a positive note, we found that the Serbian legal framework is harmonized with international law and adequately protects women's rights in this vulnerable period. However, on a much more discouraging note, the provisions contained in the Serbian regime are being applied unsatisfactorily. Our research results show that women's rights provided by law are repeatedly breached. The most

¹⁵ Ibid, Recommendations 8.15, 8.17, 8.18, 8.19.

¹⁶ Ibid, Recommendations 8.30, 8.32.

¹⁷ Ibid, Recommendations 7.35, 7.10, 7.5.

frequent breaches include women being denied of their rights to information, privacy, dignity, quality health care and to freely choose proposed medical measures. Similarly, we found that the standards proposed in international guides are not adequately implemented in practice in Serbia. This is particularly the case regarding standards on communication, choice of position and moving, adequate pain relief, and the over-reliance on the use of CTG, episiotomy, birth expedition, and the Kristeller maneuver, which instead should only be employed under special circumstances and with medical indications, and of course after a thorough discussion with the woman and her companion, if there is one. There is little practical value in having even the best laws, standards, and protocols if they are not followed in the clinical setting and, when they are not followed (as is too frequently the case in Serbia), if women do not have adequate opportunity in the law to seek recourse as a result of those breaches.

On an international level, our research results show significant differences in the quality of maternal care between HICs and LMICs. Women in LMICs are more likely to have negative experiences and be subjected to at least verbal mistreatment during childbirth. Resource constraints in LMICs often prevent women from accessing adequate pain relief, while understaffed workplaces increase stress among health care providers, making them less compassionate and attentive. High workloads can lead health care workers to adopt practices that deviate from international standards and WHO recommendations – such as expediting labour, performing episiotomies, or using the Kristeller maneuver – to hasten delivery. Epidural analgesia, for example, appears to be the most effective pain relief option but requires more resources to implement and to manage adverse effects. On the other hand, precisely because of workload pressures combined with poor staffing levels, CTG is being used in the continuous manner as a ‘babysitter’ (i.e., as the ‘default practice’ instead of when truly clinically necessary and appropriate) and as an inadequate substitute for woman-centered care (WHO, 2025, p. 73).

In comparison, these challenges exist in Serbia as well, some of which may be culturally influenced, such as paternalistic decision-making regarding childbirth without the woman’s informed consent. These issues are intensified with the lack of judicial protection for women who experience trauma during childbirth, which may reflect judges’ limited experience in such cases coupled with the high social status of

medical professionals, and consequently, the small number of complaints that reach the court. In conclusion, maternal health care in Serbia, as in many LMICs, remains unsatisfactory. Women's negative experiences in maternity hospitals often influence their decision to have a second child, especially if they experienced trauma during childbirth and in postpartum. Serbia, as with many other countries, is actively and urgently seeking to increase its childbirth numbers due to a severe demographic crisis. Providing women with more positive childbirth experiences is one way to advance this governmental objective. Maintaining the status quo will only hasten Serbia's population decline.

The way forward includes better equipping health care institutions, ensuring access to effective pain relief, ensuring the possibility of partners' attendance during childbirth, providing continuous training for health care staff, addressing understaffing, and encouraging women to share their experiences and seek legal remedies. In order to provide respectful care, health facilities and health systems must be structured in a way that supports providers in different ways, including adequate infrastructure and organization of the maternity wards. Also, it seems that women-centered care can best be facilitated through continuity of midwife models of care, which emphasize the continuous education of midwives, and their improved position in the health system. Given the vulnerable position of women during pregnancy, childbirth and the postpartum period, one of the concrete changes that should be introduced is psychological support for women in maternity hospitals. Namely, such a type of support would be extremely important, especially for women who have had complications during childbirth and particularly those who have had a traumatic experience during their first birth. The conversation about postpartum depression and support for women should start already in maternity hospitals, which also requires a partial reorganization of work and the employment of competent staff who could provide women with adequate psychological support. Similarly, professional support from midwives who help with lactation has to be more available in the maternity care.

Publicly raising awareness in Serbia is a crucial step, and this paper aims to contribute to ongoing efforts to improve maternal care, while also offering lessons that other LMICs can take into consideration.

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Povzetek v slovenskem jeziku

Članek preučuje oskrbo matere skozi celoten proces nosečnosti, poroda in poporodnega obdobja z vidika zakonodaje in politike. Analizirane so mednarodni pravni okviri in klinični standardi skupaj z dokumentiranimi izkušnjami žensk v praksi, tako na globalni ravni kot tudi v Srbiji. S primerjavo normativnih zavez in njihovega izvajanja v Srbiji članek opredeljuje ključne vrzeli med formalnimi predpisi in dejanskimi izkušnjami. Članek raziskuje tudi strukturne, institucionalne in pravne dejavnike, ki prispevajo k tem neskladjem, ter se zaključí s priporočili na področju politike in zakonodaje, namenjenimi izboljšanju skladnosti, odgovornosti in kakovosti oskrbe matere.

BEYOND CONSENT: SELF-DETERMINATION AND PROTECTING HIGH-RISK PATIENTS IN HEALTH CARE

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Abstract Modern healthcare is built on the principle of informed consent which is the basis of patient autonomy and self-determination. However, this model has its very clear limits when applied to high-risk and vulnerable patients whose decision-making capacity is impaired. This study examines what lies behind consent in healthcare and asks how legal systems can protect high-risk patients without undermining their dignity, agency and human rights. The analysis adopts a comparative legal approach. It relies on international instruments and national examples from diverse legal traditions. The article argues that vulnerability should not serve as a justification for paternalism or uncontrolled coercion. Going beyond consent does not mean abandoning autonomy, it means reconceptualizing it in a way that ensures self-determination and protection for those most vulnerable in health care systems.

Keywords

informed consent,
patient autonomy,
vulnerability,
supported decision-
making,
human rights in health
care

1 Introduction

Imagine a patient who fails to fully understand their medical options - an elderly man with advanced dementia who refuses necessary surgery, or a teenager trapped in addiction who insists he does not need treatment. Modern healthcare is based on informed consent, the idea that patients have the right to decide about their treatment. But what happens when patients are high-risk and vulnerable, unable to protect their own interests or make informed decisions? “Beyond consent” means finding a way to support patient self-determination while simultaneously protecting vulnerable patients who lack full decision-making capacity. This study explores this balance, rooted in international human rights law but illustrated with real-world examples. We will examine how law and ethics address patients with cognitive impairments, psychiatric illnesses, addictions, and other high-risk situations, and propose innovative approaches to protect their well-being without sacrificing their dignity and autonomy. Methodologically, this article uses a doctrinal and comparative legal analysis. The study primarily relies on binding international human rights instruments (the United Nations Convention on the Rights of Persons with Disabilities¹ (CRPD), the European Convention on Human Rights and Biomedicine² (the Oviedo Convention), the Convention on the Rights of the Child³ (CRC), and the UNESCO, Universal Declaration on Bioethics and Human Rights⁴ (UNESCO Declaration on Bioethics) and their authoritative interpretive bodies, complemented by the jurisprudence of the European Court of Human Rights (ECtHR) and selected national courts. Regarding national examples, the jurisdictions were chosen to showcase differences between legal traditions and regions. The selection is not intended as an exhaustive comparative survey but rather aims to demonstrate the range of approaches that States have adopted in balancing patient autonomy with protective measures for vulnerable populations.

¹ Convention on the Rights of Persons with Disabilities, adopted on 13 December 2006 by the United Nations General Assembly, UN Doc. A/RES/61/106, entered into force on 3 May 2008.

² Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, opened for signature on 4 April 1997 in Oviedo, ETS No. 164.

³ Convention on the Rights of the Child, adopted on 20 November 1989 by the United Nations General Assembly, UN Doc. A/RES/44/25, entered into force on 2 September 1990.

⁴ UNESCO, Universal Declaration on Bioethics and Human Rights, adopted on 19 October 2005 by the General Conference of UNESCO at its 33rd session.

Respect for patient autonomy – the right of an individual to make decisions about their own body and health – is a fundamental principle of modern medicine. Legally, this is enshrined in the requirement of free and informed consent for any medical intervention. For example, the Oviedo Convention explicitly states that “*an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.*” This means that treating a patient without their consent generally violates the person’s right to bodily integrity and autonomy. The EU Charter of Fundamental Rights similarly derives the patient’s right to informed consent from the right to personal integrity.⁵ In essence, informed consent is a practical expression of self-determination in healthcare: patients have the right to choose (or refuse) a treatment after being given clear information about the risks and benefits (Kraljić, 2010, p. 187–199).

This model of patient self-determination emerged as a response to the historical paternalism of medicine, where doctors once made unilateral decisions on behalf of patients. Today, almost all national laws have a provision that states that patients must participate in decisions about their health and voluntarily consent to treatment. Intervention without consent is usually considered a violation of rights, unless justified by exceptional circumstances. Providing treatment without the patient’s consent would be a violation of their bodily integrity and personal identity. The primacy of consent is also reflected in global bioethics: The UNESCO Universal Declaration on Bioethics affirms that medical interventions require prior, free and informed consent and that special protection must be provided for those who cannot consent.

The ideal of complete autonomy, however, has its limits. In actual clinical practice, not all patients are always fully autonomous. Some individuals lack the mental capacity to understand complex medical information or to foresee the consequences of their decisions. Others may be under the pressure of internal compulsions (for example, in the case of severe addiction) or may be minors and therefore dependent on others for decision-making. In these cases, health professionals face a tension between respecting the patient’s expressed wishes and preventing serious harm. The following sections consider who these high-risk or vulnerable patients are and how

⁵ Charter of Fundamental Rights of the European Union, proclaimed on 7 December 2000 in Nice and adapted on 12 December 2007 in Strasbourg, OJ C 326, 26 October 2012.

law and ethics have evolved to protect them beyond simple consent.

2 High-Risk Patients and the Limits of Consent

High-risk patients refer to individuals who are particularly vulnerable when making decisions about their own medical care. This vulnerability may arise from age (for example, young children or the elderly), cognitive or intellectual limitations, mental illness, or conditions such as severe substance abuse that can impair judgment. These patients are high-risk either because they are unable to protect their own interests or because they may be vulnerable to rights violations if additional safeguards are not in place. Simply obtaining consent (or refusal) from such patients may not be sufficient to ensure their well-being or respect for their true wishes. In some cases, they may lack the capacity to give valid consent; in other cases, they may consent or refuse in a way that endangers their health due to impaired judgment.

Legal capacity – the ability to understand and make decisions – is a key issue here. Under traditional law, adults are presumed to have the capacity to consent to or refuse treatment. However, if evidence shows that a person is unable to understand information or make a sound decision, they may be deemed incompetent to make that decision. Classic examples are an unconscious patient in an emergency situation (temporarily unable to consent) or a person with advanced dementia (perhaps permanently unable to fully understand). In such situations, requiring strict consent could paradoxically leave the person without protection (for example, treatment for a life-threatening condition would not be provided because the patient cannot consent). Therefore, every society has developed mechanisms that go beyond consent in these cases – from surrogate decision-making and guardianship to involuntary treatment laws – to protect those who are unable to make adequate decisions for themselves.

However, these safeguards must be balanced against the person's right to self-determination. The risk is that vulnerability can become a gateway to paternalism or even abuse. International standards stress that vulnerability should not mean a complete loss of autonomy. For example, the UN Principles for the Protection of Persons with Mental Illness (adopted by the UN General Assembly in 1991) state that even if someone has a mental illness, any treatment must be tailored to preserve

personal autonomy as much as possible.⁶ Treatment should be provided in the least restrictive environment and with the least invasive means necessary. These principles reflect the rule that interventions beyond consent are permitted only as a last resort and with strict safeguards, always with the best interests and rights of the patient in mind.

So, who falls into these high-risk patient categories? We will focus on a few main groups:

1. Patients with cognitive impairments (such as intellectual disabilities or diseases such as Alzheimer's disease), who may not fully understand medical information.
2. Patients with psychiatric disorders, who may have impaired judgment during acute episodes or pose a danger to themselves.
3. Patients with substance use disorders, whose compulsions may override rational health decision-making.
4. Children and adolescents, who are legally dependent on adult decisions and whose capacity to understand develops with age.
5. Elderly patients, who often face a combination of physical frailty, potential cognitive decline, and social dependence, making them vulnerable to the decisions of others.

Each of these groups faces different challenges regarding autonomy and protection. In the following sections, we will address each of these, examining how law and practice seek to go beyond consent – and how international human rights law should guide these efforts.

2.1 Patients with Cognitive Impairments

Patients with cognitive impairments include people with intellectual and developmental disabilities, as well as those with conditions such as dementia or brain injuries that affect their ability to understand. These patients may not fully understand complex medical information or the consequences of their decisions,

⁶ United Nations General Assembly, Principles for the Protection of Persons with Mental Illness and the Improvement of Mental Health Care, adopted on 17 December 1991, UN Doc. A/RES/46/119.

complicating the standard informed consent process. However, they are individuals with their own will, preferences and rights, and international law is evolving to recognise this.

The traditional solution for an adult lacking decision-making capacity has been to appoint a guardian or legal representative to consent on their behalf. Under this model of substitute decision-making, a doctor or court would first determine that the person lacks capacity and then another person (the guardian, family member or doctor) would make decisions in the best interests of the patient. This approach prioritizes protection but risks overriding the person's own wishes. In the past, it was common for people with intellectual disabilities or advanced dementia to be completely excluded from decision-making: decisions were simply made for them, not with them.

Modern human rights law has begun to challenge this paternalistic model. The CRPD, adopted in 2006, marked a paradigm shift. Article 12 of the CRPD declares that people with disabilities have the right to equal recognition before the law, which essentially means that mental or intellectual disability does not deprive a person of legal capacity. The CRPD requires States to move away from substitute decision-making and towards systems of supported decision-making (Gordon et al., 2022, p. 6002). In other words, rather than automatically relinquishing decisions to a guardian, the person should be given whatever support they need to make their own decisions to the best of their ability. This can include providing information in plain language, using visual aids, involving a trusted support person or advocate, and providing additional time.

The CRPD Committee (the expert body monitoring implementation) has emphasized that substitute decision-making is incompatible with the principles of the CRPD (Dute, 2015, pp. 315–320). In its first general comment, the Committee stressed⁷ that mental capacity (the ability to make decisions) is not the same as legal capacity (the right to make decisions) (Waddington & McSherry, 2016, pp. 279–304). Historically, many systems have conflated the two – if a person was deemed intellectually incapable of making decisions, they were deprived of the legal right to

⁷ Committee on the Rights of Persons with Disabilities, General comment No. 1 (2014) on Article 12: Equal recognition before the law, adopted at the Eleventh session, 31 March–11 April 2014, UN Doc. CRPD/C/GC/1, para 13.

decide. The CRPD rejects this: even if a person's decision-making capacity is impaired, their legal right to decide remains (Bartlett, 2012, pp. 752–778). States must therefore abolish substitute decision-making regimes and develop alternatives to supported decision-making. In practice, this led to guardianship laws being reviewed worldwide. Some countries have introduced supported decision-making arrangements – for example, in parts of Canada and Australia, an adult can appoint a supporter to help them interpret and communicate their decisions without usurping their decision-making entirely (Korać Graovac & Čulo, 2011).

However, this vision is challenging to realise. There will always be extreme cases – for example, people with profound cognitive impairment or advanced dementia – who, even with all possible support, are unable to formulate decisions about critical treatment. International law recognises that special safeguards may be necessary in such situations (Sorta-Bilajac, 2010). For example, Article 7 of the UNESCO Declaration on Bioethics states that if a person is incapable of giving consent, he or she must be afforded special protection by law.⁸ The earlier Principles for the Protection of Persons with Mental Illness and the Improvement of Mental Health Care (1991) similarly required that any decision declaring a person incapacitated should be made by an impartial tribunal and reviewed regularly.⁹ In practice, this means that if a guardian is to make a decision, it should genuinely reflect what the patient would want if they were able to speak. This is often referred to as the surrogate decision standard: decisions are based on the patient's known values and preferences, rather than simply on what the doctor or guardian believes is best.

An example is the use of advance directives for future incapacity. Many jurisdictions allow people to write advance directives for health care, or wills, stating their preferences for treatment in the event that they are later unable to give consent. In the case of cognitive degenerative diseases such as Alzheimer's, this can be a powerful tool for self-determination. Advance directives are increasingly recognised in legislation and bridge the gap between consent and protection: care is guided by the patient's own voice, rather than the paternalistic decisions of others (Chatham et al., 2025, pp. 1524–1531). In Europe, the legal recognition of advance directives

⁸ UNESCO, Universal Declaration on Bioethics and Human Rights, adopted on 19 October 2005 by the General Conference of UNESCO at its 33rd session.

⁹ United Nations General Assembly, Principles for the Protection of Persons with Mental Illness and the Improvement of Mental Health Care, adopted on 17 December 1991 by General Assembly Resolution 46/119, annex, OHCHR.

varies considerably. Germany is a good example - since 2009, the German Civil Code (§ 1901a BGB) explicitly recognises advance directives (Patientenverfügung) as binding, provided they address specific medical situations and interventions (Wiesing et al., 2010, pp. 779–783). France also strengthened the legal standing of advance directives through the Claeys-Leonetti law of 2016.¹⁰ This does allow physicians to depart from advance directives in emergencies or when they are deemed inappropriate (Boulanger et al., 2017). The notion of “manifestly inappropriate” under French law is narrow in this case and mostly includes directives drafted in overly general or ambiguous terms or outdated in light of medical progress. In Italy, Law No. 219/2017 introduced the Disposizioni Anticipate di Trattamento (DAT), which formally recognises living wills.¹¹ Denmark maintains a national registry for living wills through the Danish Health Authority, and Finland recognises advance directives through the Act on the Status and Rights of Patients (Forsius et al., 2025). On the other hand, there are several countries – including Poland, Romania, and Slovakia – that still lack legislation on advance directives.

Despite these advances, real-world practice varies. In some countries, full custodial care (where the individual loses all decision-making rights) is still applied to people with intellectual disabilities, sometimes with little regard for their personal wishes. However, this is gradually changing. Many jurisdictions are exploring intermediate steps, such as limited guardianship, shared decision-making schemes, and mandatory consideration of the person’s will and preferences in any decision.¹² In the European context, the CRPD has provided an impetus for revising laws on capacity and consent in order to strengthen the human rights of people with psychosocial or intellectual disabilities (Stavert, 2015). This includes involving people with disabilities in developing policies that affect them, rather than relinquishing decisions solely to experts.

¹⁰ France. (2016). Loi n° 2016-87 du 2 février 2016 créant de nouveaux droits en faveur des malades et des personnes en fin de vie.

¹¹ Italy. (2017). Legge 22 dicembre 2017, n. 219: Norme in materia di consenso informato e di disposizioni anticipate di trattamento. Gazzetta Ufficiale della Repubblica Italiana, No. 12.

¹² For example, Peru with its Legislative Decree No. 1384 in 2018, which establishes supported decision-making; or Ireland with its Assisted Decision-Making (Capacity) Act in 2015 which introduced a tiered system of decision-making supports.

For people with cognitive disabilities, moving beyond the framework of consent means not to erode the person's autonomy too quickly. This requires mechanisms to support their self-determination and using substitute decision-making only as a last resort. The guiding principle is to do what is necessary to help and protect the patient, but no more – always preserving as much of their own will as possible.

2.2 Patients with Psychiatric Disorders

Perhaps the greatest tension between self-determination and compulsory care arises in the field of mental health. Patients with serious psychiatric disorders – such as schizophrenia, bipolar disorder, psychosis, or severe depression – can sometimes have impaired judgment, pose a risk to themselves or others, or even lack insight into their illness. Many countries have mental health laws that allow for involuntary hospitalization or treatment in certain circumstances, usually when the patient is considered dangerous or incapable of making rational decisions due to their mental state. This is an area where the law explicitly contemplates circumventing the usual rules of consent: treating someone against their will in the interests of their own protection or public safety.

Mental health care has historically been relatively paternalistic. Under older standards (some of which persist), a person could be committed to a psychiatric hospital if they were likely to harm themselves or others as a result of their mental illness, or sometimes simply because treatment was considered in their best interests. Once admitted, they could be forcibly treated or subjected to therapy without consent, based on the doctrine that doctors or the court knew what was best for the patient. The European Court of Human Rights (ECtHR), in the 1992 case of *Herczegfalvy v. Austria*, recognized that a psychiatric patient who was incapable of giving consent could, if objectively necessary for the treatment, be treated against their will.¹³ The ECtHR held that “a measure which is a therapeutic necessity cannot be regarded as inhuman or degrading.”¹⁴ This shows that medical paternalism can be justified in the field of mental illness under certain conditions.

¹³ Judgment of the European Court of Human Rights of 24 September 1992, application no. 10533/83, *Herczegfalvy v. Austria*.

¹⁴ *Ibid.*, para 82.

However, international law is moving towards a more rights-based approach. As mentioned earlier, the CRPD calls for a fundamental rethink. Disability rights advocates argue that involuntary psychiatric treatment, if based solely on a person's mental disability, is a form of discrimination and violates a person's right to autonomy and integrity. The CRPD does not explicitly prohibit involuntary hospitalization, but its Committee has interpreted Article 14 (liberty and security of person) to mean that hospitalization on the basis of disability is not permissible. In other words, mental illness cannot in itself be a reason to lock someone up or to render treatment without the person's consent (Bartlett, 2012). The Committee and other UN experts (including the Special Rapporteur on torture) have even called for an "*absolute ban of forced psychiatric interventions*" and to explore alternative solutions.¹⁵ This is a dramatic departure from older thinking, which essentially called for an end to the routine use of involuntary hospitalization and forced treatment.

Despite reforms, the reality remains that involuntary treatment is still practiced in most regions of the world, and there is a debate about how far it should go. On the one hand, there is the ethical argument of therapeutic necessity: if someone is in the midst of a psychotic episode, perhaps suicidal or incapable of recognizing reality, are we really respecting their autonomy by respecting their refusal of treatment? On the other hand, the use of force in medicine, even for supposedly good reasons, can be deeply traumatic and violate human dignity.

Recent research and policy trends are focused on minimizing coercion. For example, the World Health Organization's QualityRights initiative promotes voluntary and community-based mental health care, eliminating practices such as long-term confinement or isolation.¹⁶ Some countries are investing in community-based crisis services (mobile crisis teams, crisis homes) that can respond to psychiatric emergencies in a more collaborative manner, hopefully reducing the need for involuntary hospitalizations. Programs such as Open Dialogue (originating in Finland)¹⁷ focus on intensive, patient-centered therapy early in psychosis, involving

¹⁵ Office of the United Nations High Commissioner for Human Rights, Committee on the Rights of Persons with Disabilities opens ninth session, Press release. Retrieved from: <https://www.ohchr.org/en/press-releases/2013/04/committee-rights-persons-disabilities-opens-ninth-session> (accessed: April 15, 2023).

¹⁶ World Health Organization, WHO QualityRights initiative – improving quality, promoting human rights, Knowledge Action Portal. Retrieved from: <https://www.knowledge-action-portal.com/en/content/who-qualityrights-initiative-improving-quality-promoting-human-rights> (accessed: January 24, 2026).

¹⁷ Council of Europe, Open Dialogue Model – Finland and internationally, Community-Based Initiatives, Human Rights and Biomedicine. Retrieved from: <https://www.coe.int/en/web/human-rights-and-biomedicine/open-dialogue-model>

the patient and their social network in decision-making from the start – reports suggest that this leads to less medication use and possibly fewer cases of involuntary treatment. A study from 2025 found that evidence-based interventions reduce coercive measures by 20-60% (Rojnic Kuzman, Fiorillo & Beezhold, 2025, p. e174).

Caring for psychiatric patients without their consent is a delicate balancing act. A fundamental human rights principle is that any deviation from the patient's expressed wishes must be absolutely necessary and proportionate and used only when no less severe measure could prevent serious harm. Moreover, even if treatment is provided without consent, the patient should be involved to the greatest extent possible – informed about what is happening and their views should be taken into account. International standards now insist that involuntary treatment should not mean a loss of rights and that patients still retain the right to humane treatment.

2.3 Patients with Substance Use Disorders

Addiction is often characterized by compulsive behavior and impaired self-control. This raises the question: if a person with severe alcohol or drug addiction refuses treatment, is that refusal truly informed and free, or is it motivated by the addiction itself? And if it is motivated by compulsive behavior, should the State or family intervene?

In many countries, the standard approach is that adults with addictions are considered capable of making their own decisions about their health, despite their illness, unless there is a clear state of incapacity.¹⁸ In practice, this means that a person addicted to opioids or alcohol cannot generally be forced to undergo treatment simply because they continue to abuse substances. The principle of autonomy applies: they have the right to refuse treatment, even if this decision is detrimental to their health. However, there are important exceptions. Several jurisdictions have enacted laws allowing for the involuntary hospitalization of people with substance use disorders in certain circumstances. For example, in the United States, as of a few years ago, 37 states and the District of Columbia had laws allowing

biomedicine/community-based-initiatives/-/asset_publisher/VE1niSrFa8t0/content/l-approche-du-dialogue-ouvert-finlande-et-niveau-international (accessed: January 24, 2026).

¹⁸ Mostly Western European jurisdictions - in England, Northern Ireland, Scotland and Wales, for instance, involuntary treatment cannot be based exclusively on the use of drugs or alcohol and must be combined with a mental health condition that places the individual or others at significant risk of harm.

for involuntary hospitalization for substance abuse or alcoholism.¹⁹ These laws typically require a showing that the person's substance use poses a serious and imminent risk to themselves or others (for example, repeated near-fatal overdoses or a pregnant woman whose continued drug use is endangering her fetus). In Sweden, the LVM Act (*Lag om vård av missbrukare i vissa fall*) enables compulsory closed care of adults with substance use disorders (Reitan, 2016, pp. 60–69). In the Australian State of New South Wales, the Involuntary Drug and Alcohol Treatment Program, established in 2012, permits detention for treatment of individuals who lack the capacity to make decisions about their substance use, and includes discharge supports transferring individuals to community care for up to six months (Ritter & Stooze, 2016, p. 138). In several Canadian provinces, mental health legislation permits involuntary treatment when substance use co-occurs with a mental health disorder (O'Reilly & Gray, 2014, pp. 65–67).

Family members or doctors can ask the court to commit the person to treatment for a limited period of time, even if the person refuses help. Significantly, however, even when such laws exist, they are rarely used. In the approximately 40% of U.S. states that have provisions for civil commitment to a drug treatment facility, studies have found that they are never or rarely used (Christopher et al., 2015). Many families and even judges do not use this avenue, either because they are unaware of the law or because they are reluctant to override the person's will unless absolutely necessary. The common view is that unless the addiction has led to criminal activity or an acute medical emergency, treatment should remain a choice.

In some countries, particularly parts of East and Southeast Asia and Latin America, there are extreme examples where people who use drugs are rounded up and placed in compulsory detoxification camps or rehabilitation centres without due process (Bazazi, 2018, pp. 1064–1065). These centres have been criticised for abuse – reports by human rights organisations describe how some of these facilities use forced labour or degrading treatment in place of evidence-based care (Zamudio, Chávez & Zafra, 2015).

¹⁹ Hazelden Betty Ford Foundation, Involuntary commitment for substance use disorder, Addiction Research. Retrieved from: <https://www.hazeldenbettyford.org/research-studies/addiction-research/involuntary-commitment> (accessed: January 24, 2026).

Another critical perspective comes from public health research: forced treatment for addiction may not be effective and may even be harmful. Studies suggest that involuntary interventions for substance use are generally less effective than voluntary treatment and may carry risks (Bazazi, 2018, pp. 1064–1065). One risk, for example, is that forcing someone to abstain without their consent can reduce their tolerance for drugs; upon release, if they relapse (since they have not truly embraced recovery), they face a higher risk of overdose. Given these factors, many experts say the emphasis should be on strengthening voluntary pathways to addiction treatment (Chlebcová, Boleková & Višňovská, 2019). This includes making treatment accessible, affordable, and removing stigma so that people are more likely to seek help on their own.

In seeking a balance between self-determination and protection for addicts, several proposals have emerged. One is to include a capacity assessment in addiction cases: to determine whether a person's decision-making is truly so affected by their substance use that they are essentially unable to make decisions (similar to an incapacity test). In rare cases, severe changes in the brain caused by substances can render a person temporarily incapable of rational decision-making, which may justify a substitute decision-maker (similar to severe delirium or intoxication in the emergency room). However, these cases are likely to be the exception. Another proposal is to use court-supervised treatment agreements – e.g., drug courts, where individuals agree to undergo treatment as an alternative to criminal sentences (with some element of coercion, since the alternative is prison, but at least the person has some choice when choosing treatment over prison).

It is important to respect the personhood of addicts. The principle of “do no harm” applies. Any measure beyond consent should be demonstrably more beneficial than harmful. Given that involuntary treatment can have the opposite effect, the threshold for its use must be high and supervision strict. Self-determination should be recognised and used wherever possible.

2.4 Children and the Elderly

Two age-defined groups deserve special discussion: minors (children and adolescents) and elderly patients. Both groups often fall into the high-risk category regarding healthcare decisions, but for very different reasons – the former primarily

due to legal status and adulthood, the latter often due to medical frailties.

2.4.1 Children and Adolescents

In the case of children, the law generally does not recognize full autonomy. Minors (usually under 18) cannot give legally binding consent to most medical treatments. Instead, consent is given by a parent or legal guardian on the assumption that they will act in the child's best interests (Barzó, 2023). However, this does not mean that children have no say. Modern paediatric ethics supports the concept of consent – even if it is not legally required, children who are old enough to understand should be included in discussions and their wishes should be respected to an appropriate extent (Katz, Webb & the Committee on Bioethics, 2023). For example, a 7-year-old child may not choose to undergo chemotherapy, but doctors will explain it to him in simple terms and find out if he agrees; a 16-year-old child, although still a minor, may have sufficient maturity to make certain decisions about his care in collaboration with his parents and doctors.

International human rights law, through Article 12 of the CRC, states that children have the right to express their views freely in all matters affecting them, and these views should be given due weight in accordance with the child's age and maturity. This means that the views of a mature adolescent on medical treatment should not be lightly ignored. Many countries have adopted laws or policies that recognize mature minors – for example, a 16-year-old – can consent to or refuse certain treatments without parental intervention if they are considered mature enough (as is the case in some jurisdictions for decisions regarding mental health counseling or contraceptive services). In England and Wales, the landmark House of Lords decision in *Gillick v West Norfolk and Wisbech Area Health Authority* established that a child under 16 is legally competent to consent to medical treatment if they possess sufficient maturity and intelligence to understand the nature and implications of the proposed treatment – a standard now widely known as Gillick competence.²⁰

However, there are limitations. If a minor (or their parent) refuses treatment that is clearly life-saving or necessary, the State can intervene. Courts around the world have repeatedly ordered treatment of children against the will of their parents: a

²⁰ *Gillick v West Norfolk and Wisbech Area Health Authority* [1986] AC 112 (HL).

common scenario is when parents refuse a blood transfusion for their child on religious grounds (e.g. Jehovah's Witnesses) or when a teenager with cancer wants to stop painful treatment, but doctors believe that he or she is curable. In such cases, judges apply the best interests of the child test. A child's right to life and health may override the normal rule of parental authority. For example, the *Supreme Court of Canada in AC v. Manitoba* (2009)²¹ upheld a forced blood transfusion for a 14-year-old Jehovah's Witness, emphasizing that the child's welfare is paramount.

These interventions beyond consent (or beyond parental consent) are a form of protective paternalism in law. But they are fraught with ethical dilemmas. The key is that they are absolutely necessary: society should override the decision of a family or minor only in extreme situations where the child's life or long-term health is seriously at risk.

Children in healthcare have the right to protection and participation. We go beyond simple consent (since children cannot legally consent) by using a surrogate decision-maker, but we should also seek to hear the child's voice. The international community is urgently calling for a balance in which we gradually extend the child's autonomy as they mature (in CRC terminology - evolving capacities), while protecting them from serious harm.

2.4.2 Older Patients

At the other end of the age spectrum, we find older patients who often face threats to self-determination. Aging itself does not diminish a person's rights – an 80-year-old has the same right to consent as a 30-year-old. The Inter-American Convention on the Protection of the Human Rights of Older Persons (2015) explicitly states that every older person has the inalienable right to free and informed consent in matters of health.²² This was partly a response to prevalent age discrimination in healthcare, where the choices of older patients could be ignored or overridden.²³ The

²¹ Judgment of the Supreme Court of Canada of 26 June 2009, *A.C. v. Manitoba* (Director of Child and Family Services), 2009 SCC 30, [2009] 2 S.C.R. 181.

²² Inter-American Convention on the Protection of the Human Rights of Older Persons, adopted on 15 June 2015 at the 45th Regular Session of the General Assembly of the Organization of American States, entered into force on 11 January 2017.

²³ American Bar Association, Building the case for a convention on the rights of older persons, *Bifocal* Vol. 46 Issue 3. Retrieved from:

Convention clearly states that age alone is not a reason to bypass consent – older people must be treated as autonomous subjects.

However, many older people face cognitive decline (such as Alzheimer's disease or other forms of dementia) or other disabilities that may affect their decision-making. In these cases, these issues overlap with the previous discussion of cognitive disabilities. An older person who is no longer mentally competent falls under the same frameworks of guardianship or supported decision-making. The problem is that conditions like dementia are progressive – someone may be capable today, but not in a year. This is why advance care planning in geriatrics is so important. Encouraging older adults to express their values and wishes regarding future health care (through advance directives, durable powers of attorney for health care, etc.) is a key proposition for ensuring that their self-determination is respected, even if they later lose the capacity to make decisions.

Another common scenario is an elderly patient who is mentally competent but is subjected to subtle pressure or coercion. Elder abuse can take the form of relatives pressuring the older person to refuse certain treatments (perhaps to save money or expedite an inheritance) or to agree to things they do not want. Protecting autonomy in this case may require screening and advocacy – healthcare providers must be alert to signs that the older person's consent is not truly voluntary. Some jurisdictions have ombudspersons for the elderly or patient advocates who can intervene if an elderly patient's rights are being violated in a healthcare or long-term care facility.²⁴

Both children and older people show that age requires an individualized approach beyond the simple model of adult consent. In case of older people, we should strongly support their autonomy and intervene only when medical incapacity truly requires it, and even then, we follow the person's advance directives or likely wishes. In both groups, the principle is to respect the human dignity of the person at every stage of life – children must not be considered merely objects of medical decisions and older people as passive recipients of care. International human rights frameworks require that the inherent rights and wishes of every person, whether they are 8 or 80, be taken into account.

https://www.americanbar.org/groups/law_aging/publications/bifocal/vol46/vol46issue3/conventiononolderpersonsrights/ (accessed: January 24, 2026).

²⁴ For example, Hungary, Finland, Norway, Sweden.

3 Moving Forward: Innovative Approaches and Recommendations

Protecting high-risk patients while simultaneously respecting their self-determination is a challenge. Based on the previous analysis of legal frameworks and ethical considerations, we present key proposals that transcend a simple consent model for vulnerable patients.

States should reform laws to replace guardianship and surrogate decision-making with networks of supported decision-making. This means legislating formal mechanisms for patients with cognitive or psychosocial disabilities to receive assistance with decision-making. This will meet the requirements of the CRPD and keep the patient at the center of decision-making. Several jurisdictions have already taken significant steps in this direction. Peru (Legislative Decree No. 1384 of 2018) and Colombia (Law 1996 of 2019) have abolished guardianship for persons with disabilities and replaced it with supported decision-making frameworks. Ireland's Assisted Decision-Making (Capacity) Act 2015 introduced a tiered system of supports – from decision-making assistance to co-decision-making and, only as a last resort, decision-making representation. In Germany, the 2021 reform of guardianship law (Betreuungsrechtsreform) reinforces the principle that assistance must be oriented to the will and preferences of the person concerned. All of these examples show that the transition from substitute to supported decision-making is legally feasible. Empirical evidence also supports this. A 2024 systematic review of 140 studies on supported and shared decision-making interventions in mental healthcare found favourable outcomes across several dimensions. According to a 2024 study, facilitated treatment planning was associated with reductions in suicidal ideation, improvements in recovery measures such as empowerment, knowledge and quality of life, and a reduction in the use of involuntary hospitalisation (Francis, Hazelton & Wilson, 2024).

Health systems must support and respect advance directives, living wills and health care powers of attorney. Patients at risk of losing capacity (due to progressive illness or temporary incapacity) should be assisted in documenting their treatment preferences while they are able to do so. Legislation should ensure that these instructions are binding on healthcare providers (within reason and the law). This extends the right to self-determination to periods when the patient cannot actively consent. There are several great examples of this already happening in certain

jurisdictions. Germany's Civil Code has recognised binding advance directives since 2009, France's Claeys-Leonetti law of 2016 strengthened patients' rights to anticipatory decision-making, and Italy's Law No. 219/2017 introduced advance treatment provisions. India's Mental Healthcare Act of 2017 introduced the right to make advance directives in the context of mental health treatment, which is a significant innovation in the Global South.

Another suggestion is to develop clear protocols to assess a patient's decision-making capacity whenever a non-standard situation regarding consent arises. Capacity assessments should be conducted by qualified professionals, be specific to the decision in question, and be free from bias (not assuming incapacity solely on the basis of age, disability, or addiction). Regular reassessment is important, as capacity may fluctuate (e.g., a psychiatric patient may regain capacity after an acute episode).

It is also important to always utilize a the least restrictive alternative that can achieve the health goal, consistent with human rights principles. If some form of coercion is deemed necessary (e.g., temporary detention for emergency detoxification of an overdose victim), it should be as finite as possible, with a clear therapeutic purpose.

Any legal framework that allows for involuntary treatment (of mental illness, addiction or other conditions) should include robust safeguards. For example, independent advocacy services or ombudspersons should be available to represent the patient's voice (for example, mental health advocates who visit psychiatric wards to ensure that patients understand their rights and can defend themselves against abuse).

Naturally, any treatment provided without the patient's consent must meet the highest standards of care and ethics. In particular, in the case of psychiatric and addiction treatment, evidence-based practices should be mandatory. Coercive environments often fall short in quality, which is unacceptable. If the State forces someone into treatment, it has a duty to provide effective and humane treatment, not just detention.

Hospitals and health care facilities should use ethics committees or case conferences in complex situations where a patient's decision-making capacity or refusal of treatment is in question. These committees can bring multidisciplinary perspectives to ensure that any decision that overrides the patient's wishes is carefully considered and made only if it is truly justified. This introduces a level of accountability.

Some advocates are seeking an explicit "right to supported decision-making" or "right to mental capacity" in national laws, in line with Article 12 of the CRPD, to cement a change in legal culture. Others are proposing a human right to avoid undue interference, which would require doctors to demonstrate necessity before acting against the patient's will.

Implementing these recommendations will undoubtedly require changes in legislation, policies and professional practice. It may also require resources – decision-making support networks or community-based care alternatives can be resource-intensive. However, the investment is worth it if it leads to a more ethical health care system that respects the rights of vulnerable populations.

4 Conclusion

"Beyond consent" does not mean abandoning consent – it means building on informed consent to address the realities of vulnerable patients. High-risk patients challenge us to refine the way we view autonomy. International law is very clear on this: every person, regardless of disability or vulnerability, has the right to self-determination and to be treated with dignity. Concurrently, human rights frameworks recognize the need to protect people from serious harm, even when they are unable to protect themselves.

The way forward is through an approach that is inclusive, innovative and compassionate. We need to embrace solutions such as supported decision-making, advance directives and peer support to minimise the need for coercion. It is an approach that does not see autonomy as a black and white switch (on or off) but as a spectrum that we can enhance with support. If protective intervention is needed, it must be customized, transparent and accountable. In short, autonomy and protection are not mutually exclusive: we provide the best protection by empowering patients' voices wherever possible.

In practice, a health system that truly goes beyond consent will have fewer lawsuits over forced treatment and more bedside conversations about what patients want, fear and value. It will not treat consent as a formality (signing a form), but as an ongoing dialogue that adapts even when patients cannot speak for themselves.

The measure of a humane health system is how it treats the most vulnerable. High-risk patients deserve protection and respect. Protection should not be used as a code word for paternalism, but as a commitment to caring for patients in a way that is consistent with their own humanity and will. This is what healthcare beyond consent means – a system in which even those who cannot say “yes” or “no” are heard.

Legal Acts, Case-law

- Charter of Fundamental Rights of the European Union, proclaimed on 7 December 2000 in Nice and adopted on 12 December 2007 in Strasbourg, OJ C 326, 26 October 2012.
- Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, opened for signature on 4 April 1997 in Oviedo, ETS No. 164.
- Convention on the Rights of Persons with Disabilities, adopted on 13 December 2006 by the United Nations General Assembly, UN Doc. A/RES/61/106, entered into force on 3 May 2008.
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Povzetek v slovenskem jeziku

Sodobno zdravstvo temelji na načelu prostovoljne privolitve, ki je podlaga za avtonomijo in samoodločanje pacientov. Vendar ima ta model zelo jasne omejitve, ko se uporablja pri visoko ogroženih in ranljivih pacientih, katerih sposobnost odločanja je omejena. Študija preučuje, kaj se skriva za privolitvijo v zdravstvu, in zastavlja vprašanje, kako lahko pravni sistemi zaščitijo visoko ogrožene paciente, ne da bi pri tem ogrožali njihovo dostojanstvo, avtonomijo in človekove pravice. Analiza uporablja primerjalno-pravni pristop. Opira se na mednarodne instrumente in nacionalne primere iz različnih pravnih tradicij. Članek zastopa stališče, da ranljivost ne sme služiti kot utemeljitev za paternalizem ali nekontrolirano prisilo. Preseganje soglasja ne pomeni opustitve avtonomije, temveč njeno ponovno opredelitev na način, ki zagotavlja samoodločanje in zaščito tistih, ki so v sistemih zdravstvenega varstva najbolj ranljivi.

THE CASE FOR LEGALIZING AND REGULATING SURROGACY IN SINGAPORE

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Abstract Singapore faces severe demographic challenges, including low fertility rates and an aging population, necessitating a reevaluation of current family formation policies, particularly the ban on gestational surrogacy. It is argued that the legalization and regulation of surrogacy in Singapore is needed to address demographic pressures and infertility. A domestic regulatory framework would provide a safe pathway to parenthood while mitigating the legal and ethical risks of unregulated cross-border arrangements. Furthermore, legalization could stimulate demand for specialized healthcare and legal services. To align with Singapore's conservative sociocultural norms, the proposed framework should initially be based on altruism and permit access only to married heterosexual couples. Ultimately, legalizing surrogacy under stringent oversight, featuring clear eligibility criteria and a dedicated regulatory body, would balance reproductive autonomy with collective values. This approach fosters a more inclusive society while prioritizing child welfare and preventing exploitation, thereby offering a pragmatic solution to mitigate Singapore's demographic crisis.

Keywords

bioethics,
infertility,
legislation,
motherhood,
reproduction,
surrogacy

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1 Introduction

Surrogacy has emerged as an issue of considerable interest that has aroused much controversy within Singapore, prompted by the nation's steep demographic decline (Hashmi & Mok, 2013), advancements in assisted reproductive technologies (ART) and evolving societal attitudes (Chin, 2023). To date, surrogacy remains banned under Singapore's healthcare regulations, with strict prohibitions on assisted reproductive techniques related to the procedure (Chin, 2023; Sim & Ray, 2021). Specifically, under Regulation 36 of the Healthcare Services (Assisted Reproduction Service) Regulations 2023, it is a prohibited practice to "transfer an embryo into the body of a woman who intends to give the child up for adoption," which effectively outlaws gestational surrogacy within the country. Furthermore, Regulation 31 mandates that restricted procedures, including embryo transfers, can only be provided to a patient who "is legally married to a man" and with her husband's consent, explicitly excluding single women and same-sex couples from accessing these services (Ministry of Health Singapore, 2023). As personal and sociocultural viewpoints on surrogacy continue to evolve and diversify in Singapore over time, there has been much discussion about whether the current ban on surrogacy should be revisited and reconsidered (Au-Yong, 2019; Chin, 2023; Sim & Ray, 2021). Here, various arguments for legalizing surrogacy in Singapore are explored, based on local circumstances and comparative international developments. The analytical approach adopted is a normative legal analysis, drawing on comparative international regulatory frameworks and local sociocultural realities to evaluate the case for reform. Some relevant laws and regulatory safeguards for permitting surrogacy will be proposed, based on the local sociocultural context of Singapore (Chin, 2023; Heng, 2007).

Based on ongoing discussions about surrogacy at both the local and international levels, there are some compelling reasons why Singapore should reconsider its ban on the procedure (Au-Yong, 2019; Chin, 2023; Heng, 2007; Sim & Ray, 2021). First, legalized surrogacy provides an opportunity for infertile couples to form a family where regular assisted reproduction techniques such as IVF (in vitro fertilization) would fail due to insurmountable medical or biological barriers (Chin, 2023; Sim & Ray, 2021). Current healthcare regulations in Singapore only allow legally married heterosexual couples access to fertility treatment (Au-Yong, 2019; Chin, 2023; Heng, 2007; Sim & Ray, 2021). De facto same-sex couples and cohabiting partners from unregistered common-law marriages are prohibited from accessing any form of

assisted reproduction treatment since such relationships are not legally recognized in Singapore (Au-Yong, 2019; Chin, 2023; Heng, 2007; Sim & Ray, 2021). Second, legalizing surrogacy could curtail illegal and unregulated cross-border surrogacy cases, which pose considerable legal and safety risks to all parties involved (Pascoe, 2018; Piersanti et al., 2021; Shepherd, 2022). If surrogacy were to be legally permitted and regulated in Singapore, the intended parents, surrogate mothers, and resulting offspring would enjoy stronger protection and legal rights (Chin, 2023). Third, legalizing surrogacy and regulating it locally within the country would allow Singapore government policymakers to implement various safeguards necessary to address the ethical, health, and social problems that may be specific to the local context, as well as ensure that all surrogacy arrangements align with local family laws and sociocultural values (Au-Yong, 2019; Chin, 2023; Heng, 2007; Sim & Ray, 2021).

2 Benefits of Legalizing Surrogacy

The legalization of surrogacy in Singapore has the potential to generate significant tangible economic benefits, particularly for the healthcare and legal sectors. Most obviously, the implementation of a regulated surrogacy framework would lead to increases in the number of specialized medical services needed (fertility treatment procedures, obstetric services, and counseling for the intended parents and surrogates) (Heng, 2007). Such increase in demand can result in new jobs, investment in medical facilities, and enhance training of medical professionals, strengthening Singapore's status as a regional hub for assisted reproductive technologies in Asia. Moreover, a well-regulated legal framework for governing surrogacy would create demand for professional contract drafting and legal advice, thereby providing local lawyers and law firms with the opportunity to administer surrogacy contracts and arbitrate legal disputes (Shepherd, 2022). By implementing a moderate and flexible regulatory framework on surrogacy, Singapore can thus attract both local and foreign patients, as well as promote knowledge exchange and best-practices development in an open, transparent and accountable process. Furthermore, permitting surrogacy under a clearly-defined legal framework could enable Singapore to become a regional medical tourism hub for assisted reproductive medical services. Because Singapore has an established reputation of excellence in the provision of healthcare services, together with a well-regulated and trustworthy legal system, it has much potential in attracting international patients who would otherwise have to contend with unregulated surrogacy arrangements in countries with inconsistent or underdeveloped regulatory oversight of medical services

(Piersanti et al., 2021). However, such opportunities must be carefully balanced with the strict enforcement of appropriate legal safeguards so as to avoid the rampant commercialization and potential exploitation that has often accompanied surrogacy tourism in various parts of Asia, where lax regulation has occasionally resulted in inequitable practices and unfavorable outcomes for surrogates, intended parents and offspring alike (Hibino, 2022).

Additionally, legalizing surrogacy in Singapore could also provide a catalyst for positive social change by embracing and affirming diverse and alternative family structures within Singapore's multi-cultural and multi-religious society. However, to reconcile this progressive vision with the conservative realities of current Singaporean policymaking, it is important to clarify the article's normative position. While surrogacy has the potential to validate the existence of atypical and non-traditional families, the regulatory model proposed herein reflects a pragmatic compromise that prioritizes political feasibility. By initially limiting access to married heterosexual couples, the proposed framework (Table 1) aligns with existing state policies that heavily favour the traditional family unit, while still addressing the urgent medical needs of infertile couples. It is anticipated that such a conservative and limited initial framework (Table 1) could serve as a foundational step, eventually paving the way for broader inclusivity as societal norms continue to evolve. Additionally, laying out formal legal protections for all parties involved in surrogacy could help Singapore create a more egalitarian environment as the surrogate and intended mother will be afforded protections and autonomy under a clearly defined legal framework (Chin, 2023; Sim & Ray, 2021). Such regulatory protections could provide important legal recognition that challenges traditional gender stereotypes, promote women's reproductive rights and freedom from coercion, in response to longstanding debates over personal choice and autonomy (Piersanti et al., 2021). By advancing these social aims, Singapore can benefit from international experiences and contribute to a framework which honors the rights of all parties involved in surrogacy, addressing their competing needs and priorities, while protecting the welfare of both families and children.

Drafting a robust and comprehensive legal framework for the regulation of surrogacy must first and foremost prioritize safeguarding the dignity, security and welfare of all parties involved, particularly those most vulnerable – surrogate mothers and resulting offspring. Unregulated surrogacy arrangements can lead to violations of personal autonomy, exploitative commercialization of women's bodies

and numerous uncertainties on the legal status of children and their rights – issues consistently highlighted and articulated in international debates (Fрати et al., 2021). Having a formal legalized surrogacy framework will thus allow Singapore to guarantee that each and every surrogacy contract will observe basic tenets of informed consent, non-exploitation, privacy, and respect for individual autonomy. This would thus provide governance on human rights issues arising from the competing interests of intended parents, surrogates, and offspring, particularly when there are differentials in bargaining power or legal protections (Bara et al., 2023). Furthermore, strict regulation will establish a transparent process that eliminates abusive practices and maintains the integrity of family formation, while reinforcing Singapore's family values and protecting vulnerable parties involved in the surrogacy process.

3 Arguments for Permitting Surrogacy in Singapore

Currently, Singapore faces increasingly severe demographic challenges that provide compelling reasons for rethinking its ban on surrogacy (Sim & Ray, 2021). In particular, the country's persistently low fertility rates and rapidly aging population pose dire long-term consequences for its economic productivity, as well as family support and social network systems for the elderly (Xuan, 2024). Such worrying demographic trends call for urgent measures to assist family formation among its citizenry, particularly married couples facing severe infertility problems (Sim & Ray, 2021). The experiences of the United Kingdom (UK) and Hong Kong where surrogacy is regulated under tightly controlled regulatory regimes may provide some valuable examples for Singapore to learn and emulate from. In particular, these jurisdictions have well-developed existing legal frameworks for surrogacy that uphold prevailing family norms, while protecting all parties involved and addressing pressing medical needs (Sim & Ray, 2021). Concurrently, Singaporean policymakers must ensure that the legalization of surrogacy is congruent with the nation's core social objectives, such as protecting child welfare and ensuring that they are brought up in a stable family environment (Au-Yong, 2019).

Moreover, a rising number of Singaporeans face infertility challenges, due to the prevalent trend of late marriages and parenthood within the country. Hence there is much demand for alternative means and pathways of attaining parenthood. For some women who experience more severe forms of infertility, surrogacy offers a way to pursue family-building aspirations that may not be possible due to

insurmountable medical or biological barriers. A well-regulated surrogacy framework can therefore turn the lives of intended parents around, allowing them to conceive genetically-related offspring with due recognition and rights within the auspices of a legally enforceable agreement. Due to the current ban on surrogacy in Singapore, many infertile couples attempt to bypass such legal restrictions by resorting to cross-border surrogacy arrangements to address their infertility challenges. This often results in adverse outcomes for the child, such as challenges in establishing legal parentage with the possibility of statelessness and lack of family security (Pascoe, 2018). The thoughtful regulation of surrogacy within a stringent legal framework would not only address the pressing needs of infertile couples aspiring to start a family, but also provide regulatory protection for the health, safety and welfare of the resulting offspring within the auspices of a formal legal contract (Chan, 2021).

Additionally, shifting cultural and societal norms together with changing family structures in Singapore is altering public opinion on surrogacy. It is anticipated that there will be greater acceptance of alternative family formation in the future, as social attitudes evolve with the emergence of a new generation. Recent empirical evidence supports this trajectory. For instance, the 2021 Marriage and Parenthood Survey conducted by the National Population and Talent Division (NPTD, 2022) found a notable shift in perceived gender roles, with 99% of married respondents agreeing that fathers and mothers are equally important as caregivers, and the proportion favouring full-time maternal care declining significantly. Similarly, the Gen Z and Millennial Survey conducted by Deloitte (2024) found that younger Singaporeans increasingly prioritise inclusivity and accept diverse social structures. However, current Singapore government policy towards family formation remains highly conservative and focuses almost exclusively on traditional heterosexual marriage, while actively discriminating against and excluding all other alternative forms of family formation. Under the Women's Charter, same-sex marriages are legally void, and Article 156 of the Constitution further protects policies that promote heterosexual marriage. Public policies significantly disadvantage non-conventional families: single parents and same-sex couples are excluded from the Baby Bonus Cash Gift and the Parenthood Tax Rebate, face severe restrictions in public Housing Development Board (HDB) eligibility – generally only being able to apply as singles after the age of 35 – and encounter structural legal hurdles in inheritance laws and child guardianship and custody arrangements, all of which are designed to favour children born within a recognized heterosexual marriage (New Naratif, 2024).

Furthermore, under Regulation 31 of the Healthcare Services (Assisted Reproduction Service) Regulations 2023, IVF and other assisted reproduction procedures are restricted to women who are legally married to a man, effectively banning single women and same-sex couples from accessing fertility treatment in Singapore (Ministry of Health Singapore, 2023). Such trends are evident in local discussions, which not only increasingly acknowledge the needs of childless couples, as reflected by various new legislative proposals, but also increasingly recognize that alternative pathways of family formation are socially acceptable as legitimate means of achieving this end. These include surrogacy arrangements, provided these are congruent with local sociocultural values and operate under appropriate legal and ethical oversight (Heng, 2007). The ongoing transition towards more inclusive societal norms offers a more conducive environment for policymakers seeking to legalize surrogacy, such that any legal changes being proposed should reflect the broad range of personal beliefs and emerging social attitudes within Singaporean society.

The absence of a formal legal framework for surrogacy in Singapore has resulted in the growth of unregulated and unsafe surrogacy arrangements that are often carried out abroad or in other gray legal situations. Many Singaporean couples seek out arrangements involving cross-border surrogacy, which expose them to legal ambiguities, potential exploitation, as well as difficulties in establishing parental rights for the resulting offspring (Au-Yong, 2019; Chin, 2023; Sim & Ray, 2021). Such a lack of regulatory oversight of overseas surrogacy arrangements not only exposes surrogate mothers to increased medical risks at the hands of unregulated agencies and profit-driven fertility clinics but also increases the risks of exploitative arrangements taking place, especially in less-regulated jurisdictions (Hibino, 2022). The legalization and regulation of surrogacy in Singapore would thus overcome many of such challenges by redirecting surrogacy practices into appropriate transparent channels with open accountability, which would protect the rights and ensure due obligations of all parties involved. Such a policy change would also reduce reliance on surrogacy tourism and rampant commercialization of reproduction, which can overcome issues of exploitation and abuse of surrogate mothers and resulting offspring.

4 Proposed Laws and Regulations

In light of the various potential benefits and challenges of surrogacy that have hitherto been discussed, a robust and comprehensive legal framework with appropriate safeguards must be adopted if surrogacy is to be permitted in Singapore (Table 1). The regulation of surrogacy should focus on the complexities of both international and domestic arrangements and draw from international experiences to avoid the excesses of unregulated commercialization and exploitation (Hibino, 2022). Codified statutes should clarify the rights and duties of each party involved, including the intended parent(s), surrogate mother(s) and child(ren), while specifying minimum enforceable standards for informed consent, medical assessment and contractual obligation. Laws should also be premised on ethical principles used to protect the identity, dignity, legal status and health of the child and surrogate, as well as define parental rights for intended parents upon birth (Pascoe, 2018).

As outlined in Table 1, the proposed regulatory framework introduces a comprehensive, multi-phased approach to govern surrogacy in Singapore. The first phase emphasizes foundational policy and public engagement, requiring the government to explicitly acknowledge the need to lift the current ban to address severe demographic challenges, while actively conducting public consultations with healthcare professionals, religious leaders, and the general public to clarify its legal stance.

The second phase defines strict eligibility criteria aligned with conservative sociocultural values. Access to surrogacy would be restricted to legally married heterosexual couples with a demonstrated medical necessity (e.g., women without a uterus), explicitly excluding single individuals, de facto same-sex couples, and lifestyle-motivated use. At least one commissioning parent must retain a genetic link to the child. Surrogate mothers would similarly be limited to parous married women who are Singaporean citizens or permanent residents. Establishing such criteria is an essential first step toward ethical surrogacy arrangements, as regulations should mandate rigorous medical and psychological screening of all intended parents to ensure their readiness and suitability for parenthood in a stable family environment. Additional surrogate eligibility requirements – such as marital status and familial connections with the commissioning parents – should be clearly specified in any future surrogacy framework for Singapore (Heng, 2007). These measures would minimise medical risks to surrogates, provide ethical safeguards by ensuring

informed consent from all parties, and circumvent exploitative commercial arrangements. Drawing on international experience, Singaporean policymakers must formulate eligibility criteria that reflect local family values and social realities, while addressing the shortcomings of exclusionary or insufficient regulatory regimes in other jurisdictions (Kashyap & Tripathi, 2022).

The third phase focuses on establishing infrastructure and ethical standards. It proposes the creation of an independent government-affiliated regulatory agency under the Singapore Ministry of Health (MOH) to oversee both local and overseas arrangements, review cases individually, and deploy social workers for counseling. This phase strictly mandates financial regulation by banning commercialized surrogacy; compensation must be limited to the reimbursement of direct expenses, with all payments rigorously documented and audited to prevent illicit transactions. Furthermore, stringent medical protocols would be set, including the judicious use of assisted reproductive technology, a general ban on third-party egg donation to prevent complex genetic relationships, and the requirement of a formal (though non-binding) prenatal testing agreement regarding congenital deformities. Such a specialized regulatory body would be particularly crucial for vetting the eligibility of intended parents and surrogates, evaluating drafted contracts, monitoring compliance with legal requirements, resolving conflicts, maintaining records, and offering continuous advice on best practices drawn from well-established legal processes in other jurisdictions such as the UK and Hong Kong (Sim & Ray, 2021). By investing regulatory authority over surrogacy in a dedicated government agency, Singapore can better protect the rights of all parties involved, ensure a legal environment that is more transparent, predictable, and accountable to all stakeholders, and circumvent the risks of unregulated commercial surrogacy (Shepherd, 2022).

The fourth and final phases center on establishing a robust, continuously reviewed legal framework that prioritizes child protection and ensures consistent treatment of domestic and overseas surrogacy cases. To deter the circumvention of domestic laws, extraterritorial prohibitions would penalize citizens procuring overseas surrogacy that violates government policy, and adoption orders would be denied for resulting non-traditional family arrangements. Crucially, the framework requires codifying laws to facilitate the legal transfer of parenthood to commissioning parents via adoption—since current law presumes the birth mother is the legal mother—while stipulating that they remain financially liable for a child's upbringing even if

born with deformities. To protect the rights of surrogate mothers and prevent the commodification of women's bodies, all surrogacy arrangements must be drafted by legal professionals and endorsed by regulatory authorities. These contracts must explicitly outline provisions for medical care, parental responsibilities, dispute resolution, and fair, non-exploitative financial compensation for the surrogate's time, labor, and health risks (Pascoe, 2018; Piersanti et al., 2021). Without such legislation, disputes over parental rights, custody, or breach of contract would result in indefinite litigation. Therefore, Singapore's surrogacy legislation must require prior judicial or regulatory approval of contracts to provide legal clarity, enforce obligations, and promptly resolve disputes, ultimately safeguarding the welfare of all parties with a paramount focus on the child's best interests (Chan, 2021; Kennedy, 2022). Finally, the legal framework for surrogacy must be continuously reviewed and enforced by the Ministry of Health (MOH) of Singapore (Au-Yong, 2019; Chin, 2023; Heng, 2007; Sim & Ray, 2021).

Analyzing and comparing the legal frameworks governing surrogacy in both the UK and California (USA) could provide valuable lessons for Singapore. The UK regulatory regime, under the Human Fertilisation and Embryology Act, only permits altruistic surrogacy with commercial surrogacy being strictly prohibited (Olaye-Felix et al., 2023). A parental order process is required to safeguard the welfare of the child and clarify the legal relationships with respect to the child born from surrogacy arrangements. State laws in California permit both altruistic surrogacy and compensated surrogacy with a strong emphasis on requiring legally binding agreements to be first put in place before any medical steps are taken, so as to provide certainty on the rights and obligations of all parties involved (Ayala et al., 2024). Together, these regulatory models show how Singapore can balance the best interests of the child and ethical compliance with clarity and certainty in surrogacy contracts. By adopting the successful aspects of surrogacy regulation from other jurisdictions (Sim & Ray, 2021), Singapore can create a legal framework that ensures accountability, protects vulnerable parties, and reflects local sociocultural values.

Furthermore, the increasingly transnational nature of surrogacy calls for international cooperation to harmonize laws with respect to cross-border surrogacy arrangements. The disparate laws that vary from country to country often create legal ambiguities with regard to legal parentage recognition, as well as raise questions on the rights of offspring born out of surrogacy arrangements (Piersanti et al., 2021). With the increasing growth of the international surrogacy market, barriers to

accessing surrogacy locally – such as legal bans or high costs – have driven intended parents to seek lower-cost and less regulated options abroad. This phenomenon has led to disparities and stratified access to surrogacy based on socioeconomic status, where only those with sufficient means can afford to navigate complex cross-border arrangements (Whittaker et al., 2022). Hence, harmonization of laws – such as through multilateral agreements or international guidelines on cross-border surrogacy arrangements – could help ease the burdens on all parties involved, by providing a consistent basis for legal recognition, parental rights, and protections for surrogate mothers and offspring from jurisdiction to jurisdiction. Such measures would thus reduce the risks of "procreative tourism" by ensuring that regulatory gaps and legal loopholes do not undermine ethical principles or the welfare of all parties involved in surrogacy arrangements.

5 Ethical, Social, and Economic Implications

Besides child welfare, another key ethical dimension of surrogacy relates to the rights and welfare of surrogate mothers, which must be upheld by any future legal framework governing surrogacy in Singapore. This is necessary to protect surrogates from exploitation, coercion, or medical risks, particularly in surrogacy arrangements where bargaining power asymmetries may be accentuated and incentives for abuse heightened (Pascoe, 2018). At the policy level, this means enforceable standards must be put in place to ensure genuine autonomy, access to adequate health care, and informed consent throughout the entire process, in addition to legal protections that recognize the bodily integrity of surrogates and their entitlement to fair treatment. In many jurisdictions, a sharp distinction has often been made between altruistic and commercial surrogacy partly in response to public apprehensions about the commodification of women's bodies and human rights abuses directed towards surrogates, which highlights the need for legal frameworks to be harmonized with prevailing ethical standards and moral values (Aguiling-Pangalangan, 2024). Hence, it is imperative that Singapore must ensure that its legal framework for regulating surrogacy appropriately safeguards surrogate mothers and reflects a community-level approach to family and dignity.

At the social level, the issue of surrogacy in Singapore raises significant questions regarding prevailing public attitudes and how its legalization might impact traditional notions of the family. Local public debates on surrogacy often reveal the tensions between evolving views on family diversity versus the age-old concept that a child is

entitled to a mother and a father within the context of traditional family structure (Chan, 2021). Ministerial statements and policy discourse in Singapore suggest that some sectors of the public are concerned about changes to parental roles, mainly in relation to single or same-sex intended parents. Key ethical concerns include the fragmentation of parental responsibilities and the commodification of reproduction, which has sparked heated debates regarding social acceptance of new family structures (Au-Yong, 2019; Chin, 2023; Heng, 2007; Sim & Ray, 2021). Current developments suggest that Singapore policymakers will have to consider regulatory measures that reflect such social concerns but also take into account incremental shifts in social values and aspirations over time.

From an economic perspective, the legalization of surrogacy in Singapore will likely yield some benefits and challenges for both the healthcare sector and the overall economy. Costs associated with surrogacy agreements are significant and are not limited to medical procedures, but also include psychological support, legal services, and ongoing health monitoring of surrogates and intended parents (Frati et al., 2021). Permitting and regulating surrogacy mitigates risks associated with unregulated cross-border surrogacy, which often takes a toll on families and state institutions when unexpected disputes arise or health issues occur (Hibino, 2022). The increasing globalization of the reproductive market illustrates that insufficient regulation, or poorly enforced regulation, fuels surrogacy tourism that is characterized by cost disparities and exploitative practices, particularly in jurisdictions with lax oversight (Hibino, 2022). For Singapore, careful management of these economic effects will ensure equitable access and avoid the detrimental consequences of rampant commercialization and unchecked growth.

In order to prevent exploitation, Singapore must create specific safeguards to circumvent the various pitfalls associated with international surrogacy arrangements. Countries in Asia provide evidence that commercial surrogacy arrangements fueled by medical tourism and increasing globalization of healthcare services often result in the exploitation of poorer women who are motivated to become surrogates due to their dire economic circumstances, often being exposed to poor working conditions and insufficient healthcare (Hibino, 2022). Even in jurisdictions where there have been efforts to limit or prohibit commercial surrogacy arrangements, the practice continues, indicating that punitive measures are not a deterrent, as these just push surrogacy underground into the black market. Stringent oversight – including regulations for mandatory health checks, independent legal advice, and ongoing

audits of surrogacy agencies and fertility clinics – could help safeguard surrogate mothers, especially in jurisdictions with large socioeconomic inequalities. In drafting laws to govern surrogacy, Singapore needs to learn from these international experiences, by developing regulatory frameworks that safeguard the wellbeing of surrogates and resulting offspring, ensure total disclosure of remuneration, and ban any practices that incentivize coercion and commodification (Hibino, 2022).

The ongoing tension between individual reproductive autonomy and established cultural norms is a key consideration in the legalization of surrogacy in Singapore. While the valid and legitimate grounds of autonomous choice and reproductive freedom are certainly good enough justifications for legalizing surrogacy, lawmakers must also consider local collective values that are underpinned by sociocultural conservatism in Singapore that emphasize the traditional family model. Other jurisdictions have adopted approaches to surrogacy regulation that indicate a cautious compromise. For example, the UK and Hong Kong have sought to initially limit access to specific groups of intended parents, so as to avoid social discord, while upholding some degree of reproductive autonomy (Sim & Ray, 2021). On the other hand, overly restrictive regulatory regimes such as India, which do not allow certain surrogacy arrangements, demonstrated that legal frameworks that are ill-equipped to adapt to social realities can often backfire, such as driving the surrogacy market underground (Kashyap & Tripathi, 2022). For Singapore, thoughtful calibration of surrogacy legislation to carefully balance the reproductive autonomy and family aspirations of intended parents with prevailing sociocultural norms and family values may pave the way for greater inclusivity, while preserving individual dignity in surrogacy.

In summary, ongoing public debates on surrogacy in Singapore highlight the dynamic interplay between key ethical, legal and social issues that will require careful consideration from a policy perspective. On the one hand, proponents often emphasize that legalized surrogacy can overcome infertility and increase reproductive autonomy, providing a regulated avenue for infertile couples seeking children, if robust protective safeguards are put in place. On the other hand, opponents warn that surrogacy may lead to the commodification of women and children, undermine traditional family structures, and invoke unresolved ethical concerns about motherhood and the best interests of the child (Tan, 2020). While the arguments in favour of legalizing surrogacy are compelling, it is crucial to acknowledge and engage with key counterarguments opposing the legalization of

surrogacy. Critics legitimately fear that even with regulations, legalizing surrogacy could inadvertently normalize the transactional exchange of reproductive labour, potentially exploiting economically vulnerable women. Feminist scholars have argued that commercial surrogacy risks commodifying women's bodies and alienating them from their reproductive labour, as power imbalances between wealthy intended parents and economically disadvantaged surrogates can severely undermine true informed consent and bodily autonomy (Attawet et al., 2024; Wilkinson, 2016). In transnational and commercial contexts, structural inequalities often leave surrogates disempowered, facing both psychosocial distress and oppression due to the contractual nature of the arrangements (Attawet et al., 2024). Furthermore, the concern that surrogacy might erode the traditional family unit is a deeply held conviction among conservative segments of Singaporean society, which must be addressed through stringent eligibility criteria and clear legal definitions of parentage. From a conservative and religious standpoint, gestational surrogacy is sometimes viewed as a threat to traditional marriage fidelity and lineage, as it fragments the biological, gestational, and social roles of motherhood (Deonandan, 2020). In addition, child welfare advocates raise concerns about the psychological impact on children born through surrogacy, particularly regarding their right to identity and access to information about their gestational origins (Wade, 2020). To mitigate these profound ethical and social concerns, any proposed framework in Singapore must incorporate rigorous psychological screening, independent legal counsel for surrogates to prevent coercion, and transparent mechanisms that prioritize the best interests and identity rights of the child. In order to resolve differing priorities and contrasting opinions, legislation on surrogacy must be based on empirical evidence, continuous ethical reflection and prioritize the interests of children, without marginalizing the interests or dignity of surrogate mothers or intended parents.

6 Conclusion

In summary, the arguments in favor of legalizing surrogacy in Singapore underscore the need to advance reproductive options while avoiding the risks associated with unregulated surrogacy arrangements. A regulatory framework based on strong ethical foundations and well-established legal benchmarks would address urgent demographic, medical, and social challenges, while enabling intended parents to start families in a safe and equitable manner. Recommendations made on the basis of both local priorities and international best practices illustrate the importance of

clearly defined eligibility criteria, transparent contractual and oversight structures, and legal mechanisms for ensuring institutional accountability and child welfare. Ultimately, the successful legalization of surrogacy in Singapore requires a regulatory framework that incorporates prevailing sociocultural values while balancing the interests of all stakeholders concerned, without compromising human dignity or social cohesion.

Permitting surrogacy would thus formally provide Singapore with the means to address its severe demographic challenges, while adapting to new social realities at the same time. Implementation of comprehensive and enforceable regulations will ensure transparency, prevent exploitation, and protect the rights of all parties involved. Such an approach mitigates risks associated with unregulated surrogacy arrangements, including legal ambiguity, medical risks, and unfair treatment of surrogates and resulting offspring. By doing so, Singapore not only shields its citizens from the various pitfalls documented in less regulated jurisdictions, but can also foster a more forward-thinking and inclusive society. In the future, ongoing engagement of all stakeholders through periodic evaluation of policy positions together with public education, is crucial to nurture the continued evolution and effectiveness of surrogacy governance in Singapore.

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Povzetek v slovenskem jeziku

Singapur se sooča z resnimi demografskimi izzivi, vključno z nizko rodnostjo in staranjem prebivalstva, kar zahteva ponovno oceno sedanjih politik na področju ustvarjanja družine, zlasti prepovedi gestacijskega nadomestnega materinstva. Trdi se, da sta legalizacija in ureditev nadomestnega materinstva v Singapurju potrebni za obvladovanje demografskih pritiskov in neplodnosti. Nacionalni regulativni okvir bi zagotovil varno pot do starševstva, hkrati pa zmanjšal pravna in etična tveganja, povezana z nereguliranimi čezmejnimi dogovori. Poleg tega bi legalizacija lahko spodbudila povpraševanje po specializiranih zdravstvenih in pravnih storitvah. Da bi se uskladil s konservativnimi družbenokulturnimi normami Singapurja, bi moral predlagani okvir sprva temeljiti na altruizmu in omogočati dostop le poročenim heteroseksualnim parom. V končni fazi bi legalizacija nadomestnega materinstva pod strogim nadzorom, z jasnimi merili za upravičenost in posebnim regulativnim organom, uravnovežila reproduktivno avtonomijo s kolektivnimi vrednotami. Ta pristop spodbuja bolj vključujočo družbo, hkrati pa daje prednost blaginji otrok in preprečuje izkoriščanje, s čimer ponuja pragmatično rešitev za ublažitev demografske krize v Singapurju.

Appendix

Table 1. Suggested stepwise approach for the legalization and implementation of surrogacy in Singapore.

Phase	Step/Action	Details
1 st Phase: Foundational Policy & Public Engagement	1. Address Current Prohibition & Clarify Legal Stance	Acknowledge that the current ban on surrogacy needs to be lifted, in view of the severe demographic challenges faced by Singapore (Xuan, 2024). The Singapore government must clarify its stand on surrogacy (Chan, 2021; Tan, 2020).
	2. Conduct Public Engagement & Consultations	Policymakers should conduct a public consultation on the legalization of surrogacy, and actively consult the views of healthcare professionals, religious and community leaders, as well as the general public (Heng, 2007).
	3. Determine Regulatory Scope & Structure	Decide to legalize surrogacy with strict regulations, to protect all parties involved (Chin, 2023). Singapore could legalize surrogacy in two stages: start with a narrow, uncontroversial legal framework (i.e. altruistic surrogacy), and then move to a more nuanced approach later (i.e. limited commercialization of surrogacy) (Sim & Ray, 2021).
2 nd Phase: Defining Eligibility & Scope	4. Define the Eligibility Criteria for the Commissioning Parents	Restricted only to married heterosexual couples - The Singapore government will likely prohibit surrogacy for single individuals and <i>de facto</i> same-sex couples to align with the country's conservative sociocultural values (Chan, 2021; Tan, 2020).
		Medical necessity requirement - Surrogacy should be approved only because of medical necessity (Chin, 2023; Heng, 2007) (i.e., women without a uterus, medically unfit to carry a pregnancy to term)
		Lifestyle choice prevention - Prevent the non-judicious use of surrogacy by healthy and fertile women for spurious reasons, such as preserving beauty or advancing careers (Heng, 2007).
		Genetic link requirement - At least one commissioning parent must contribute their gametes to the surrogacy procedure (Sim & Ray, 2021).
	5. Define the Eligibility Criteria for the Surrogate Mother	Review and approval - As an additional safeguard to prevent abuse, surrogacy should be reviewed and approved by the Ministry of Health (MOH) on a case-by-case basis for each patient (Heng, 2007).
		Citizenship/residency requirement - Surrogates should be restricted to Singaporean citizens and permanent residents, so as to avoid the complications of transnational surrogacy (Heng, 2007). Exceptions may be made for foreigners who are close relatives of the commissioning couple (confirmed by DNA testing) (Heng, 2007).

Phase	Step/Action	Details
		Marital and parental status - Surrogate mothers should be restricted to parous married women with stable family relationships (Heng, 2007). Single women without any children of their own should be banned from acting as surrogate mothers under all circumstances (Heng, 2007).
3 rd Phase: Establishing Infrastructure & Ethical Standards	6. Create an Independent Government-affiliated Regulatory Agency to Handle Both Local and Overseas Surrogacy Arrangements	Ban on third-party intermediaries - Explicitly ban healthcare professionals and institutions from soliciting surrogate mothers on behalf of their patients (Chin, 2023; Heng, 2007). Instead, an independent government agency should handle ethical recruitment, counseling, and reimbursement of surrogates independently of doctors and clinics handling fertility treatment (Chin, 2023; Heng, 2007).
		Deployment of social workers - Healthcare social workers should be assigned by this agency to counsel and check on the welfare of the surrogate mother and commissioning couple (Heng, 2007).
		Post-overseas procurement protocol - If a child is procured overseas against government policy (i.e. by single individuals or <i>de facto</i> same-sex couples), the child should be received at customs and placed in foster care pending a suitability assessment of the commissioning parent(s) (Chan, 2021). If the assessment is unsatisfactory, the child should be put up for adoption by a married heterosexual couple (Chan, 2021).
	7. Implement Screening and Review Processes	The Ministry of Health (MOH) should set up a system for independent review and approval of surrogacy on a case-by-case basis for each prospective commissioning couple (Heng, 2007). There should be rigorous pre-conception suitability assessments of intended parents (Sim & Ray, 2021).
	8. Mandate Strict Financial Regulation	Ban on commercialized surrogacy - Because this will likely be morally and ethically repugnant to the conservative sociocultural norms of Singapore (Heng, 2007).
		Compensation model - Monetary compensation must be based on the reimbursement of direct expenses (Heng, 2007).
		Documentation and audit of payments - All payments made to surrogate mothers must be rigorously documented and strictly audited to prevent illicit under-the-table monetary payments (Heng, 2007). Healthcare professionals and institutions must be explicitly banned from managing payments to surrogate mothers due to pertinent conflicts of interest (Chin, 2023; Heng, 2007).
	9. Set Stringent Medical Protocols	Judicious use of assisted reproductive technology (ART) procedures – Set stringent guidelines for the judicious use of hormone stimulation and IVF procedures in 'traditional' surrogacy (especially when cheaper

Phase	Step/Action	Details
4 th Phase: Legal Framework & Child Protection		intrauterine insemination would suffice for healthy/fertile surrogate mothers) (Heng, 2007).
		Ban on third-party egg donation - Generally disallow the combination of surrogacy with donor eggs from a third woman (neither the commissioning mother nor surrogate mother) (Heng, 2007), except under specific circumstances. For example, to maintain genetic relationship or same ethnicity as the intended commissioning mother (Heng, 2007).
		Prenatal testing agreement (Non-binding) - Mandate that the surrogate mother and the commissioning parents should first make a formal but non-legally binding agreement on what to do if prenatal testing or birth reveals congenital deformities (i.e., abortion, acceptance, institutionalization, or adoption) (Heng, 2007). This agreement must be documented, signed, and notarized.
	10. Legal & Contractual Safeguards	Legal formalization - All surrogacy contracts must be handled by lawyers, and signed by the surrogate mother and commissioning parents in the presence of appropriate witnesses (Piersanti et al., 2021).
		Consistency in surrogacy regulation - The government should treat domestic and overseas surrogacy cases consistently (Tan, 2020).
		Exclusion of adoption for non-traditional family arrangements -An adoption order shall not be made in cases where the applicants resorted to overseas surrogacy for non-traditional family arrangements (i.e, single individuals or <i>de facto</i> same sex couples), with the intention of leaving the child without either a father or a mother (Chan, 2021).
		Extraterritorial prohibition - There should be legislation prohibiting Singapore citizens from procuring overseas surrogacy against government policy (i.e. by single individuals or <i>de facto</i> same-sex couples) (Chan, 2021).
	11. Ensure Commissioning Parent Liability	If the commissioning parents refuse to accept a child born with congenital deformities, they should be made financially liable for the high cost of its "special needs" upbringing (Heng, 2007).
	12. Establish Legal Parenthood Mechanism	Codify laws to transfer legal parenthood to the commissioning parents via adoption (Sim & Ray, 2021). This process is crucial because under current Singapore law, the woman who gives birth is generally considered the legal mother (Sim & Ray, 2021). The adoption framework may need amendment to accommodate the legal transfer of parentage following surrogacy (Tan, 2020).
Final Phase	Implementation & Ongoing Review	The legal framework for surrogacy must be continuously reviewed and enforced by the Ministry of Health (MOH) of Singapore (Au-Yong, 2019; Chin, 2023; Heng, 2007; Sim & Ray, 2021).

THE LEGAL DEFINITION OF DEATH IN THE UK: AN ANALYSIS AND A PROPOSAL

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Abstract The UK does not have a statutory definition of death. Since the 1980s, an emerging clinical concept of death, named ‘Death determined using Neurologic Criteria’ (DNC), has gradually been acknowledged by the UK courts. While several recent cases have contested this position, DNC is now regarded as the medical and legal definition of death. The absence of a statutory definition of death, coupled with the complex and counterintuitive nature of DNC, has provided sceptics ambiguity with which to challenge the medicolegal status quo. The common law approach to defining death appears increasingly unsatisfactory; there is now a strong argument to enact relevant legislation in the UK. This paper proposes legislation which would bring greater legal clarity, certainty and consistency to the determination of death, and would address many of the practical and conceptual problems that currently exist.

Keywords

brainstem death,
definition of death,
death by neurologic
criteria,
intensive care,
legislation



1 Introduction

Death represents a moment of enormous personal, cultural, philosophical and legal significance. Yet the legal boundary between life and death is looking increasingly controversial in the UK. Medical advances have forced clinicians, lawyers and scholars to think more precisely about what differentiates life from death, and the diagnosis of death has now become highly nuanced. The emergence of modern intensive care medicine in the mid-20th century created many new dilemmas, including the clinical phenomenon now named 'Death determined using Neurologic Criteria' (DNC). There is no statutory definition of death in the UK. Instead, the legal definition of death represents the common law endorsement of current medical practice. In recent years, however, several domestic cases have contested this position. Protracted legal disputes have many adverse effects: they propagate uncertainty about the definition of death or an individual's legal status, they cause costly delays, and they lead to conflict and distress for relatives and healthcare staff.

This doctrinal research paper examines the legal definition of death in the UK and sets out a case for enacting a statutory definition. It explores the academic literature concerning the history of death and the emergence of DNC, as well as the UK's evolving clinical guidelines; it describes the current legislation related to death and the 'statutory gap' which seemingly arises; and it analyses the series of court cases which have gradually fashioned a common law definition of death in the absence of legislation. It concludes by proposing and justifying wording for a statutory definition of death for the UK. Such legislation would arguably bring greater clarity and certainty to the medicolegal position surrounding death in a more satisfactory and timely way than the common law approach.

2 Defining Death: Historical, Medical and Legal Context

2.1 A Brief History of Death

For most of human history the identification of death was relatively straightforward and reliable, requiring only the observation of physical signs such as decapitation, rigor mortis or decomposition (Johnson, 2017, p. 267). Ancient writers recognised the significance of respiration, with passages describing the 'breath of life' found in ancient Egyptian medical papyri, the Quran and the Old Testament. By early modern history the importance of the heartbeat was becoming clear. In 1846, the Academy

of Sciences in Paris awarded Dr Eugène Bouchut a prize for his proposal to diagnose death by listening for heart sounds using the recently invented stethoscope (Gardiner & McGee, 2020, p. 138). From this period onwards, the concept of death as the loss of circulation and respiratory function attained ‘near universal acceptance, across cultures and religious traditions’ (Johnson, 2017, p. 267). In the 1950s, the development of resuscitative techniques, in particular cardiopulmonary resuscitation and mechanical ventilation, cast new doubt on the assumed interdependence between the body’s circulatory, respiratory and neurological functions (Lewis & Bernat, 2022, p. 12). Patients who had suffered cardiorespiratory arrest – who would previously have been declared dead – could now be resuscitated and sustained on a ventilator despite permanently losing brain function (Gardiner & McGee, 2020, p. 139). Mollaret & Goulon (1959) first described this clinical syndrome, publishing a case series of twenty-three deeply comatose patients with absent brainstem reflexes and brain activity. They called it *‘le coma dépassé’* (‘a state beyond coma’). Doctors working in newly established Intensive Care Units (ICUs) began to speculate if these patients were in fact already dead. In 1968, the Ad Hoc Committee of the Harvard Medical School published an influential paper proposing that death could be determined using neurological criteria alone. This permitted the withdrawal of futile life-support from patients with profound neurological injuries.

2.2 Medical Consensus in the UK

2.2.1 Medical Guidelines

In 1976, the Conference of Medical Royal Colleges published a statement entitled ‘Diagnosis of Brain Death.’ This stated, ‘It is agreed that permanent functional death of the brainstem constitutes brain death and that once this has occurred further artificial support is fruitless and should be withdrawn.’ The UK neurologic criteria differed from the earlier Harvard publication by focusing specifically on brainstem function (as opposed to the ‘whole brain’ approach adopted in the US). This 1976 statement was principally concerned with legitimising withdrawal of life-support in futile situations but did not make the conceptual leap to claim that brain death represents the death of the person. An amended guideline was published three years later:

It is now universally accepted, by the lay public as well as the medical profession, that it is not possible to equate death itself with cessation of the heartbeat ... It is the conclusion of the conference that the identification of brain death means that the patient *is dead* (Conference of Medical Royal Colleges, 1979, p. 332).

A subsequent review by the Royal College of Physicians (1995) recommended that the preferred terminology – in the UK at least – was ‘brainstem death’. This paper uses the terminology now recommended by leading scholars in the field: ‘Death determined using Neurologic Criteria’, or ‘DNC’ (Lewis & Bernat, 2022, p. 5).

In 2008, the Conference (now called the Academy) of Medical Royal Colleges published an updated consensus guideline called the ‘Code of Practice 2008’ (hereinafter: Code 2008). The Code 2008 articulated the underlying medical definition of death (one predicated upon the loss of brainstem function) and set out exacting standards for the preconditions, exclusions and confounders relevant to brainstem testing. It detailed the specific diagnostic tests and processes required to confirm death. The Code 2008, therefore, provided comprehensive and authoritative clinical guidance for the diagnosis of all adult and child deaths in the UK. An updated version of the Code of Practice was released in January 2025 (hereinafter: Code 2025), providing revised practical guidance for the diagnosis and confirmation of all deaths. The updated Code 2025 is clear that it does not represent a redefinition of death but instead reiterates the brainstem-centred definition found in the 1995 and 2008 versions (indeed, the same definition which has been accepted in UK clinical practice since 1979). The Code 2025 therefore provides important continuity and reassurance that historical diagnoses of death remain valid (Scott & Thomas, 2026).

2.2.2 A Unifying Concept of Death

A so-called ‘unifying concept of death’ has therefore emerged in recent decades (Gardiner et al, 2012, p. 16), one which has been reiterated in each update of the Code. Death has come to be defined as the death of the brainstem (that is, the irreversible loss of the capacity for consciousness and the irreversible loss of the capacity to breathe). However, this single underlying condition can be identified using different criteria: somatic, circulatory or neurological. The criterion used to identify that death has occurred will depend on the particular clinical circumstances (for example, circulatory criteria used after a failed resuscitation attempt, or

neurological criteria used in a ventilated ICU patient with profound brain injuries). Importantly, the underlying definition of death remains the same in every case. These distinctions become important later when considering possible statutory language, and the respective contribution of clinicians and parliamentarians in the legislative process.

2.3 The Significance of Death and the ‘Statutory Gap’

Whilst laypeople might assume there is a clear dichotomy between life and death, clinicians often perceive death as a transformative process without a clearly definable end-point (Laurie, Harmon & Dove, 2019, p. 572). Body systems decline and stop at different times, a process which can now be manipulated or delayed by medical intervention. The circulatory or neurologic criteria used by doctors to identify that death has occurred necessarily strike a pragmatic balance between convenience, certainty and timeliness (Gardiner & McGee, 2020, pp. 64–65). It is not clear therefore where a justifiable legal dividing line should be drawn along the continuum of bodily disintegration. For myriad reasons though, the law does require a clear distinction. Death has significant implications for probate and inheritance, the disposal of bodies, and coronial or criminal investigations. It is also the moment at which most rights and interests are lost, or after which life-support can be withdrawn and organs donated (Brazier, Cave & Heywood, 2023, p. 531). As Wicks summarises, “There needs to be a clear-cut, and unambiguous, definition of death within the law because legally we treat a dead body very differently from the way we treat a living person” (Wicks, 2017, p. 120).

It is perhaps surprising there is still no statutory definition of death in the UK. Numerous domestic statutes deal with various matters arising after death. The Births and Deaths Registration Act 1953 govern the requirements for certifying and registering a death, whereas The Removal of Bodies Regulations 1954 concerns the repatriation of bodies outside of England. The Coroners and Justice Act 2009 outlines the powers a coroner has to investigate unnatural or suspicious deaths. Recently, The Medical Certificate of Cause of Death Regulations 2024 established a new statutory basis for Medical Examiners to scrutinise and certify all non-coronial deaths in England and Wales. Yet none of these statutes or regulations actually define what death is or when it occurs. Considering the various requirements, restrictions or powers bestowed by legislation, the absence of a precise definition seems incongruous. Only one Act of Parliament has previously raised the possibility

of a statutory basis for defining death, but ultimately a definition never materialised: the Human Tissue Act 2004, and the related Human Transplantation (Wales) Act 2013, which governs the use of human organs for research and donation. Within this framework, the Human Tissue Authority (HTA) was granted statutory authority to issue relevant codes of practice, including on the ‘definition of death for the purposes of [the] Act’ (Human Tissue Act 2004, s26(2)(d)). Yet the HTA has never done so, and their latest guidance simply refers back to the clinical definition of death given by the Code of Practice (Human Tissue Authority, 2023, p. 12). As such, a statutory definition of death remains elusive.

2.4 Legislating Death in the United States

In this respect the UK is an outlier, as a large number of countries have enacted legislation concerning the definition or diagnosis of death (Bernat & Beresford, 2013, p. 430). For example, the US has enacted a statutory definition of death in the majority of states for over 40 years. The Uniform Determination of Death Act (hereinafter: UDDA) 1980 simply states:

An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brainstem, is dead. A determination of death must be made in accordance with accepted medical standards.

This model statute thereby aimed to create uniformity between all states (Sarbey et al., 2022, p. 277). It provides common language to determine all deaths, principally by incorporating a neurologic criterion into their existing (common-law) circulation-based definition of death (Gardiner, McGee & Bernat, 2020, p. 1224). Strictly speaking, the UDDA does not provide a definition of death, but does provide the *criteria* for determining death has occurred (Uniform Law Commission, 2014, p. 2). The Uniform Law Commission argues the UDDA was a necessary statutory solution to address growing interstate confusion and inconsistency. They claim the UDDA brings national uniformity to the determination of death; reduces confusion regarding a patient’s legal status; limits needless delays; reduces court litigation; and promotes more equitable and efficient provision of ICU resources (Uniform Law Commission, 2014, p. 2).

3 The Definition of Death in UK Common Law

3.1 DNC in the Courts

During the second half of the 20th century, whilst doctors slowly grappled with new clinical and ethical dilemmas arising from the emergence of DNC, a number of contested cases began filtering into the legal arena. The UK courts first formally acknowledged DNC in *R v Malcherek*; *R v Steel* [1981], where the Court of Appeal conjoined two criminal cases. In each case a victim had been assaulted, DNC had been declared and life-support was withdrawn. Yet both murderers argued it was the doctors who had ‘killed’ the victims by discontinuing life-support. Both appeals were dismissed on the basis of causation, but the obiter remarks proved insightful into the court’s reaction towards the novel clinical element of the cases:

Modern techniques have undoubtedly resulted in the blurring of many of the conventional and traditional concepts of death ... There is, it seems, a body of opinion in the medical profession that there is only one true test of death and that is irreversible death of the brainstem ... When that occurs, it is said the body has died (*R v Malcherek*; *R v Steel* [1981], p. 694).

The judges cautiously acknowledged the emerging medical consensus without expressly endorsing it. They also differentiated the contrasting professional responsibilities in this area, suggesting the courts were being guided by – but not scrutinising – the medical consensus. The judges held, “It is no part the task of this court to inquire whether the criteria, the royal medical colleges’ confirmatory tests, are a satisfactory code of practice” (*R v Malcherek*; *R v Steel* [1981], p. 695).

3.2 Re A [1992]

This deference to medical expertise was later reinforced in a civil case which directly addressed the issue of DNC. In 1992, Johnson J heard a case concerning an infant who had been admitted to hospital due to cardiac arrest (*Re A* [1992]). Two ICU consultants tested him according to “... the criteria now generally accepted in medical circles ... Both doctors concluded that A was brainstem dead”. The parents promptly lodged an application to prevent the removal of life-support. Johnson J found the medical evidence compelling, holding, “I have jurisdiction to make a declaration that A is now dead for all legal, as well as medical, purposes”. This

confirmed in common law the guidance from the Conference of Medical Royal Colleges (1979), which stated that DNC indicated the death of the individual. Johnson J did not rule that the legal definition of all death was therefore ‘brainstem death’ (which would have created a very narrow, technical definition); he did, however, hold that death can be declared using brainstem criteria alone. Furthermore, the ruling did not direct clinicians to withdraw life-support but provided reassurance they would not be acting unlawfully if they decided to do so. Johnson J merely made a determination of fact regarding the diagnosis of death and the patient’s legal status. The medical concept of DNC was thereby formally endorsed in common law.

3.3 Airedale NHS Trust v Bland [1993]

The following year, the common law definition of death was strengthened further. In *Airedale NHS Trust v Bland* [1993], the Law Lords considered the case of a patient who had sustained a severe hypoxic brain injury resulting in a Permanent Vegetative State (PVS). An important presumption for their Lordships was that Bland was not yet dead: “In the eyes of the medical world and of the law a person is not clinically dead so long as the brainstem retains its function” (p. 856). Lord Goff expanded the point:

... doctors no longer associate death exclusively with breathing and heartbeat, and it has come to be accepted that death occurs when the brain, and in particular the brainstem, has been destroyed; ... Anthony’s brainstem is still alive and functioning and it follows that ... he is still alive and should be so regarded as a matter of law. (p. 863)

Lord Browne-Wilkinson made further comments acknowledging how evolving medical science had led doctors to redefine historical certainties: “Until recently there was no doubt about what was life and what was death. A man was dead if he stopped breathing and his heart stopped beating ... [Recent developments have] led the medical profession to redefine death in terms of brainstem death ...” (p. 878)

Bland was highly significant. Despite principally being concerned with the withdrawal of life-sustaining treatments from living patients, the Law Lords authoritatively confirmed that death defined in terms of brainstem function represented the legal definition of death. It is interesting the Lords adopted the concept without actually analysing or justifying it (Donnelly & Lyons, 2023, p. 356), instead opting for passive

acceptance of medical expertise. This indicates “... the legal definition of death in the UK is merely the judicial application of the current medical definition of death” (Wicks, 2017, p. 119).

3.4 Re A [2015]

In *Re A (A Child)* [2015], Hayden J conspicuously linked the legal definition of death to the specific wording of medical guidelines for the first time. A 19-month-old boy had choked on a piece of fruit, resulting in a severe hypoxic brain injury. Brainstem testing was undertaken in accordance with Academy of Medical Colleges’ Code of Practice (2008), confirming the child was dead. His family however questioned ‘whether brainstem death was synonymous with clinical/legal death.’ Hayden J quoted from the Code 2008 at length, reiterating its brainstem definition of death. He revisited *Bland*, commenting how the clinical predicament incredulously described by Lord Brown-Wilkinson as the ‘ventilated corpse’ was now commonplace. Applying this to A, Hayden J held the child had indeed died and authorised the withdrawal of life-support to allow him ‘dignity in death’.

Re A (A Child) [2015] therefore confirmed that irreversible cessation of brainstem function – determined in accordance with the Code of Practice – constituted both medical and legal death. The Courts adopted the practice of quoting directly from the Code of Practice in several subsequent judgments (see *Oxford University NHS Trust v AB* [2019] and *North West Anglia NHS Foundation Trust v BN* [2022]). There is, however, something of a circular argument emerging here. The Code 2008 notes that although courts have consistently upheld previous iterations of the guidelines, the courts adopted these guidelines because they represent the consensus view of the medical profession. Each profession seemingly derives legitimacy and validity for the Code 2008 from the tacit endorsement of the other. Whilst this self-reinforcing circularity may help to strengthen the acceptance of DNC in both medical and legal circles, it might seem questionable to external or lay observers who seek a robust, externally valid and independent medicolegal definition of death which does not rely on circular reasoning or inter-professional reinforcement.

4 Recent Controversies and Legal Challenges

4.1 Re M [2020]

By 2020, the common law approach to DNC in the UK appeared settled. Yet in recent years this position has been strongly contested in a number of high-profile cases. In January 2020, a hospital sought a declaration that it would be lawful to discontinue mechanical ventilation of a four-month old baby (*Manchester University NHS Foundation Trust v Namiq and others* [2020]). After careful observation it became clear to clinicians that the infant had sustained a profound brain injury following an umbilical cord prolapse at birth. Brainstem testing confirmed DNC, yet the parents refused to accept this conclusion or the implication that life-support should be withdrawn. In the High Court, Lieven J concluded the infant was dead based upon the clinical evidence, by applying the Code of Practice, and by considering the previous authorities, which she referred to as ‘plainly correct’. The parents attempted to appeal but their application was denied. In *Re M (Declaration of Death of Child)* [2020], the Court of Appeal ruled that ‘brainstem death’ was “established as the legal criteria in the United Kingdom by the House of Lords decision in *Bland*. It is not, therefore, open to this court to contemplate a different test.” The Court of Appeal went further to add it was not their role to consider whether a different criterion should replace the DNC formulation found in the Code of Practice.

Re M is notable for a number of reasons. First, the Lordships prior comments in *Bland* regarding the brainstem and death were, strictly speaking, obiter (Butler-Cole, 2020, [28]). *Bland* had bestowed significant authority to the concept of DNC, despite principally being concerned with the withdrawal of nutrition from a living patient. Despite this, *Re M* seemingly elevates obiter comments in *Bland* to binding precedent. The Court of Appeal in *Re M* declined the opportunity to scrutinise the robustness or coherence of the UK’s DNC criteria or consider alternative formulations. Furthermore, *Re M* strengthens the notion that the diagnosis of death is an entirely clinical matter with which the courts will seldom interfere. The courts instead determine factual questions about whether the accepted medical standards have been applied and satisfied. As Butler-Cole points out, “[It is] impossible to imagine any other outcome where there is a consensus of medical opinion as to the existence of brainstem death than an order confirming the same” (Butler-Cole, 2020, [66]). The time delay involved in the case was significant. Four months passed

between the diagnosis of death and *Re M* reaching the Court of Appeal. The judges were keen that applications to court were made far earlier in future cases.

4.2 Archie Battersbee

In April 2022, twelve-year-old Archie Battersbee was found in a state of cardiac arrest. It took approximately 40 minutes to resuscitate his heart, after which he was placed onto life-support. After being assessed for several weeks, the hospital sought permission from the courts to perform DNC testing on Archie (*Barts Health NHS Trust v Dance & Battersbee* [2022a]). Arbuthnot J ruled that testing should be ‘carried out with great care following strictly the guidance’. At a subsequent hearing however, it transpired the clinicians had been unable to complete the required DNC tests due to a technicality (*Barts Health NHS Trust v Dance & Battersbee* [2022b]). This meant they were unable to proceed with testing. Instead, the hospital submitted abundant clinical evidence and expert opinions, seeking a declaration that Archie was dead. Arbuthnot J carefully considered the family’s counter submissions, which included the legal ambiguity created by the lack of a statutory definition, the reliability of DNC tests, and the extent to which prior case law was binding. She held that she was bound by the decisions in *Bland* and *Re M* regarding the brainstem definition of death. However, she then misdirected herself by relying on the ancillary evidence in lieu of the Code’s tests:

The earlier authorities ... have been based in recent years on the results of the brainstem death tests. In my judgment, the lack of the test in Archie’s case caused as it is by his very severe brain damage, does not prevent me from anxiously considering the abundant clinical evidence in these proceedings and coming to a conclusion... [172]-[173]

Arbuthnot J thereby separated the determination of DNC from the Code’s requirements, instead making the declaration a matter of judicial interpretation of ancillary investigations and expert opinion. This was unprecedented in the legal history of DNC in the UK. On this erroneous basis she ruled that Archie was dead. The Code is clear however that it is not possible to diagnose DNC without the required tests. This had been established in *Re A (A Child)* [2015] and confirmed in numerous subsequent cases (see *Oxford University NHS Trust v AB* [2019], *North West Anglia NHS Foundation Trust v BN* [2022], *HSC Trust v RL* [2022] and *Re M* [2020]).

It is difficult to know whether Arbuthnot J's ruling reflected her unfamiliarity with the underlying science and case law, or indicated a misguided attempt to extend the common law using judicial interpretation. In the absence of DNC tests, it would have been more appropriate for her to have proceeded by evaluating Archie's best interests in order to determine if mechanical ventilation should be discontinued. Unsurprisingly, Archie's family appealed, arguing that Arbuthnot J had been wrong to declare death in the absence of the Code's tests. In *Barts Health NHS Trust v Dance & Battersbee* [2022c], the Court of Appeal overturned the earlier judgment, noting that none of the doctors involved had proposed declaring death in the absence of the tests and that the Code was clear that specific testing was required to demonstrate loss of brainstem function:

We...strongly caution judges in future cases of this kind from being drawn into attempting to declare death on a basis outside the Code where none of the medical witnesses has themselves made a diagnosis of death. [37]

The court held Arbuthnot J had been wrong to declare death once it became clear the DNC tests could not be performed and that a best interest's analysis was required instead. *Battersbee* therefore eventually confirmed that the Code of Practice tests *must* be performed before DNC can be established; if not, the patient cannot be declared dead using neurologic criteria (Choong, 2022, p. 43). As with *Re M* [2020], it had taken a prolonged legal process to reach this inevitable outcome.

4.3 Baby A

Following *Battersbee*, a number of cases soon made their way to court. In *Guy's & St Thomas' NHS Foundation Trust v A (A Child)* [2022a], a hospital applied for a declaration of an infant's death. Baby A sustained a hypoxic brain injury following cardiac arrest, with DNC tests confirming the child had died. Several days later, however, the infant started to breathe independently again. Presented with a case in which doubt was cast upon the certainty and reliability of DNC testing was thrown into doubt, Hayden J remarked that the court was in 'unfamiliar territory'. An expert witness later suggested the apparent recovery was because the infant's unfused skull bones allowed the intracranial pressure (and hence brainstem compression) to be relieved over time (*Guy's & St Thomas' NHS Foundation Trust v A (A Child)* [2022b]). This case presented the first instance in which the reliability of the tests was seriously

questioned. It may therefore provide unwarranted hope to the sceptical families who find themselves doubting a hospital's diagnosis of DNC.

4.4 Recent Cases

In *St George's University Hospitals NHS Foundation Trust v Casey* [2023a], a declaration was sought that a brain-injured patient had died following an assault. His family however argued that DNC did not equate to 'ordinary' death. They also questioned both the reliability and the validity of the DNC tests. They further argued that, following *Battersbee*, the legal approach had changed to one of weighing the best interests of the person involved. MacDonald J rejected their arguments, noting that *Battersbee* was distinguishable from other cases precisely because the DNC tests had not been performed – it therefore provided no authority in cases where the tests had been successfully administered. It ultimately took 11 weeks for the legal processes to be exhausted and the inevitable death declaration to be granted. Similarly, in *UHBW NHS Foundation Trust v The Mother of G* [2024], a mother refused to accept a DNC diagnosis following her daughter's self-poisoning. The clinical evidence of death, including the 'rigorously conducted' Code of Practice tests, was overwhelming. G's mother did not provide any substantive argument why she disagreed with the clinicians; she simply wanted more time to allow for a miracle.

Casey and *The Mother of G* demonstrate the way in which the lacuna created by the absence of a statutory definition of death, coupled with uncertainty or confusion generated by *Battersbee* and *Guys v A*, can lead to prolonged and adversarial court proceedings. In *Casey* [2023a], the Official Solicitor ominously suggested that legal challenges are becoming more prevalent, as evidenced by the increasing number of DNC cases coming before the courts (Lyons & Donnelly, 2023, p. 160). The rulings in such cases, however, have been universally supportive of the clinicians' determination of DNC. The Court of Appeal in *Casey* [2023b] was clear:

... the approach in [*Bland* and *Re M*] reflects a widely held consensus ... that brainstem death, correctly diagnosed, is the proper indicator of death in the legal sense. The contrary is not reasonably arguable at any level of court.' [29]

If this position is genuinely not arguable, it is concerning how much time and resources such cases consume as they slowly progress through the legal system. Peel J criticised the time delays in *The Mother of G*, commenting that it is 'unreasonable to

wait any length of time for determination of such sensitive matters.’ Similar cases continue to come before the courts. As of January 2026, the High Court has now formally endorsed the Code of Practice 2025 and its definition of death (*Barts Health NHS Trust v MC and ML* [2025]). However, as long as sceptical and grieving families continue to dispute the neurological elements of the Code, hospitals and the courts will continue to expend significant time, money and resources to litigate these ultimately futile appeals.

5 The Case for a Statutory Definition of Death

The absence of a statutory definition of death, and the resulting ambiguities and uncertainties, provide families with the legal ammunition to legally challenge the validity of the medical approach to determining death, particularly when using neurological criteria. This is unfortunate, as protracted legal proceedings can have several adverse implications.

5.1 Common Law Consequences: Ambiguity and Uncertainty

First, prolonged proceedings result in uncertainty concerning the patient’s legal status. Following *Battersbee* [2022c], the Court of Appeal confirmed it was ultimately for the courts to declare death in contested cases. Donnelly & Lyons (2024) highlight the enigmatic period which seemingly arises between completion of DNC tests and the subsequent declaration by the courts. In *Casey*, they suggest legal proceedings created a ‘liminal state’ between medical and legal death, arguing that for several weeks Casey was ‘neither dead enough to be a corpse nor sufficiently alive to warrant legal representation’. They notice he was not entitled to the same legal protections as a living but incapacitated patient, yet there was a presumption that his interests did not apply (Donnelly & Lyons, 2024, p. 117). Until the clinical determination of death was retrospectively confirmed by the Court of Appeal, it seems Casey was not truly dead. Donnelly and Lyons therefore suggest that, in between DNC testing and legal ratification, such patients should only be ‘presumed dead’.

Uncertainty arises in other ways. To most clinicians, DNC is an established and widely accepted medical concept. Yet it remains unfamiliar and counterintuitive to the lay public, perhaps owing to deeply ingrained historical notions of what constitutes death. The fact that families increasingly challenge the determination of DNC in court – and are perhaps encouraged to do so by ideologically-motivated

legal representatives (Wolley, 2022) – undermines the validity and security of DNC declarations in the public's eyes. It portrays DNC as an obscure concept which remains open to reasonable doubt and dispute. Conversely, death determined by somatic or circulatory criteria is a more intuitive concept for the lay public and more closely aligned with familiar notions of death (Capron, 2022, p. 90). For example, following a cardiac arrest it has never been argued in court that a refrigerated corpse in a mortuary is not dead. Death in that context appears understandable and self-evident, with bereaved relatives readily accepting the criteria used to establish that death has occurred. The same acceptance cannot be assumed for neurological criteria. In such cases, the courts inevitably become a forum for sceptical families to challenge the legal validity of the clinicians' counterintuitive concept.

5.2 Common Law Consequences: Delays and Circularity

Aside from conceptual and legal ambiguity, the current approach of retrospectively endorsing DNC diagnoses has other adverse effects. Recent disputes have demonstrated the significant time it can take for legal processes to be exhausted (*Re M* [2020]). For the entirety of legal proceedings, these dead patients occupy a scarce ICU bed connected to multiple pieces of life-support equipment, cared for on a one-to-one basis. This clinical undertaking has considerable practical, financial and resource implications, representing an enormous opportunity cost. In a publicly funded healthcare system with finite resources such as the UK's National Health Service (NHS), the provision of futile intensive care to a deceased patient is neither equitable nor economical, given that such resources could instead be directed towards living patients who are able to benefit or recover. The emotional toll and moral distress that may arise for healthcare staff whilst providing this care (whilst also undertaking adversarial court proceedings) should also not be underestimated (Mir, 2022).

Furthermore, it is arguable that the legal process is little more than a 'rubber-stamping' exercise – indeed, there has never been a successful legal challenge to a medical determination of DNC (Gardiner, McGee & Shaw, 2021, p. 294). The courts merely determine whether the Code has been properly applied. Hayden J's recommended wording for a legal declaration of DNC in *Re A (A Child)* [2015] was later adopted verbatim in *Re M*, *Casey* and *The Mother of G*. It seems once the medical facts have been established, legally ratifying DNC becomes automatic and formulaic, making lengthy delays all the more unjustifiable. Formulaic legal proceedings also

reinforce the inherent circularity in which the legal and medical professions each derive legitimacy for the Code when they apparently endorse the other. There appears to be no independent standard with which to calibrate or justify this self-reinforcing medicolegal position.

Finally, common law evolves incrementally. Judgments are necessarily predicated upon particular facts, arguments and appeals in specific cases (Capron, 2020, p. 85). As *Battersbee* [2022b] also demonstrated, it is possible for judges to err when adjudicating complex medical concepts. For an authoritative body of DNC jurisprudence to develop, relevant contested cases must be adjudicated. With a complex concept such as DNC, it is perhaps easy to appreciate why the common law has failed to develop ‘clearly, quickly or uniformly’ (Capron, 2020, p. 85). This current legal approach to determining death – where courts ratify medical standards and criteria – appears increasingly adversarial, prolonged, circular, formulaic and unsustainable. Whilst it is true that the courts have so far proven uniformly supportive of DNC declarations, the ensuing legal processes lead to delays, conceptual ambiguity, costly utilisation of resources and considerable emotional distress for relatives and staff.

5.3 Benefits of Legislation

5.3.1 Improved Clarity, Certainty and Consistency

Enshrining the medical definition of death (along with its diagnostic criteria) in legislation would induce greater certainty and consistency in future cases by providing an unambiguous and incontrovertible medicolegal standard. This would help negate some of the self-reinforcing circularity and time delays generated by retrospective court endorsement of the Code of Practice. Legislation would more legitimately cement the definition of death (with its circulatory *and* neurologic criteria) into law, emphasising to all parties that, when properly established by clinicians, a diagnosis of DNC emphatically signals medical and legal death. It would circumvent the ambiguous ‘liminal state’ arising between the diagnosis and a later court declaration (Donnelly & Lyons, 2024, p. 119), by removing the need to later judicially ratify DNC.

A statutory definition would signal to families that determining DNC in accordance with accepted medical guidelines is a diagnostic matter entirely for clinicians. Codifying the medical definition of death into legislation appears the most appropriate mechanism to emphasise the biological basis of DNC (Bernat and Beresford, 2013, p. 430) and the clinical experience required to make the diagnosis, whilst simultaneously pre-empting superfluous judicial interference or delay. In overruling *Arbuthnot J in Battersbee* [2023c] the Court of Appeal “was, entirely reasonably, concerned about the judicial assumption of clinical responsibility”. A US appellate court has likewise pithily cautioned against judges overreaching in medical cases, writing, “The judiciary is called upon to serve in black robes, not white coats. And it must be vigilant to stay in its lane and remember its role” (*Tex. Health Huguley Inc v Jones* [2021]).

5.3.2 Practical Benefits

Strengthening the clarity and consistency around the legal definition of death would engender practical benefits. Reducing the need to judicially ratify death should hopefully reduce the number and duration of legal challenges. Clinicians would be empowered to make defensible decisions about treatment limitations or the withdrawal of futile life-support, reassured by the knowledge that their factual determination of death was recognised in statute. This should hopefully spare clinicians and potential litigants ‘the expense and exhaustion of court proceedings’ (Skegg, 1976, p. 191) to debate the definition and diagnostic process. Promoting faster resolutions and avoiding protracted legal proceedings also has beneficial effects in terms of maximising scarce ICU resources, and in reducing the associated emotional distress and distraction for the healthcare staff. The formation of a statutory definition of death also presents an opportunity to revise and harmonise many other death-related statutes and regulations. A standardised, stand-alone statutory definition may help to address some of the inconsistencies or omissions currently found in other legislation.

5.3.4 The Role of Parliament

The medical definition of death, as we have seen, is a highly nuanced, technical concept encompassing detailed neuroanatomical understanding and philosophical deliberation over many years (President’s Council on Bioethics, 2008). It seems inescapable that any statutory language will be strongly influenced by current medical

understanding and practices. Indeed, the *definition* and *criteria* used to diagnose death are arguably the exclusive preserve of the medical profession: after all, it is a highly consequential condition identified using clinical assessment, professional judgment and practical skills. Given the range and magnitude of legal, personal and social consequences arising from a determination of death, it would be inappropriate for the definition or diagnosis to be subject to personal preferences, interpretation or religious belief. Individuals, society, clinicians and the courts all require a clear and certain answer to the question – when is a person dead? Arguably, only the medically endorsed definition and criteria can satisfy such exacting requirements.

This is not to say that Parliament would have no effective role in the legislative process. Capron (2022) has argued that any legal definition of death encompasses value judgments about what it fundamentally means to be a living part of civilised society. When considering any statutory endorsement of the medical definition of death, Parliament might consider some of the ancillary issues which *are* amenable to public engagement and debate. Parliament could explore issues such as religious objections to the use of neurological criteria to diagnose death, similar to that seen in the US state of New Jersey (Sarbey et al., 2022, p. 281). Equally, Parliament might debate the need (or not) to obtain consent from relatives prior to DNC testing, or review the composition and Terms of Reference of the medical group, which is to provide the consensus guidelines, or when and how these guidelines should be reviewed. Parliamentary scrutiny could allow for broader public engagement with a complex issue and hopefully the opportunity to better educate the public (Brazier et al., 2023, p. 537). Some semblances of public engagement or education may help make the resulting legislation more palatable to the public when attempting to incorporate controversial medical, social or moral issues into laws that affect the status of all citizens.

5.4 The Case Against Legislation

5.4.1 Should DNC be Defined in Legislation?

It is debatable whether such a technical clinical issue is appropriate for statutory recognition, given the comprehensive medical guidance available. It might also be argued that the neurological criteria used to determine death vary around the world, indicating a reasonable degree of uncertainty or inconsistency with the concept (*Re M* [2020]). This might undermine the case for enacting prescriptive legislation. But

the international variation in DNC diagnoses may not be as significant or relevant as is supposed. The US legislation utilises a ‘whole-brain’ criterion of death, requiring cessation of *all* functions of the *entire* brain. Conversely, the UK and a smaller number of Commonwealth countries utilise a ‘brainstem’ criterion, requiring cessation of brainstem function alone. In practice, injuries severe enough to permanently damage the brain cortex inevitably damage the brainstem as well; similarly, the clinical tests used in ‘whole-brain’ jurisdictions are merely tests of brainstem function. As such, ‘brainstem’ and ‘whole-brain’ criteria can effectively be regarded as synonymous in clinical practice (Laurie, Harmon & Dove, 2019, p. 577). Indeed, a growing number of international consensus guidelines appear to be slowly gravitating towards the UK’s brainstem criterion of DNC, including those from the World Brain Death Project (Greer et al., 2020), the Canadian Journal of Anaesthesia (Shemie et al., 2023), and the Australian and New Zealand Intensive Care Society (2021).

5.4.2 Discrepancies in Medical Guidelines

The statutory definition of death in the US (described by the UDDA 1980) has faced increased criticism. There is concern amongst clinicians and academics that it is outdated and incoherent because it requires cessation of *all* functions of the *entire* brain, yet, it does not require similar all-encompassing cessation of circulatory functions (Gardiner & McGee, 2022, p. 69). Further confusion arises because the UDDA does not specify which medical standards are considered authoritative, so there appears to be growing divergence between medical guidance and the wording of the UDDA (Gardiner & McGee, 2022, p. 71). Judges therefore have to determine whether or not the medical guidelines are consistent with the statute’s requirements, at times leading to emotive and prolonged legal disputes (*In re Guardianship of Hailu* [2015]). Medical practice often evolves at a rapid pace. It is possible that legislation which has failed to make adequate allowances for future developments may require alteration in order to keep legal standards consistent with medical practice. Conversely, as long as the matter is treated as a question of medical fact, ‘changes in medical approach can be accommodated within the law without any requirement for further legislation’ (Brazier, Cave & Heywood, 2023, p. 536). Gardiner & McGee (2020) argue that this makes the UK’s current approach more flexible than jurisdictions with legislation, because the common law approach is better able to adopt to future medical advances. But this argument merely gives weight to the

notion that any statutory language must be carefully worded, future-proof, and perhaps qualified by reference to currently accepted medical standards.

Finally, when drafting statutory language, there might be uncertainty regarding the 'level' of definition required (Capron & Kass, 1972, p. 102). A definition of death that is too philosophical or conceptual would be impractical when addressing real-world questions about the status of particular individuals. Conversely, a highly technical, criterion-based definition might prove too inflexible or prescriptive, or soon become out-of-date in light of medical advances. A significant challenge, therefore, in drafting legislation is to strike an appropriate balance between clarity, inclusivity and specificity, yet remaining accommodative of future medical developments without the need for later statutory reform.

6 A Statutory Definition of Death for the UK?

This final section proposes and justifies hypothetical language for legislation defining death, informed by current medical understanding in this highly technical area. Statutory wording such as this would arguably provide greater legal clarity, certainty and consistency for all stakeholders than the current common law approach.

6.1 A Proposed Statute

The following wording could be used to enshrine a clear and concise definition of death into legislation in the UK:

- 1) Death is the permanent loss of the capacity for consciousness combined with the permanent loss of the capacity to breathe.
- 2) An individual is dead when they have sustained either –
 - a. permanent cessation of circulation to the brain, or
 - b. permanent cessation of brainstem function.
- 3) The confirmation of death must be made in accordance with accepted medical standards as set out in the Code of Practice by the Academy of Medical Royal Colleges or its successor organisation.

The statute would apply to all deaths in the UK, ensuring national uniformity and consistency. It is independent from all other legislation regulating end-of-life events and processes, including organ donation, death registration, coronial investigation

and Medical Examiner scrutiny. It mirrors the dual-criteria approach of the UDDA (Uniform Law Commission, 2014, p. 1), yet is firmly modelled on both the definition *and* criteria found within the latest Code of Practice.

Section (1) provides a conceptual definition of death which is clinically and philosophically robust and increasingly endorsed worldwide. It articulates the same underlying definition of death found in the Code of Practice 2025, the President's Council on Bioethics (2008) and the World Brain Death Project (Greer et al., 2020). It describes the loss of the two most relevant capacities – both anatomically mediated in the brainstem – which allow an individual to engage and interact with the world at the most fundamental level. Loss of these capacities emphatically indicates death.

Section (2) provides the diagnostic criteria to confirm that death has occurred. The statute refers to 'individuals', making it applicable regardless of age, race, sex, geographical location or personal characteristics. The phrase 'is dead' is a clear and determinative statement about an individual's current legal status, but which does not contain inferences about rights, actions or obligations.

'Cessation of circulation' remains the most intuitive and familiar criterion of death to the lay public; it is also the most frequently used in clinical practice (Capron, 2022, p. 90). The inclusion of the circulatory criterion into legislation acknowledges this reality. To foster legitimacy and broad support, any statute must be acceptable to the public at large. Lord Bingham once argued that all laws must be 'accessible, intelligible, clear and predictable' (Bingham, 2011, p. 47). The proposed legislation therefore 'allows public perception to change incrementally rather than radically' (Capron, 2022, p. 90) in this complex area by not enforcing a sole neurologic criterion of death.

Section (3) requires the confirmation of death to be made 'in accordance with accepted medical standards as set out in the Code of Practice'. For many decades in the UK, the Academy of Medical Royal Colleges has produced the widely accepted consensus guidelines for diagnosing and confirming death, including DNC; the Academy is therefore specifically named in the legislation. This aims to avoid the uncertainty and conflict seen in the US, caused by the UDDA's imprecise wording, where it is not clear exactly which medical guidelines are determinative (Russell et al., 2019, p. 228). Reference to 'accepted medical standards' prevents the statute from becoming overly detailed and prescriptive, or too weighed down with medical

minutiae. This includes technicalities such as the specific clinical tests or ancillary investigations required; the practical conduct of DNC testing; the requirement (or not) to obtain consent before testing; or the precise meaning of current medical terminology. This allows the legislation to remain pragmatic and usable, but also flexible and adaptive to future developments in medical understanding and practices. The statutory wording is thereby ‘future-proofed’ against later medical developments, creating legal certainty whilst allowing for medical evolution and innovation. This also ensures that the legislation will not need to be amended each time there is a new clinical development in this complex and evolving area.

6.2 Exclusions

A number of elements are deliberately excluded from the legislation, in part to keep the statute as clear, concise and universal as possible. These additional elements would arguably be more amenable to Parliamentary scrutiny than the underlying scientific principles, prior to inclusion in accompanying guidance or explanatory materials. They might include some of the social, moral or religious issues raised by the definition and diagnosis of death. For example, the proposed statute deliberately avoids reference to subsequent rights, obligations or related activities such as organ donation or the withdrawal of life-support. This is because death should be independently defined and established in law, not merely an instrumental designation in order to accomplish another end. For clarity and coherence, any legal definition of death must stand separately from its ramifications. For example, an individual’s legal status as either ‘dead’ or ‘alive’ cannot depend on whether or not they are potentially an organ donor; this inconsistency might generate public unease and widespread loss of confidence in organ donation processes.

The legislation also does not include accommodation for a religious objection to diagnostic criteria, in particular the neurologic criteria. This is to ensure universal applicability and consistency of a concise statute based upon current medical principles; the definition of death should not vary based on personal, religious or family preferences. That said, case law repeatedly demonstrates that members of some faith groups are reluctant to accept the neurological criteria as a means to establishing death (most recently, *Barts Health v MC* [2025]). Freedom of conscience and religion is important (and protected) in a pluralistic multicultural society (Human Rights Act 1998, Article 9(1)), although some limitations on religious expression can be imposed for lawful reasons (Human Rights Act 1998, Article 9(2)). Consideration

of religious exemptions would therefore seem appropriate for scrutiny and debate by an inclusive, democratically elected body, which may choose to provide additional guidance or (non-statutory) exemptions for individuals belonging to particular faith groups.

Similarly, Parliament might consider or debate the need to obtain consent before DNC testing. Many international guidelines state there is no need to seek family consent for testing (Greer et al., 2020), and consent is likewise not mentioned in the latest Code of Practice. This issue has been debated in court (*Casey* [2023a]), but currently remains unresolved; for now, the decision whether or not to test appears to remain one for clinicians. Given the uncertainty and potential for a wide variety of conflicting opinions on this contentious issue, it seems appropriate for parliamentary discussion and debate before drafting any legislation.

7 Conclusion

Death is a highly significant moment in an individual's existence. Given the medicolegal ramifications which follow the determination of death, it is perhaps surprising there is no statutory definition in the UK. The concept and definition of death have been repeatedly (and increasingly) challenged in the courts, leading to debate, confusion and uncertainty about the definition of death and the criteria used to diagnose it. Clarity and consistency of legal terminology is important if laws and decisions are to be applied uniformly and justly. The absence of a statutory definition of death in the UK, coupled with the unfamiliar and counterintuitive nature of DNC, has provided sceptical families ambiguity with which to repeatedly challenge and doubt the medicolegal *status quo*.

There is now a strong argument to enact a statutory definition of death in the UK. It would bring greater clarity, certainty and consistency to the legal definition of death. Legislation would cut through the formulaic circularity generated between the common law and medical guidelines by providing a robust, independent and incontrovertible legal standard. By circumventing prolonged legal disputes, a statutory definition of death would reduce uncertainty, delays, and the consequent inefficient utilisation of scarce ICU resources. This paper proposes a statute that is medically and philosophically robust, concise, precise, universal and justifiable. Such a statute would provide the requisite certainty, clarity and consistency regarding an individual's legal status in a definitive yet timely manner.

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Povzetek v slovenskem jeziku

V Združenem kraljestvu ni zakonske opredelitve smrti. Od leta 1980 britanska sodišča postopoma priznavajo nastajajoči klinični koncept smrti, imenovan »smrt, ugotovljena na podlagi nevroloških merik« (DNC). Čeprav je bilo to stališče v nekaterih nedavnih primerih izpodbijano, se DNC danes šteje za medicinsko in pravno opredelitev smrti. Odsotnost zakonske opredelitve smrti, skupaj z zapleteno in protislovno naravo DNC, je skeptikom ponudila dvoumnost, s katero lahko izpodbijajo medicinsko-pravni status quo. Pristop common law k opredelitvi smrti se zdi vse bolj nezadovoljiv. Tako obstaja močan argument za sprejetje ustrezne zakonodaje v Združenem kraljestvu. Članek predlaga zakonodajo, ki bi prinesla večjo pravno jasnost, gotovost in doslednost pri ugotavljanju smrti ter bi obravnavala številne praktične in konceptualne težave, ki trenutno obstajajo.

PHARMACEUTICAL LIABILITY FOR UNEXPECTED ADVERSE DRUG REACTIONS: A COMPARATIVE STUDY OF SLOVENIAN AND GERMAN LAW

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Abstract Medicinal products are vital to healthcare, yet their use entails unavoidable risks, especially unexpected adverse drug reactions. This article examines how Slovenian and German law allocate civil liability for such harm and what implications arise for injured persons. It argues that Slovenia's framework is normatively sound but fragmented, with evidentiary support for claimants underdeveloped, whereas Germany's is more coherent and claimant-oriented. Both rely on strict liability and continuous pharmacovigilance but diverge in evidentiary and institutional design. Using a doctrinal-comparative method, the article analyses Slovenian and German statutes in light of Product Liability Directive (EU) 2024/2853. It finds that Slovenian law lacks key safeguards, including an express, sector-specific presumption of causation and a statutory right of access to safety data, and imposes no insurance duty. German law offers clearer rules, procedural support, and mandatory financial coverage. The Directive's innovations point toward a more claimant-friendly model, offering Slovenia an opportunity for reform.

Keywords

pharmacovigilance,
pharmaceutical liability,
product liability,
tort law,
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1 Introduction and Methodology

The pharmaceutical industry develops, manufactures, and markets medicinal products, which require strict regulation due to their impact on human life and a clear legal framework, typically through marketing-authorisation regimes and patent protection (Drofenik & Kerč, 2020, pp. 24-25). Because medicines are *sui generis* goods, regulation must balance industry interests with patients' rights. Liability may arise before or after market entry, including labelling, storage, pharmacovigilance, and use (Možina & Brvar, 2017, pp. 143-145), potentially involving multiple actors.

Users may sustain harm from adverse drug reactions (ADRs), and may seek legal redress, particularly when a manufacturer has withheld relevant information. Under point 51 of Article 6 of the Slovene Medicinal Products Act (Zakon o zdravilih, hereinafter: ZZdr-2),¹ an ADR is defined as any harmful and unintended response to a medicinal product administered at the correct dose for the purposes of prevention, diagnosis or treatment of disease, or for the modification of physiological function. An unexpected adverse reaction refers to any such reaction not listed in the Summary of Product Characteristics (SmPC); in other words, its seriousness, nature or outcome is inconsistent with the SmPC. A distinction is also drawn between adverse reactions and side effects - the latter encompassing undesirable, but either harmful or non-harmful effects resulting from the properties of the medicine when used at the correct dose (Možina, 2006, pp. 312-313). In some literature, however, the two terms are treated as interchangeable (see Due, 2023, p. 16).

Due to the inherent nature of medicinal products, harm may still occur to users despite safety measures such as regulatory oversight and adverse-reaction monitoring. Such harm may result from defective products, for example contaminated batches, manufacturing irregularities, or formulation errors, as well as from unexpected adverse reactions caused by inadequate pre-market testing, withheld information by manufacturers or pharmaceutical companies, or insufficient post-marketing research (Dangerous Drugs Leading to Products Liability Lawsuits, 2024). The development and monitoring of medicines is a multi-stage process,

¹ Zakon o zdravilih (Medicinal Products Act), Official Gazette of the Republic of Slovenia, Nos. 17/14, 66/19, 102/24 – ZZKZ, 24/25 and 27/25 – corr.

requiring continuous oversight both during trials and after market entry. Affected individuals may seek compensation under civil liability, raising questions of who bears responsibility and what must be proven. This article argues that Slovenia's framework, though normatively in place, remains fragmented and procedurally incomplete, whereas Germany's system is more coherent and claimant-oriented, as analysed through doctrinal comparison within the evolving EU context.

General tort liability in Slovenian law is set out in the Obligations Code (Obligacijski zakonik, hereinafter: OZ).² Article 10 of the OZ encapsulates the *neminem laedere* principle - the duty not to cause harm. Once wrongfulness, compensable damage, and causation are established, fault is presumed. By contrast, under strict liability no proof of fault is required (see further: Samec Berghaus, Bitrakov & Drnovšek, 2024, pp. 43-46). Within the Slovenian legal order, two acts are particularly relevant: the ZZdr-2 and the Consumer Protection Act (Zakon o varstvu potrošnikov, hereinafter: ZVPot-1),³ each of which contains specific liability provisions. Under the maxim *lex specialis derogat legi generali*, claims should be brought under the more specific statute, with the OZ applying subsidiarily to fill any lacunae. Accordingly, it is essential to determine which statute constitutes the *lex specialis*. Although ZZdr-2 and ZVPot-1 both regulate liability - albeit not as comprehensively as the OZ - they do so in diametrically opposed ways; the ensuing competition between statutes generates legal uncertainty and unpredictability. From this perspective, a precise delineation of the applicable regime is essential to ensure legal certainty.

At the core of these issues lies the product-liability regime for manufacturers of medicinal products, which in Slovenian law operates at the intersection of general tort rules and sector-specific statutes. The provisions of ZZdr-2, ZVPot-1, and the OZ frequently overlap or are construed divergently, generating legal uncertainty and disadvantaging injured parties.

This article adopts a doctrinal-comparative methodology to examine civil liability for harm caused by unexpected adverse drug reactions in Slovenian law and to compare it with the German legal framework. The doctrinal part of the analysis interprets the

² Obligacijski zakonik (Obligations Code), Official Gazette of the Republic of Slovenia, No. 83/01 (with subsequent amendments: 97/07 – UPB, 64/16 – odl. US; 20/18 – OROZ631).

³ Zakon o varstvu potrošnikov (Consumer Protection Act), Official Gazette of the Republic of Slovenia, No. 130/22.

relevant EU, Slovenian and German provisions by using textual, systematic and teleological methods, with particular attention to the relationship between general product liability rules and sector-specific pharmaceutical liability regimes. The comparative part follows a functional approach: it does not seek to measure litigation outcomes empirically, which would be difficult given the scarcity of Slovenian case law in this field, but instead compares how the two legal systems address the same practical problem, namely the injured patient's ability to obtain compensation for harm caused by medicines.

The comparison is guided by five analytical criteria that are particularly relevant in pharmaceutical injury cases: the clarity of the applicable liability regime, the allocation of the burden of proof, especially with regard to causation, the claimant's access to safety-related information, the relevance of limitation periods for latent health damage, and the existence of financial safeguards such as liability insurance. Germany is selected as the comparator not as an ideal model, but because the German Medicinal Products Act (*Arzneimittelgesetz*, hereinafter: AMG)⁴ contains several instruments that are either absent from or less clearly developed in Slovenian law, including a specific pharmaceutical liability regime, a statutory presumption of causation, a right of access to information and mandatory financial coverage.

The article addresses three research questions. First, which rules govern civil liability for harm caused by unexpected adverse drug reactions in Slovenian law? Secondly, how does the Slovenian framework differ from the German model of pharmaceutical liability under the AMG? Thirdly, can the new EU product liability framework, especially its rules on disclosure of evidence and rebuttable presumptions, offer guidance for strengthening claimant protection in Slovenia?

The article first outlines the EU-level framework governing manufacturers' liability, including the implications of Directive (EU) 2024/2853 (hereinafter: Directive 2024/2853).⁵ It then turns to Slovenian law, mapping the relevant rules on the liability of manufacturers and marketing authorisation holders, causation, defences and liability insurance. The following section addresses German law, with particular

⁴ *Arzneimittelgesetz* (Medicinal Products Act). *Bundesgesetzblatt I*, p. 3394; last amended by Art. 2 of the Act of 23 October 2024 (*Bundesgesetzblatt I*, p. 324). Consolidated version consulted on 3 November 2025.

⁵ Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products and repealing Council Directive 85/374/EEC, OJ L 2024/2853.

attention to pharmaceutical-company liability under the Medicines Act, the presumption of causation, the right to information and financial coverage. The article then provides a comparative discussion of the Slovenian, German and EU approaches, before concluding with the main findings and reform implications for Slovenian law.

2 EU-Level Framework for Liability in the Context of Medicinal Products

Given the structural imbalance between individual claimants and manufacturers in most product-related harm cases, the European Union introduced a regime of strict liability for defective products in Council Directive 85/374/EEC (hereinafter: Directive 85/374)⁶. This Directive laid down essential rules for individuals injured by defective products, providing a harmonised legal framework that did not require proof of fault.

In 2024, Directive 85/374 was repealed and replaced by Directive 2024/2853. Member States must transpose it by 9 December 2026, pursuant to Article 22(1). One of the core innovations is the explicit inclusion of software - including AI-enabled systems and connected digital services - as standalone products falling within the scope of product liability. This reflects the increasing role of software in determining the safety and functionality of modern products. The revised Directive also introduces important evidentiary reforms, including mechanisms for presumptions of defectiveness and causation, as well as the right of claimants to request disclosure of relevant evidence, thereby alleviating the burden of proof in favour of the injured party (see more Li & Faure, 2024, pp. 166-167). Article 9(1) of Directive 2024/2853 provides that in a product liability lawsuit, if the claimant presents facts and evidence making the claim plausible, “the defendant is required to disclose relevant evidence that is at the defendant’s disposal” upon the court’s order. This marks a change from the old 1985 Directive 85/374, which had no such disclosure mechanism, often leaving victims struggling to obtain technical evidence held by manufacturers. The revised law thus gives courts a tool to force manufacturers to share internal documents or data relevant to the alleged defect,

⁶ Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ L 210.

helping claimants access proof that would otherwise be out of reach. If a defendant fails to comply with a court's evidence disclosure order, the Directive 2024/2853 presumes the product was defective. Article 10(2)(a) establishes that "the defectiveness of the product shall be presumed" if "the defendant fails to disclose relevant evidence pursuant to Article 9(1)". In other words, when a manufacturer withholds evidence that the court ordered it to produce, one of the statutory conditions for presuming a product defect is met. This presumption is rebuttable - the manufacturer can still offer proof to contest defectiveness - but unless rebutted it spares the claimant from having to affirmatively prove the defect. Notably, the Directive 2024/2853 includes other triggers for a defect presumption (such as the product's non-compliance with safety regulations or an obvious malfunction). However, failure to disclose evidence is a key new trigger, directly aimed at discouraging defendants from hiding information. As Li & Faure (2024) observe, the revised Directive "sets up the conditions to presume the defectiveness of the product" when evidence is withheld. These innovations greatly strengthen the claimant's hand: they either gain the evidence needed to prove their case, or benefit from a legal presumption of defect that the defendant must overcome. This eases the victim's path to compensation by reducing the obstacles in proving a defective product caused their damage.

Directive 85/374 already recognised that Member States may adopt or retain special liability regimes for certain sectors - most notably pharmaceuticals. According to Recital 13, "in so far as effective protection of consumers in the sector of pharmaceutical products is already attained in a Member State under a special liability system, claims based on this system should similarly remain possible". The new Directive 2024/2853 preserves this flexibility. Recital (10) affirms that "the right to make [pharmaceutical-related] claims should remain unaffected by this Directive", provided they do not undermine the objectives of the harmonised regime. In addition, Recital (11) clarifies that national compensation schemes (e.g., social security, insurance funds) remain outside the scope of the Directive, explicitly mentioning non-defective pharmaceuticals as an example.

The distinction between the general product liability regime and the special framework applicable to pharmaceuticals has also been examined by the Court of Justice of the European Union, which emphasised that medicinal products occupy

a special status due to their therapeutic purpose, setting them apart from ordinary consumer goods.⁷

Because Directive 85/374 already allowed Member States to retain pre-existing special liability schemes - for pharmaceutical products - the EU regime set up a harmonised strict-liability framework for defective products while leaving room for special regimes to continue operating (Recital 13; see also Recitals 10–11 of Directive 2024/2853). Within that space, Member States may enact or maintain sector-specific rules for medicinal products; this article focuses on Slovenia and Germany.

Germany provides a dedicated pharmaceutical liability regime under the AMG. The AMG establishes a special strict-liability scheme (*Arzneimittelhaftung*) for harm caused by medicinal products and, inter alia, contains a presumption of causation under specified conditions (e.g., Section 84(2) of the AMG). This yields a more granular level of claimant protection than the Slovenian ZZdr-2, which does not regulate civil liability in comparable detail and therefore requires subsidiary recourse to the OZ.

Like Slovenia, the German legislature transposed Directive 85/374 by a separate Product Liability Act (*Produkthaftungsgesetz*, hereinafter: *ProdHaftG*).⁸ Section 15 *ProdHaftG* expressly excludes the application of the *ProdHaftG* to human medicinal products governed by the AMG; liability under other provisions (i.e., the AMG regime) remains unaffected. With the upcoming implementation of Directive 2024/2853, the German legislature plans to replace the *ProdHaftG* with a new *ProdHaftG-E*, in which the current 15th section will become Section 21, maintaining the same content (*Bundesministerium der Justiz und für Verbraucherschutz*, 2025). No changes are necessary in pharmaceutical liability law: liability under the AMG remains the primary regulation (*lex specialis*) and already meets the standards established by the new EU product liability framework. The new EU product liability rules will govern other medical products, digital health applications, and digital

⁷ See Judgement of the Court of Justice of 22 December 2022, *Case C-530/20, EUROPTIEKA SLA*, ECLI:EU:C:2022:1014; see also Judgement of the Court of Justice of 19 May 2009, *Joined Cases C-171/07 and C-172/07, Apothekerkammer des Saarlandes and Others v. Saarland and Ministerium für Justiz, Gesundheit und Soziales*, ECLI:EU:C:2009:316, para. 31.

⁸ *Produkthaftungsgesetz* (Product Liability Act). *Bundesgesetzblatt I*, p. 2198; last amended by Article 5 of the Act of 17 July 2017 (*Bundesgesetzblatt I*, p. 2421). Consolidated version consulted on 3 November 2025.

software in the medical sector. By contrast, Slovenia's Consumer Protection Act (ZVPot-1) implements the general product liability regime but - unlike German law - does not carve out pharmaceuticals from its scope; still, in light of the EU *acquis* (Directive 85/374, Recital 13; Directive 2024/2853, Recitals 10–11), claims under more claimant-friendly national rules outside the product-liability regime remain possible, which in Slovenia points to the OZ as *lex generalis* (see also Samec Berghaus, 2025).

This EU-level backdrop frames the national analysis that follows. The next chapter examines, in turn, the applicability and interplay of ZZdr-2, ZVPot-1 and the OZ in Slovenia, with particular attention to allocation of risk, causation standards, defences, limitation periods, and the availability of liability insurance.

3 Liability under the Relevant Rules of Slovenian Law

3.1 Delineation of Regimes

In the Slovenian legal system, two sector-specific statutes are relevant to liability for harm caused by medicinal products: ZZdr-2 and ZVPot-1. Since both instruments regulate liability, the threshold question is whether medicinal products can be treated as goods within the meaning of ZVPot-1 for the purpose of determining the applicable regime. Any assessment must consider that medicines constitute a special category of goods, subject to specific rules on quality, safety and efficacy (ZZdr-2). In a broad sense, medicines may be subsumed under the concept of goods in ZVPot-1; however, as emphasised in the EU framework, both Directive 85/374 and the new Directive 2024/2853 were adopted on the understanding that they do not displace Member-State rules in certain sectors, one of which is medicinal products for human use. The practical consequence is this: where a field is specifically regulated (here, the pharmaceutical sector in Slovenia), general consumer-law provisions must yield to the sector-specific rules insofar as the latter would otherwise be encroached upon. In Slovenia, the field of medicines is primarily regulated by ZZdr-2.

From the foregoing - and from the fact that ZZdr-2 itself implements EU legislation (see Article 2 of the ZZdr-2) - it follows that ZVPot-1 does not apply to matters that fall, by virtue of EU-driven sector regulation, within the scope of ZZdr-2.

This conclusion is reinforced by general principles of interpretation. Having regard to legislative purpose, it is apparent that ZZdr-2 - particularly its liability provision - was enacted to protect injured parties where medicines, as a distinct class of products, cause harm, and it does so by regulating more strictly and in greater detail the liability of specific actors, namely manufacturers and/or MAHs in the Republic of Slovenia. As will be shown below, Paragraph 4 of Article 27 of the ZZdr-2 imposes liability even where “the state of scientific and technical knowledge at the time when the product was put into circulation was not such as to enable the defect to be discovered.” By contrast, Article 64 of the ZVPot-1 provides the development-risk defence, allowing the manufacturer to avoid liability if it proves that, given the then current state of scientific and technical knowledge, the defect could not have been discovered. The legislative design is thus evident: ZZdr-2 affords stronger claimant protection, tailored to the specific risks associated with medicines. Consequently, ZZdr-2 is the more claimant-friendly regime in this field, consistent with the protection of the weaker party. The two statutes regulate liability in diametrically opposed ways: ZZdr-2 tightens the scope for exculpation, thereby enhancing legal certainty for injured parties. For this reason, ZVPot-1 does not govern liability for harm caused by medicines. This does not mean that ZVPot-1 is irrelevant in the broader consumer-protection context; for example, it remains pertinent to marketing and distribution practices for medicines.

When determining liability, the doctrine of manufacturer’s liability under Article 155 of the OZ is likewise unavoidable. That provision contemplates two heads of liability: (i) cases where the thing itself is defective, thereby increasing the risk of harm, and (ii) cases where the thing has dangerous properties. Primary protection for injured parties in the pharmaceutical context, however, is provided by Article 27 of the ZZdr-2, which - under the maxim *lex specialis derogat legi generali* - functions as the special regime *vis-à-vis* the OZ. The provisions of the OZ therefore apply subsidiarily, i.e., to issues not regulated by ZZdr-2. One such issue concerns causation - its standard, proof and presumptions - which will be addressed in what follows.

3.2 Medicinal Product as a “Dangerous Thing” or a “Defective Thing”?

When analysing liability for harm caused using medicinal products, Slovenian law requires a distinction between the concepts of a dangerous thing and a defective thing, as these are distinct institutions that may entail different consequences.

Medicinal products cannot be assessed as “dangerous things” in the same way as other products. Strict liability for medicinal products arises from special statutory provisions (ZZdr-2) that take into account their complexity, unpredictability, and the health status of users. The traditional criteria for dangerous things: high probability of harm and risks unmanageable even with utmost care, do not directly apply. A defective thing, by contrast, is one that fails to provide the level of safety a user is entitled to expect, including adequate instructions, warnings, and consideration of reasonably foreseeable uses. In practice, medicinal products may (depending on the facts and user conduct) be characterised as defective things, dangerous things, or a combination of both. Liability largely depends on whether users are adequately informed, as properly provided warnings and instructions generally protect manufacturers from claims for inherent risks. These rules highlight that medicinal products require a distinct assessment from ordinary products, where inherent dangers are treated differently (see more: Jadek Pensa et al., 2003, pp. 850-851; see also: Samec Berghaus, Bitrakov & Drnovšek, 2024, pp. 109-111).

3.3 The ZZdr-2 Regime

3.3.1 Liability of the marketing-authorisation holder (MAH)

Liability in the field of pharmacovigilance is governed by Article 27 of the ZZdr-2. Article 27(1) provides that “the marketing-authorisation holder for a medicinal product in the Republic of Slovenia is responsible for the development of the product and its placing on the market in accordance with the marketing authorisation, and for any damage that may arise in connection therewith, including damage resulting from inadequate quality of the medicinal product, for which the manufacturer is responsible.” The MAH need not be the manufacturer but must have a contractual arrangement with the manufacturer ensuring compliance of production with the authorisation and quality requirements (Article 27(2) of the

ZZdr-2). Where a manufacturing defect occurs, the MAH is liable to the injured party and may subsequently pursue recourse against the manufacturer.

ZZdr-2 does not speak in terms of “defectiveness” or of medicines as “dangerous things”; rather, it refers to inadequate quality (a quality defect). A quality defect is defined as any deviation from the data set out in the marketing authorisation that affects the safety or efficacy of the product (Rules on the Recall of Medicinal Products (Pravilnik o odpoklicu zdravil),⁹ Article 2). Examples include contamination, incorrect composition, damaged packaging, inconsistent instructions for use, or manufacture without authorisation (Slak, Planinšek, Miklič, & Frangež, 2019). The content and currency of the instructions for use are the responsibility of the MAH, while the manufacturer is responsible for their physical inclusion in the packaging and for proper labelling - i.e., the preparation of the finished product. The injured party may claim damages exclusively against the MAH, who bears ultimate liability.

3.3.2 Liability of the manufacturer

Although the MAH is the primary liable person, the manufacturer’s duties must be specified. Article 27(3) - (5) of the ZZdr-2 stipulates that the manufacturer is responsible not only for production as such, but also for quality control, packaging, and labelling of the medicinal product. The manufacturer is also directly liable for damage caused by falsified medicines where it is established that it removed or covered the safety features on the product and replaced them with new ones on a falsified medicinal product.

3.3.3 Causation

Causation links the harmful event to the damage and is a core element of liability in damages. Article 27 of the ZZdr-2 does not lay down rules on causation; consequently, the OZ, as *lex generalis*, applies subsidiarily. Given that liability for medicinal products is strict (objective), a rebuttable presumption of causation arises once the injured party establishes a connection between the damage and the

⁹ Pravilnik o odpoklicu zdravil (Regulation on the recall of medicinal products), Official Gazette of the Republic of Slovenia, Nos. 105/08 and 17/14 – ZZdr-2.

medicinal product, i.e., the anchor facts that trigger the presumption. It suffices for the claimant to prove this factual basis; in other words, the damage must in fact occur in connection with the use of the medicine.

By way of example, in cases involving substandard-quality medicines (quality defects), the presumption may be supported where the claimant points to adverse effects listed in the package leaflet – for instance, the leaflet warns of potential cardiac disorders, and such a disorder develops within a relevant period after administration. In that scenario the risk is already signalled in the instructions and can serve as the basis for the presumption. For unexpected adverse reactions not disclosed to users, establishing causation is harder, especially where multiple medicines are taken simultaneously (polypharmacy) or where the adverse effect appears only after some time has elapsed from the start of treatment.

For situations of this kind, EU case law allows courts to find a causal link based on serious, specific and consistent indicia, even in the absence of scientific evidence establishing causation. It is for the courts – within their margin of appraisal – to assess whether the facts relied on (e.g., the temporal proximity between vaccination and the onset of the disease, and the absence of prior medical history relating to that disease) amount to serious, specific and consistent presumptions sufficient to establish defect and the causal link, notwithstanding the lack of medical proof. The Court of Justice clarified that the claimant is not required to adduce precise and irrefutable proof of the defect and causation; rather, it is for the national court to determine, because of such indicia, whether a defect exists and whether that finding corresponds to the actual circumstances of the case. However, the indicia must be sufficiently serious, specific and consistent such that a defect in the product is the most plausible explanation for the damage, in which case the causal link may reasonably be treated as proven.¹⁰ This does not preclude courts from assessing the manufacturer's liability on other evidence as well.

¹⁰ Judgement of the Court of Justice of 21 June 2017, C-621/15, *N. W. v Sanofi Pasteur MSD SNC*, ECLI:EU:C:2017:484, paras 28 and 37.

3.3.4 Possibility of Exculpation

As noted, Article 27 of the ZZdr-2 introduces strict (objective) liability of the manufacturer and/or the MAH for medicinal products. This affords stronger protection to injured persons: under a purely fault-based regime it would be nearly impossible for many claimants to obtain compensation. They would not only have to establish the usual elements - where fault is presumed only once the first three are shown - but manufacturers/MAHs could also more easily exonerate themselves simply by proving that they exercised due care. A strict-liability regime is therefore justified not only because it alleviates the claimant's evidentiary position, but also on grounds of public-health protection: the credible threat of liability deters negligent or careless behaviour by pharmaceutical companies.

Whereas fault (negligence or intent, coupled with tort capacity) is the cornerstone of subjective liability, strict liability attaches irrespective of fault. This does not mean "liability without any fault in fact", but that fault is not a constituent element of this type of liability. The crucial difference lies in the grounds of exoneration (exculpation), which the defendant must prove. These are events or conduct that exclude liability - negative conditions of liability. Unlike in fault-based liability, where the injurer seeks to show no fault (e.g., no tort capacity or due care), under strict tort (non-contractual) liability the defendant must prove that the harm was caused by an event or conduct outside the defendant's sphere of control, i.e., not reasonably foreseeable and not preventable (Plavšak et al., 2003).

Compared with the general rules, Article 27 of the ZZdr-2 further tightens the room for exculpation. Paragraph 4 provides that the manufacturer remains liable for damage caused by inadequate quality of a medicinal product even if it proves that, at the time the product was placed on the market, the global state of scientific and technical knowledge was not such as to enable the defect to be discovered. In other words, for medicinal products the law adopts a stricter stance: compensation is due even where the defect was scientifically undetectable at the time of marketing. This again reflects the overlap between inadequate quality because of a dangerous property or a defect in a medicine. It bears repeating that not all medicines can be labelled dangerous or defective; the classification is fact-sensitive in every case.

From this provision follows a duty of ongoing pharmacovigilance. It entails the active monitoring of scientific findings and technical advances and the continuous reassessment of the benefit–risk balance, followed by appropriate measures: market withdrawal where the balance becomes unfavourable (risks outweigh benefits), or updates to the instructions for use, packaging and warnings, including variations to the marketing authorisation. A manufacturer therefore cannot rely solely on the argument that, at the time of marketing, certain properties or effects could not be detected.

In this respect, ZZdr-2 establishes a stricter liability regime than ZVPot-1, which - as noted - contains in Article 64(5) the opposite rule, i.e. the development-risk defence, allowing the manufacturer to avoid liability where “the state of scientific and technical knowledge at the time when the product was put into circulation was not such as to enable the defect to be discovered (e.g., by known methods and analyses).” At this juncture, it may again be concluded that – for reasons of public-health protection and effective compensation – medicinal products should not be treated as generic ‘goods’ under ZVPot-1, but as a specific category of products requiring a special, stricter approach.

3.3.5 Exception from liability

Article 27(6) of the ZZdr-2 provides an exception under which the MAH, the manufacturer, health-care providers and health-care professionals are not liable for damage arising from the use of a medicinal product that is not in accordance with the marketing authorisation or that has no marketing authorisation, where such use is ordered by the JAZMP (Javna agencija Republike Slovenije za zdravila in medicinske pripomočke - Agency for Medicinal Products and Medical Devices of the Republic of Slovenia) or by the competent ministry in extraordinary circumstances (e.g., epidemics, chemical accidents, nuclear disasters).

This exception is grounded in the public-interest rationale: it enables rapid intervention in crises. At the same time, it raises ethical concerns about the protection of injured persons, particularly in jurisdictions without compensation mechanisms (e.g., dedicated compensation funds).

3.3.6 Limitation of Damages Claims

A particular feature of harm associated with medicinal products is that it may manifest immediately or only after many years – for example, where a link between a medicine and a disease is discovered later. Article 352 of the OZ governs the limitation of damages claims and provides a three-year subjective period and a five-year objective period. In Slovenia, the objective limitation period is significantly shorter – only five years. By contrast, in Germany, the objective limitation period for similar claims is 30 years (see Section 4.6 below). The difference between the commencement of the subjective and objective period is that the latter runs from the occurrence of damage, whereas the former begins when the claimant learns (or could have learned) of that fact. In practice, this means that damages claim becomes time-barred five years after the damage occurs, regardless of when the claimant gained knowledge of the damage or the tortfeasor (Article 352(2) of the OZ).¹¹ No longer limitation period is provided for damage affecting fundamental values such as life or health. However, where the harm constitutes a criminal offence, the injured party may rely on the longer limitation period for criminal prosecution (Article 353(1) of the OZ), provided that the offence has been established.

3.4 Manufacturer's Liability Under the OZ

In addition to the special liability regime in Article 27 of the ZZdr-2, Article 155 of the OZ lays down the general manufacturer's liability. Paragraph 1 governs liability for damage caused by a defect in the product, whereas paragraph 2 concerns liability for damage arising from dangerous properties of a thing. The provision rests on the idea that the manufacturer must assume certain risks inherent in industrial production and, where a defect is established, liability is strict. The possibility that the manufacturer knew of the defect is not excluded; nonetheless, the injured party may still pursue compensation under the strict-liability rule (Grilc in Plavšak et al., 2003, pp. 894–895).

¹¹ See also Judgement of the Higher Court in Ljubljana of 27 August 2014, *II Cp 954/2014*, ECLI:SI:VSLJ:2014:II.CP.954.2014.1.

This provision also illustrates the interplay between defect and dangerous property. Although Article 155 is situated in the chapter on the liability of the manufacturer of a defective thing, Slovenian courts have at times drawn parallels between the two notions for the purposes of Article 155 of the OZ. In the Coca-Cola bottle explosion case¹², the lower courts relied on both concepts on the same facts - product defect and dangerous property – whereas the Supreme Court clarified the distinction: paragraph 1 addresses product defects, while paragraph 2 concerns dangerous properties inherent in the nature of the product (as with poisons or explosives), in which case the manufacturer must adopt additional precautions to prevent harm. Unlike paragraph 1, which establishes strict liability for defective products, paragraph 2 sets out fault-based liability for dangerous properties (not defects) where the manufacturer has not done everything reasonably required – by warnings, safe packaging or other appropriate measures, to prevent foreseeable harm. On this basis the manufacturer cannot be expected to anticipate every careless or improper use by a consumer (e.g., a user who, without reason, ignores clear instructions), nor to provide a separate warning for each such eventuality. For instance, it suffices that the instructions for heating milk state that the milk must be stirred while heating; there is no need to add an explicit warning that failure to do so may, in very rare cases, lead to overheating, spillage and consequent burns or other damage.¹³ It should be emphasised that instructions for medicinal products differ fundamentally from the brief usage notes found on milk cartons or beverage bottles: they are an integral, legally required component of the product, intended to ensure safe and effective use by patients and healthcare professionals. Transposed to the instructions for use of medicinal products, inadequate instructions will amount to a defect within the meaning of Article 155(1) of the OZ, because a medicinal product, as marketed, consists of the active substance (in various dosage forms such as tablets or drops), the packaging (e.g., glass or plastic), and the instructions for use (package leaflet). A defect in any of these components is a product defect.

¹² Judgement of the Supreme Court of the Republic of Slovenia of 22 October 1998, *II Ips 416/97*, ECLI:SI:VSRS:1998:II.IPS.416.97.

¹³ See Judgement of the Higher Court in Ljubljana of 13 November 2013, *I Cp 1145/2013*, ECLI:SI:VSLJ:2013:I.CP.1145.2013 and Order of the Supreme Court of the Republic of Slovenia of 15 May 2014, *II DöR 1/2014*, ECLI:SI:VSRS:2014:II.DOR.1.2014.

3.5 Taking Out Liability Insurance

Slovenian law expressly requires compulsory liability insurance for activities that involve an elevated risk of damage to third parties. Accordingly, for damage arising in the performance of their professional activity, physicians, attorneys, notaries, healthcare institutions and other comparable entities must take out compulsory insurance. No such obligation is prescribed for manufacturers of medicinal products and holders of a marketing authorization for a medicinal product. However, under the second paragraph of Article 77 of the Medicinal Products Act (ZZdr-2), a physician or veterinarian who, at a healthcare or veterinary services provider, prescribes and uses a non-routinely prepared advanced therapy medicinal product must insure their liability for any damage that may be caused to the patient or animal, for a sum insured of at least EUR 100,000.

4 Liability Under the Relevant Rules of German Law

The thalidomide tragedy of the 1960s - resulting in severe birth defects - was a watershed for German legislation, prompting reforms that introduced a stricter liability system (1976) and, later, a presumption of causation (2002) (Deutsch & Lippert, 2010, pp. 2-4).

4.1 The AMG (Arzneimittelgesetz) Regime

German law addresses liability for harm caused by medicinal products through two tracks: (i) the general, fault-based regime under the German Civil Code (Bürgerliches Gesetzbuch, hereinafter: BGB),¹⁴ and (ii) a special strict-liability regime for medicinal products under Section 84 of the AMG.

For the avoidance of doubt, general tortious producer liability under Sections 823 et seq. BGB is not displaced by the AMG. Pursuant to Section 91 of the AMG, such claims may be pursued in parallel with liability under Section 84 of the AMG. However, unlike the special AMG regime, liability under Section 823 of the BGB remains fault-based and requires proof of an intentional or negligent breach of a

¹⁴ Bürgerliches Gesetzbuch (German Civil Code). Bundesgesetzblatt I, pp. 42, 2909; last amended by Art. 1 of the Act of 17 July 2025 (Bundesgesetzblatt I, No. 163/2025). Consolidated version consulted on 3 November 2025.

duty of care, as well as causation. In pharmaceutical cases this makes the BGB route considerably more demanding in evidentiary terms and, in practice, usually secondary to the strict-liability regime under the AMG.

The ProdHaftG, which transposes the same EU directive as the Slovene ZVPot-1 (Directive 85/374), does not apply to damages caused by medicinal products authorised under the AMG (Section 15 of the ProdHaftG). In contrast, the ProdHaftG covers damage arising from unauthorised medicinal products and medical devices (Seifert, Landolt & Fritze, 2024). Compared with Slovenia - where doubts about the applicability of ZVPot-1 to medicine-related harm must be dispelled by general principles (protection of the weaker party and *lex specialis derogat legi generali*) - Germany's delineation is clearer. By analogy, in Slovenia ZZdr-2 should be the primary regime for medicinal products, while ZVPot-1 governs other products, such as medical devices or food supplements.

4.2 Liability of the Pharmaceutical Undertaking

The question of who bears civil liability in Germany is answered by Section 84(1) of the AMG, which attributes liability to the pharmaceutical undertaking (pharmazeutischer Unternehmer) whose medicinal product, placed on the market, causes the death of, or serious bodily injury or harm to the health of, a consumer. The provision sets out two alternative bases of liability, imposing an obligation to compensate where:

- the medicinal product, when used as intended or in the usual manner, produces harmful effects exceeding the level regarded as acceptable according to the current state of medical science, or
- the damage is caused because the labelling, professional information (Fachinformation), or instructions for use (Gebrauchsinformation) do not conform to the current state of medical science.

This rule recognises that medicinal products are goods of a special nature, whose adverse effects can never be fully eliminated. Liability arises only where the medicine produces effects which, despite proper use, exceed the permissible threshold defined by contemporary medical knowledge. The provision is rooted in the prohibition of 'questionable' (bedenkliche) medicines under Section 5 of the AMG, which defines

such products as those for which, according to the current state of scientific knowledge, there is a well-founded suspicion that in intended use they have harmful effects exceeding what is justifiable considering medical science. The acceptable level of risk is determined through a benefit-risk assessment, requiring that the therapeutic benefits of the product substantially outweigh its risks. Some adverse effects are therefore regarded as tolerable, if they do not outweigh the benefits. The benefit-risk ratio necessarily varies with each individual product; in the case of life-threatening diseases, even serious adverse effects may remain acceptable (Deutsch & Lippert, 2010, p. 133). In the literature, it has also been argued that a claimant who experiences adverse reactions cannot claim compensation where the medicine has fulfilled its therapeutic purpose and no alternative treatment was available (Stauch, 2011).

The first point of Section 84(1) of the AMG establishes strict (no-fault) liability of the pharmaceutical undertaking for damage caused by the harmful effects of a medicinal product used as intended or correctly, where such effects exceed the level acceptable according to medical science. ‘Intended use’ includes the instructions for use, professional information, and advertising, and may reflect the manufacturer’s tacit acceptance of certain uses of the product in practice (Deutsch & Spickhoff, 2014, pp. 1174–1176).

A particular issue arises with off-label use, defined at the EU level as “situations where a medicinal product is intentionally used for a medical purpose not in accordance with the terms of the marketing authorisation” (European Medicines Agency [EMA], 2024). In European practice, off-label use is generally seen as an exceptional departure from the authorised SmPC-based system, justified by specific patient needs, and primarily falling under the physician’s professional responsibility rather than the manufacturer’s (Diaz Hernandez, Roslin, & Mansnerus, 2024, pp. 138-139).

This creates an interplay of responsibility: the physician assumes an increased duty of care and an expanded duty to inform the patient, while the manufacturer is generally liable only for authorised uses or for off-label uses that have become widely accepted medical practice. Isolated or occasional off-label use does not, as a rule, establish manufacturer liability. German jurisprudence further clarifies that, prior to any tacit acceptance of off-label use by the manufacturer, responsibility lies

predominantly with the physician, who retains therapeutic freedom. Prescribing outside the marketing authorisation does not automatically deviate from medical standards if sufficient scientific evidence or clinical experience supports the use. In such cases, the physician must justify the choice of therapy by the specific circumstances of the patient's condition and apply an increased level of caution, monitoring, and informed consent. Conversely, failure to prescribe an evidence-supported off-label treatment may itself amount to negligent treatment (Lenk & Duttge, 2014, pp. 542-543).

The state of medical science is, however, a dynamic concept, continuously developing and being refined. Therefore, manufacturer liability may also arise when a product is used in a manner not expressly indicated in the marketing authorisation, but which has since become accepted and reasonably foreseeable due to scientific and clinical progress (Arif & Benecke, 2020, p. 62).

Liability under Section 84(1) no. 1 of the AMG therefore stems from the ongoing duty of pharmaceutical companies to investigate and monitor their products to always maintain the proper benefit – risk balance. In general terms, a company is liable where the risk proves disproportionate to the product's therapeutic efficacy. German courts, however, differ as to the relevant temporal point for assessing this balance - whether it should be measured at the time the product was first placed on the market, or later, for instance at the time of injury or at the final oral hearing. In most decisions, the courts have held that knowledge acquired up to the final oral hearing should be retrospectively imputed to the time of marketing. This means that current information about the product's risks is treated as if it had been known from the outset of its commercialisation (Landgericht Kempten, 2024, paras 77–81). Pursuant to Section 84 of the AMG, the pharmaceutical undertaking is therefore liable for design defects, manufacturing defects, and defects in warning or information.

The significance of information duties is underscored by Section 84(1) no. 2 of the AMG, which imposes liability for damage resulting where labelling, professional information, or instructions for use fail to correspond to the current state of medical science. The objective is to ensure that users can recognise contraindications and risks. The pharmaceutical undertaking is responsible for providing clear and up-to-

date instructions, and for continuous post-marketing surveillance of the medicinal product (pharmacovigilance).

From the foregoing, both doctrine and case law confirm that, on an *argumentum a contrario* basis, Section 84 of the AMG implies that where a medicinal product causes adverse effects explicitly listed in the package leaflet (and, by analogy, in the Summary of Product Characteristics), the pharmaceutical undertaking will generally not be liable for the resulting harm, since these effects are foreseen and accepted as part of the possible consequences of treatment. However, case law recognises an exception: if, after the product has been placed on the market, it becomes apparent that such adverse effects occur more frequently or more severely than initially anticipated, a renewed safety assessment is required. Failure to act accordingly - such as not updating the instructions for use or risk information to reflect new data (e.g., frequency rates or newly identified adverse effects) - may give rise to liability of the pharmaceutical undertaking (Landgericht Kempten, 2024, para. 76). In practice, the benefit-risk evaluation, even for adverse effects already described in the instructions for use, will generally be assessed at the time of trial. It may thus transpire that a risk or adverse effect, though once considered acceptable and duly disclosed, is no longer acceptable considering the current state of medical science and therefore constitutes a basis for liability.

Liability thus attaches to the pharmaceutical undertaking, defined in Section 4(18) of the AMG as including both the marketing-authorisation holder or registrant and any person marketing the product under their own name. Under Section 9 of the AMG, the decisive factor is whose name appears on the product. Where several persons fall within this definition, they are jointly and severally liable pursuant to Section 93 of the AMG. Theoretically, pharmaceutical undertakings could attempt to avoid liability by marketing products not requiring marketing authorisation without using their own name, thereby falling outside the AMG's scope. Nevertheless, they remain liable under the general civil-law regime of the BGB. Section 823 BGB provides that any person who intentionally or negligently unlawfully infringes another's life, body, health, freedom, property or other right is obliged to compensate the resulting damage. Under this provision, any participant in the process of developing a medicinal product may, in principle, be held liable (Magnus, 2018).

4.3 Possibility of Exculpation

Under Section 84(3) of the AMG, the pharmaceutical undertaking is not liable if, considering the circumstances, it can be inferred that the harmful effects of the medicinal product did not originate from the sphere of development or production. Manufacturing defects may occur not only at the stage of developing the medicinal product but also subsequently, where the information or data relating to the product are incomplete or erroneous (Deutsch & Lippert, 2010, p. 788). Because injured persons are not involved in the development process and have no access to the internal stages of pharmaceutical research and production, proving such facts is particularly difficult. For this reason, the AMG grants a special right of access to information and disclosure in Section 84a, which is presented in Section 4.5.

4.4 Presumption of Causation

To facilitate proof by the injured party, Section 84(2) of the AMG establishes a presumption of causation between the medicinal product and the damage. Where, in the circumstances of the individual case, the medicine can cause the type of harm suffered, it is presumed to have caused it. The product's potential to cause harm is assessed case-by-case, considering the composition and dosage of the medicine, the manner and duration of its prescribed use, the temporal proximity between administration and injury, the nature of the harm, and the patient's health condition at the time of treatment.

The injured party must demonstrate that damage occurred and that it can be linked to the use of the medicinal product; once this is established, causation is presumed. This constitutes a rebuttable presumption (*praesumptio iuris tantum*). The pharmaceutical undertaking may rebut it by proving the existence of another plausible cause that could have produced the damage.

German case law further clarifies the scope of this presumption. The Regional Court of Kempten emphasised that liability under Section 84 of the AMG requires twofold causation: (1) the injury must originate from the use of the medicinal product, and (2) it must also stem from deficient information about the product. The causal link between the defective information and the injury can be affirmed only where it is virtually certain that the harm would have been avoided had proper information

been provided. In that case, the claimant's statement that she would not have agreed to vaccination if she had been aware of other possible side effects was deemed insufficient, since she had previously stated that she was vaccinated to protect vulnerable persons in her environment. The court further clarified that the acceptability of harmful effects is to be determined through a benefit–risk assessment, encompassing all users of the medicine rather than the individual claimant, evaluating whether the balance of efficacy and risk remains positive for the intended patient population.¹⁵

Similarly, the Regional Court of Waldshut-Tiengen upheld the presumption of causation, since the medicine was capable of causing thrombosis and a temporal connection existed between use and harm. The product contained an active ingredient known to increase the risk of thrombosis, establishing a link between the injury and the medicine's known risk profile. The temporal proximity was also relevant, as the damage occurred after several months of use. However, the presumption was rebutted, the defendant having demonstrated other probable causes (a venous anomaly and multiple long-haul flights). The court stressed that an increased risk alone is insufficient; both the general capacity of the product to cause harm and specific causation in the individual case must be established. It thus excluded liability under the AMG, leaving open the possibility of a claim under general tort law (Section 823 of the BGB) - though none succeeded, as the causal link remained unproven, which is a prerequisite for any liability.¹⁶

From these cases it follows that causation is determined in two stages. First, the court assesses whether the circumstances justify establishing a causal link between the medicine and the injury - namely, whether the harm could plausibly result from a known risk of the product. If so, this suffices to trigger the presumption. Only thereafter does the analysis turn to the individual claimant, examining personal circumstances such as pre-existing conditions. At this stage, the burden of proof shifts to the defendant, i.e., the pharmaceutical undertaking (Deutsch & Lippert, 2010, p. 788). Courts also consider the time interval between administration and manifestation of the damage, which must be proportionate and medically plausible.¹⁷

¹⁵ Judgement of the Regional Court of Kempten of 8 August 2024, *31 O 957/23*.

¹⁶ Judgement of the Regional Court of Waldshut-Tiengen of 20 December 2018, *1 O 73/12*, ECLI:DE:LGWALDS:2018:1220.1O73.12.00.

¹⁷ See Judgement of the Federal Court of Justice of 16 March 2010, *VI ZR 64/09*, and Judgement of the Federal Court of Justice of 1 July 2008, *VI ZR 287/07*.

To further ease the evidentiary burden, German courts additionally accept *prima facie* evidence (*Anscheinsbeweis*) in establishing the causal connection.

In addition to liability for medicinal products under Section 84 of the AMG, fault-based producer liability under Sections 823 et seq. BGB also comes into play; this follows expressly from Section 91 of the AMG (Deutsch & Lippert, 2010, p. 805). As a rule, German law does not provide a general reversal of the burden of proof for fault: beyond unlawfulness, damage, and causation, the injured party must also prove the tortfeasor's negligence (Westermann, Grunewald, & Maier-Reimer, 2023, p. 4130) - a requirement that makes proof significantly more onerous than under the special AMG regime. However, because of evidential difficulties in complex manufacturing processes, German case law has developed a special rule within fault-based producer liability: once the claimant proves that the product was defective and that this defect caused the harm, there is a presumption of a breach of due care by the producer (Westermann et al., 2023, p. 4155). The burden of proof as to diligent conduct then shifts to the producer (Deutsch & Lippert, 2010, p. 805).

While the ProdHaftG (strict liability) excludes concurrence with Section 84 of the AMG (Section 15 of the ProdHaftG), fault-based producer liability under the BGB may run in parallel. Article 13 of Directive 85/374 (now repealed) stated that the Directive "shall not affect any rights which an injured person may have according to the rules of the law of contractual or non-contractual liability or a special liability system existing at the moment when this Directive is notified." In practice, fault-based producer liability has been extensively developed in the pharmaceutical field (Deutsch & Lippert, 2010, p. 805). As noted above, where medicinal products fall outside the AMG, the pharmaceutical undertaking may still incur strict liability under the ProdHaftG.

4.5 Right of Access to Information

The presumption of causation is triggered where the medicine can cause the harm in question based on known risks reflected in the instructions for use. Where the harmful effect is unknown and therefore not listed, the presumption does not arise, making proof more difficult for the claimant. In such cases, Section 84a of the AMG provides a right of access to information, enabling the injured party to request from the manufacturer data on the product's effects and interactions as well as reports of

alleged cases or suspicions of adverse reactions. This right is qualified: disclosure may be refused where it would breach confidentiality or jeopardise overriding company interests (e.g., trade secrets, prospective patents). The same applies to regulatory authorities, which may decline to transmit confidential information. By reference to Sections 259-261 of the BGB, the framework also permits the manufacturer to provide a declaration in lieu of oath as to the truthfulness and completeness of the information rendered.

To invoke the right, the claimant must show a plausible causal connection and that the requested information is material to the specific case. The Federal Court of Justice underscored that a claimant is not required *ex ante* to prove correct use of the product where doing so would require specialist knowledge; the purpose of Section 84a is precisely to open access to the evidence needed to substantiate damages claim.¹⁸ It is therefore an important procedural instrument that mitigates proof difficulties in cases involving previously unknown adverse effects.

The overarching aim is to rebalance procedural asymmetries between claimant and manufacturer, the latter possessing the development, composition and safety data for the product. The right strengthens the claimant's evidentiary position and complements the limits of proof in cases of unknown adverse effects. The claimant must be placed in a position to obtain the facts necessary to articulate a *prima facie* case capable of triggering the presumption of causation under Section 84(2) of the AMG. Any substantive counterarguments by the defendant (e.g., competing expert opinions) are not pertinent at the information-disclosure stage; they are to be addressed only in the subsequent damages' proceedings.¹⁹

As to limitation, the exercise of this right is constrained by the general subjective three-year period under Section 195 of the BGB, which begins when the claimant learns of the circumstances that justify the presumption that the harm was caused by use of the medicine. In addition, an absolute ten-year period applies under Section 199 of the BGB. Thus, a request under Section 84a AMG is time-barred after ten years, irrespective of knowledge (Deutsch & Lippert, 2010, pp. 794-797). These

¹⁸ Judgement of the Federal Court of Justice of 12 May 2015, *VI ZR 328/11*.

¹⁹ *Ibidem*.

general limitation rules apply subsidiarily, because the AMG contains no specific limitation provisions for the information claim.

4.6 Limitation of Damages Claims

As noted in the previous chapter, limitation of damages claims under the AMG is governed subsidiarily by the provisions of the BGB. According to Section 195 of the BGB, the regular limitation period is three years, commencing at the end of the calendar year in which the claimant became aware (or ought to have become aware) of the damage, of the relevant circumstances, and of the liable person. This so-called “Ultimo-Verjährung” rule benefits claimants by effectively extending the limitation period until the end of the year in which knowledge of the damage is acquired²⁰ (Westermann et al., 2023, p. 676). In Slovenian law, such a deferred commencement applies only to household claims with a one-year limitation period, pursuant to Article 355(2) of the OZ.

Section 199 of the BGB additionally provides an absolute limitation period (Verjährungshöchstfrist) for damages claims. Irrespective of Section 195 BGB, any claim for injury to life, body, health or liberty becomes time-barred thirty years after the tortious act or other harmful event.²¹ This means that the subjective three-year period cannot run indefinitely: even if the claimant has not yet become aware of the damage in full, the claim extinguishes upon expiry of the 30-year maximum period.

4.7 Obligation to Obtain Liability Insurance

Section 94 of the AMG stipulates that every pharmaceutical undertaking must provide financial coverage for compensation of damage resulting from the use of medicinal products for human use, either by means of liability insurance with an authorised insurance company or through a compensation or guarantee commitment issued by a credit institution.

The minimum insurance coverage must correspond to the amounts specified in Section 88 of the AMG. That provision establishes maximum compensation limits:

²⁰ See Judgement of the Federal Court of Justice of 12 May 2009, *VI ZR 294/08*.

²¹ See Judgement of the Federal Court of Justice of 25 July 2017, *VI ZR 433/16*, ECLI:DE:BGH:2017:250717UVIZR433.16.0.

in cases of death or personal injury to an individual, the ceiling is EUR 600,000 as a lump-sum payment or an annual annuity of up to EUR 36,000. Where compensation is owed to multiple individuals harmed by the same medicinal product, the overall ceiling is EUR 120 million as a lump-sum payment or an annual annuity of up to EUR 7.2 million. If the total compensation payable exceeds this amount and must be distributed among several injured parties, the individual sums are reduced proportionally (Section 92 of the AMG).

Any agreements limiting or excluding payment are void. A person who intentionally places on the market a medicinal product intended for human use without valid liability insurance or a guarantee or indemnification obligation in accordance with Section 94 of the AMG, or after such coverage has ceased to exist, commits a criminal offence (Section 96, no. 19 of the AMG). If the act is committed negligently, it constitutes an administrative offence (Section 97(1) and (3) of the AMG).

5 Discussion: Comparative Assessment and Implications for Slovenian Law

The comparison shows that the difference between Slovenian and German law does not lie in the abstract acceptance of strict liability. Both systems recognise that medicinal products create risks that cannot be fully controlled by ordinary fault-based liability and that patient protection requires special attention to information asymmetry, scientific uncertainty and post-marketing surveillance. The decisive divergence lies in how each legal system translates these concerns into operational legal rules.

Slovenian law has an important claimant-protective foundation. Article 27 of the ZZdr-2 establishes strict liability in the pharmaceutical context and is stricter than the general product liability regime insofar as it does not allow the development-risk defence in the same way as ZVPot-1. The central role of the marketing-authorisation holder may also be seen as beneficial for injured persons, since it identifies a responsible actor connected to the placing of the medicine on the market. These are significant advantages and show that Slovenian law is not normatively indifferent to pharmaceutical injury. Its weakness lies elsewhere: the regime is not sufficiently self-contained. Key elements, especially causation, evidentiary support and limitation, must be reconstructed through the OZ and general principles. This creates

uncertainty in precisely those cases in which claimants face the greatest practical difficulties, namely where harm appears after a delay, where medical causation is complex, or where relevant pharmacovigilance data are controlled by the manufacturer or MAH.

German law offers a more structured model. The AMG clearly functions as the *lex specialis* for medicinal-product injury, while the general Product Liability Act is excluded for claims falling within the AMG. This prevents the kind of regime collision that remains problematic in Slovenian law. More importantly, the AMG combines substantive strict liability with procedural and evidentiary tools: the presumption of causation under Section 84(2), the information claim under Section 84a, and mandatory financial coverage under Section 94. These mechanisms do not guarantee success for every claimant, nor do they remove the need to prove a legally relevant causal connection. They do, however, reduce the structural disadvantage of injured persons by recognising that the manufacturer is usually in a better position to know, collect and disclose safety-related data.

At the same time, the German model should not be idealised. Its presumption of causation operates within defined limits and may be rebutted where alternative causes are established. The information claim is also qualified by confidentiality and trade-secret considerations. In addition, fault-based producer liability under Sections 823 *et seq.* of the BGB remains available in parallel but is considerably harder to enforce, since the injured party must prove fault and causation. The German regime is therefore more claimant-oriented in its design, but not claimant-friendly in an unlimited sense. Its value as a comparator lies in its institutional coherence rather than in an assumption that claimants always prevail.

Directive 2024/2853 points in a similar direction by introducing disclosure of evidence and rebuttable presumptions of defectiveness and causation. These mechanisms are particularly relevant for complex products and scientifically demanding claims. Nevertheless, the Directive cannot by itself resolve all difficulties in pharmaceutical liability. First, it preserves space for special national liability regimes in the pharmaceutical sector. Secondly, its product-defect logic does not always map neatly onto unexpected adverse drug reactions, where the medicine may be authorised, correctly manufactured and accompanied by appropriate information, yet still produce serious harm in individual cases. The Directive is therefore best

understood as a source of procedural inspiration rather than as a complete solution for pharmaceutical injury.

For Slovenia, the comparative analysis suggests that reform should not merely transpose the Directive mechanically. A more coherent approach would be to clarify expressly the priority of ZZdr-2 for harm caused by medicinal products, introduce a sector-specific presumption of causation modelled cautiously on Section 84(2) of the AMG, and create a statutory right of access to pharmacovigilance and safety data, subject to proportionate safeguards for confidential information. The objective limitation period should also be reconsidered for latent bodily and health injuries, and compulsory liability insurance or equivalent financial coverage for MAHs/manufacturers should be introduced. Such reforms would not copy the German system wholesale, but would adapt its most relevant claimant-protective elements to the Slovenian legal context.

6 Conclusions

This article examined civil liability for harm caused by unexpected adverse drug reactions in Slovenian and German law. It has shown that Slovenian law contains a claimant-protective basis in Article 27 of the ZZdr-2, but that the regime remains insufficiently precise in its practical operation. The relationship between ZZdr-2, ZVPot-1 and the OZ is not fully clear, causation is not regulated through a sector-specific presumption, claimants have no express statutory right of access to safety data, and there is no mandatory liability insurance for MAHs or manufacturers. These gaps are especially important in pharmaceutical cases, where harm may appear only after a delay and where relevant information is usually held by the pharmaceutical undertaking.

German law provides a useful comparator because it regulates pharmaceutical liability through a clearer special regime under the AMG. The AMG excludes the general product liability regime for medicinal products falling within its scope, while preserving other claims, including fault-based producer liability under the BGB. Its main claimant-protective features are the presumption of causation, the right of access to information and mandatory financial coverage. These mechanisms do not

remove all evidentiary problems, but they create a more coherent framework for addressing them.

Directive 2024/2853 strengthens the broader EU product liability framework through disclosure rules and rebuttable presumptions. For Slovenia, its implementation should be treated not only as a formal transposition exercise, but as an opportunity to improve pharmaceutical liability more systematically. The most important reforms would be: express clarification of ZZdr-2 as the primary regime for medicine-related harm, a statutory presumption of causation adapted to unexpected adverse drug reactions, access to relevant pharmacovigilance and safety data, longer or more appropriate limitation rules for latent health damage, and compulsory financial cover.

The central conclusion is therefore not that Slovenia lacks liability rules, but that its rules are fragmented and procedurally underdeveloped. Given that life and health are at stake, a claimant-friendly and predictable framework is a constitutional desideratum. A more coherent pharmaceutical liability regime would enhance legal certainty, improve the claimant's real access to compensation and align Slovenian law more closely with the protective direction of both German law and the new EU product liability framework.

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Povzetek v slovenskem jeziku

Zdravila so ključnega pomena za zdravstveno varstvo, vendar njihova uporaba prinaša neizogibna tveganja, zlasti nepričakovane neželene učinke zdravil. Članek preučuje, kako slovenska in nemška zakonodaja urejata civilno odgovornost za takšno škodo in kakšne posledice lahko ima to za oškodovance. Članek zagovarja, da je slovenski pravni okvir normativno ustrezen, a razdrobljen, pri čemer je dokazna podpora za tožnike premalo razvita, medtem ko je nemški okvir bolj koherenten in usmerjen v tožnike. Oba sistema temeljita na objektivni odgovornosti in stalnem farmakovigilantnem nadzoru, vendar se razlikujeta v dokazni ureditvi in institucionalni zasnovi. S pomočjo doktrinarno-primerjalne metode članek analizira slovenske in nemške zakone v luči Direktive o odgovornosti za izdelke (EU) 2024/2853. Ugotavlja, da slovenski zakonodaji primanjkuje ključnih zaščitnih ukrepov, vključno z izrecno, sektorju specifično domnevo o vzročni zvezi in zakonsko pravico do dostopa do varnostnih podatkov, ter ne nalaga obveznosti zavarovanja. Nemška zakonodaja ponuja jasnejša pravila, postopkovno podporo in obvezno finančno kritje. Novosti direktive kažejo v smeri modela, ki je prijaznejši do tožnikov, kar Sloveniji ponuja priložnost za reformo.

THE IMPACT OF BULLYING ON STUDENTS' EMOTIONS, PEER RELATIONSHIPS, AND SCHOOL ABSENCE

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Abstract Peer violence, commonly conceptualized as bullying, constitutes a pervasive challenge affecting students both globally and within North Macedonia. Beyond its immediate psychological and emotional impact on victims, bullying shapes the overall school climate, influencing students' safety, inclusion, and well-being. Victimization is associated with elevated fear, social withdrawal, and disrupted peer relationships, which can reinforce cycles of aggression. Empirical analyses indicate that supportive peer interactions reduce the likelihood of being targeted. The study further highlights that awareness of bullying and students' emotional experiences are crucial for understanding the dynamics of peer victimization. These findings underscore the multifactorial and systemic nature of bullying and emphasize the importance of promoting resilience and fostering positive peer relations to ensure a safe, inclusive, and supportive educational environment.

Keywords

peer victimization,
peer connectedness,
school satisfaction,
well-being,
school climate

1 Introduction

Peer violence, commonly referred to as bullying, is a complex social phenomenon posing a serious challenge to contemporary educational systems, considering that an estimated 130 million students aged 13 to 15, over one-third of this age group, experience some form of bullying worldwide (UNICEF, 2017). It is a repeated and deliberate pattern of aggressive or hurtful behavior targeting individuals perceived as less powerful. Bullying manifests in various forms, such as physical, verbal, social/relational, and cyberbullying, each with unique characteristics (Daley et al., 2023). Of particular concern is the fact that bullying knows no borders – it occurs in urban and rural areas, in small and large schools, regardless of ethnic, social or cultural affiliation. The problem is global, but its consequences are local and personal, significantly impacting students' psychological well-being, academic performance, and social development (Jumra et al., 2025).

Previously, it was believed that bullying was an integral part of growing up and that such experience could help children become stronger (Puharić et al., 2014). However, modern research and expert observations clearly indicate that peer violence is not a harmless phenomenon, nor does it necessarily contribute to positive personal development (UNICEF, 2017). On the contrary, in recent decades, the scientific and professional community has been alarmed by the increasing intensity and complexity of peer violence, particularly in the context of new technologies and social networks, which have become a 'vector for youth violence' and have dramatically transformed the landscape of aggressive behavior (Peterson et al., 2017).

Peer relationships, involvement in violence and satisfaction with school affect the quality of life and well-being of children daily. School satisfaction, which refers to students' subjective perception of their well-being and overall experience at school, including feelings of happiness, contentment, and acceptance, is one of the key outcomes potentially impacted by peer victimization. Available knowledge and findings of previous research show that children exposed to violence at school suffer various negative consequences in multiple dimensions of their school life, such as a diminution in overall school satisfaction. Additionally, students that are subjected to violence at school and on the Internet report worse school performance and lower

attachment to school. Victimization also has a significant negative effect on students' happiness (Pakšić et al., 2025).

The breakdown of peer relationships, particularly through bullying behaviors, is also recognized in the scientific literature on children and adolescents as a threat to student well-being, producing both immediate and long-term effects (Boyle et al., 2025). Positive and continuous connections can serve as a protective factor against the negative effects of peer victimization, whereas disrupted or weak relationships often result from exposure to bullying and can further exacerbate feelings of loneliness and reduced school satisfaction.

The goal of this research is to examine the relationship between peer victimization and its effects on students' school satisfaction and peer relations, in order to understand how exposure to bullying influences students' emotional well-being and the quality of their social interactions within the school environment. It is hypothesized that students who are victims of bullying do not experience positive emotional feelings at school, have less stable and less frequent interactions with their peers, and are more likely to be absent from school compared to students who are not exposed to peer violence.

2 Literature Review and Theoretical Background

Bullying and gangs in schools are nothing new. Most people remember being targeted by their peers in childhood. Such experiences, although painful and embarrassing, are integral to social development. But for some children, being bullied by their peers is no accident. Rather, it is a constant source of frustration and fear, a never-ending battle that colors their entire experience of growing up (Landfield, 2006).

Peer violence should not be equated with ordinary conflicts between peers but should be treated as a serious social and psychological problem that requires a systemic approach to recognition, control and intervention. A conflict between two equally powerful opponents is usually not considered bullying (Buljan Flander, 2004). According to Olweus, bullying behavior can be defined as: "Intentional, repeated negative (unpleasant or hurtful) behavior by one or more persons directed against a person who has difficulty defending himself or herself" (Olweus, 2010).

Despite agreement on the basic elements that define it, there are still numerous definitions to explain this phenomenon. However, the definition of bullying proposed by UNESCO in 2023 is considered inclusive and comprehensive, emphasizing the complexity of this phenomenon and the need for a holistic approach. According to this definition: “School bullying is a damaging social process that is characterized by an imbalance of power driven by social (societal) and institutional norms. It is often repeated and manifests as unwanted interpersonal behavior among students or school personnel that causes physical, social, and emotional harm to the targeted individuals or groups, and the wider school community” (UNESCO, 2024).

In the scholarly literature, bullying behavior is most commonly classified as verbal and non-verbal, and may manifest through physical injury, damage to property, or psychological harm, such as intimidation, humiliation, and social isolation, as well as sexual harassment, which may include unwanted sexual comments, gestures, or physical contact (Markovic, 2020; Iljevski et al., 2023). Recently, researchers have adopted the means of expression as a key criterion for classifying peer violence, distinguishing between classical and electronic forms (Popadić, 2009). Nevertheless, regardless of where violence occurs, according to Košir (2013), two forms of peer violence can be roughly distinguished. The first is direct peer violence, which involves physical and verbal violence (strikes, kicks, taking property, insults, threats, and similar). The second form is called indirect peer violence, characterized by manipulating friendships to harm others through behaviors such as social exclusion and spreading of rumors or lies about an individual (Zobec et al., 2023).

Both boys and girls are vulnerable to being bullied, although some studies suggest that boys experience more physical bullying (being hit, having belongings taken), and girls experience more relational or social bullying (such as spreading of sexual rumors or other forms of sexual harassment or being systematically excluded from friendship groups). In addition, verbal bullying (nasty forms of taunting or teasing, threats) is experienced commonly by both genders in school (Schafer et al., 2004; Stanojoska et al., 2024).

Many researchers have shown that bullying is not an isolated problem, exclusive of certain countries or cultures. On the contrary, it is widely extended in societies worldwide. According to recent data, approximately one in three students aged 11

to 15 in the European Union has experienced some form of bullying or violence in school over the past year. The prevalence of this phenomenon varies across countries, ranging from 15% in countries such as Finland and Sweden to approximately 35% in Bulgaria and Romania (Neubauer et al., 2025). Prevalence of bullying ranges between 10–33% of U.S. students with 5–13% admitting to bullying others, and 50–70% of adolescent students having witnessed bullying in some context (Soto et al, 2025). Similarly alarming patterns are evident in Australia, where the impact of bullying and other harmful behaviors on children and young people has reached devastating proportions, with approximately one in four Year 4 to Year 9 Australian students (27%) having reported being bullied every few weeks or more often (Department of Education, 2025). Relevant data on representative samples show that peer violence is widespread among students in North Macedonia. The Health Behavior of School-Aged Children (HBSC) survey is one of the largest international surveys involving children. Under the HBSC, data is collected every four years, on nationally representative samples of 11, 13 and 15-year-old students. A newly released national report has revealed alarming levels of peer violence among school-aged children in North Macedonia, with one in ten students reporting regular bullying at school at least two to three times a month and one in six experiencing cyberbullying (Cvetanoska et al., 2025).

Bullying can be associated not only with physical consequences but also with significant long-term psychological and social impairments. Peer violence is associated with emotional distress, loneliness, anxiety, depression, sleep disturbance, psychosomatic complaints, and self-harm/suicidal thoughts, and in some adolescents, substance use (Hong et al., 2019). Attention deficit disorders, decreased academic motivation, and school avoidance behavior are also common (Espelage & Holt, 2013).

Being victimized by peers, appears to encourage anxious-withdrawal behaviors, which in turn may impact on the opportunities youths have to interact within the peer group and develop significant relationships. The most frequently cited motivation for victimization is that the victims “did not fit in”. Thus, it is understandable that many victimized children and adolescents report experiencing elevated levels of loneliness. Furthermore, it has been argued that a perceived lack of control over peers’ aggressive behavior may lead to increased feelings of loneliness and unhappiness. Victims of peer maltreatment report feeling lonelier, less

happy, and having fewer close friends at school than their peers (Almeida et al., 2021). Concurrently, others may avoid victims for fear of being bullied themselves or losing social status among their peers. Although victims respond in various ways to bullying, avoidance behaviors (such as not going to school and refusing to go to certain places) are also common (Veenstra et al., 2005).

All of these statements are supported and confirmed by relevant research studies, including a study conducted in Thailand in 2017 on a sample of 7,825 students, which found that victimized students were 28% less likely to be happy, indicating that bullying victimization has a significant negative effect on students' happiness (Aunampai et al., 2022).

A study conducted on a sample of 5,823 students in Denmark demonstrated a strong and graded association between loneliness and exposure to bullying. Even students with low exposure to bullying (once or twice in the past couple of months) showed significantly elevated odds of loneliness compared to non-exposed students. Students exposed to bullying at school several times a week were 11.5 times more likely to experience loneliness than those who were not exposed (Madsen et al., 2024). In Spain, a sample of 1,239 participants revealed that chronic victims of bullying consistently exhibited the lowest levels of social preference, perceived popularity, and friendship over time. The persistently low levels of social status and friendship highlight the rejection and isolation that chronic victims experience from their classmates (Romera et al., 2020).

Many studies also document that peer victimization can negatively impact engagement and success in school, while also increasing school absenteeism and other avoidance behaviors. Such results were also obtained from a study conducted with 1,815 students from 12 elementary schools in one school district that included both urban and suburban areas of a mid-Atlantic state in the USA. The study showed that unexcused absences from school were positively related to peer victimization, $r(1749) = 0.21$, $p < 0.001$ (Meehan, 2023).

The findings are also confirmed by the analysis of surveys collected from nationally representative samples of a total of 113,200 students from 25 countries, which again showed that victims of bullying reported poorer emotional adjustment and weaker relationships with classmates. Victimized students were often marginalized from the

main peer group, which limits their access to prosocial peers who could serve as positive role models for appropriate social skills and provide protection against bullying. Therefore, regardless of the underlying mechanism, involvement in bullying is consistently found to be negatively associated with multiple aspects of school functioning (Nansel et al., 2004).

Drawing on the reviewed literature, which highlights the consistent negative effects of bullying on children's emotional well-being and peer relationships, the present study aims to provide a clearer understanding of the psychosocial consequences of bullying within the local school context in Bitola.

3 Methodological Framework

We conducted our research process from December 2024 to March 2025. To fulfill the set objectives of the research, we used a survey questionnaire which participants accessed by scanning a QR code, while we carried out data collection and processing using the digital platform SurveyMonkey, which enabled the research to be administered efficiently and precisely.

The research sample included a total of 608 participants. The sample demonstrated an approximately balanced gender distribution, comprising 52.07% male students and 47.93% female students.

Furthermore, the sample included an equal number of participants from all schools in the city of Bitola, with thirty-two students from each school.

The distribution of respondents by grades and classes indicates a dominance of students from primary education. The largest proportion of respondents comes from the 8th grade (31.51%) and 9th grade (32.01%), which together comprise 63.52% of the total sample.¹ The remaining 36.48% are secondary school students. These students come from a total of seven secondary schools, with 64 students from the two general high schools, while the rest are from a total of five vocational

¹ This distribution corresponds to the fact that in the city of Bitola there are almost twice as many primary schools as secondary schools. This uneven institutional distribution logically leads to a higher number of primary school students being included in the research.

schools. A roughly equal representation of respondents is ensured from each school and from each grade, from the first to the fourth year.

This distribution corresponds to the age structure of the participants, with a predominance of students aged 12 to 14 years. This distribution reflects the institutional structure of education in the city of Bitola, where the number of primary schools is almost double that of secondary schools. This unequal institutional distribution logically resulted in a higher inclusion of primary school students in the research sample.

We selected students randomly, without intervention or recommendations. For example, we selected a certain class or grade according to the specific day of the survey, and we selected students according to the ordinal number in the diary (for example, odd numbers). If it was necessary to select a student of a certain gender and the next number in the diary did not match, the selection of the first next student of the desired gender was continued.

Namely, the random selection of students minimizes the risk of bias, providing an equal chance for inclusion of each student, regardless of individual characteristics. On the other hand, the even distribution according to educational levels, gender and age groups enabled us to cover different segments of the student population, which helped to ensure the validity and integrity of our results.

The survey questionnaire consists of 47 (forty-seven) semi-open and open-ended questions, divided into six sections: the demographic characteristics of the respondents, recognition of bullying, respondents' personal experiences (their potential victimization), the emergence of negative emotions resulting from experienced bullying, as well as their reactions and existing prevention methods. Data processing combined descriptive statistical analysis of the data from the survey questionnaires answered through the use of a software solution for statistical data processing (SPSS). The study applied the χ^2 (Chi-square) test, correlation analysis, and regression analysis (multiple and simple), with statistical significance determined at the level of $p < 0.05$.

4 Results and Discussion

The fact that peer violence is a serious problem in the Municipality of Bitola is evidenced by the findings, which reveal a concerning 33.78% of students report that violence occurs within their schools. Out of 596 students who answered the question, 156 students or 26.2% identified themselves as victims of bullying, while 45 of them were unsure if they had ever been victimized. The results show that the majority of students (41%) were rarely victims of violence, while 27.6% stated it happened to them several times a week. It is concerning that 17.3% were victims on a daily basis and 14.1% once a week, indicating serious and repetitive victimization among a significant portion of the respondents.

Table 1: Personal victimization (victims of violence) by gender

		Have you ever been a victim of violence at school (bullying)?			Total
		Yes	No	I don't know	
Sex	Male	71	221	18	310
	Female	85	174	27	286
Total		156	395	45	596

Table 2: Chi-square test: Personal victimization by gender

Chi-Square Tests			
	Value	Df	Asymptotic Significance (2-sided)
Pearson Chi-Square	8.617 ^a	3	.035
Likelihood Ratio	9.015	3	.029
Linear-by-Linear Association	.326	1	.568
N of Valid Cases	596		

a. 2 cells (25.0%) have expected count less than 5. The minimum expected count is .48.

Analysis of the data also shows gender-based differences in victimization. Females were victimized at a higher rate (85 out of 286) than males (71 out of 310), a result that is statistically significant (Pearson Chi-Square: $\chi^2 = 8.617$, $df = 3$, $p = 0.035$)

Of the victims of peer violence, nearly half reported experiencing emotional stress, anxiety, reduced self-confidence, and self-esteem. A smaller portion indicated that the violence negatively affected their academic performance (14.10%) and physical health (12.82%), while 25.64% reported feeling social isolation. Particularly alarming is the fact that nearly 20% of the victims experienced thoughts of self-harm and

suicidal ideation, highlighting the profound psychological consequences that can result from bullying.

Table 3: Personal victimization by emotional state at school

		<i>Have you ever been a victim of violence at school (bullying)?</i>			Total
		Yes	No	I don't know	
<i>How do you feel at school?</i>	Other	18	20	5	43
	Happy	112	353	34	499
	Sad	9	10	1	20
	Lonely	12	4	3	19
	Scared	5	8	2	15
Total		156	395	45	596

Table 4: Chi-square test: Personal victimization by emotional state at school

Chi-Square Tests			
	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	34.552 ^a	8	.000
Likelihood Ratio	32.588	8	.000
Linear-by-Linear Association	1.443	1	.230
N of Valid Cases	596		
a. 6 cells (40.0%) have expected count less than 5. The minimum expected count is 1.13.			

The cross-tabulation and Chi-square (χ^2) test from the tables above indicate that students who have been victims of peer violence at school feel happy less frequently, and more often feel lonely, sad, fearful, or 'other' (likely negative emotions), compared to their peers who have not had such experiences. Approximately 90% of children who were not victims reported feeling happy at school, while this percentage was about 20% lower among victims.

The Pearson Chi-square test is statistically significant ($\chi^2 = 34.552$, $df = 8$, $p < .001$), indicating that the differences in the distribution of emotional states between victims and non-victims are not due to chance. Specifically, there is a significant association between victimization and emotional well-being at school.

We can draw similar conclusions from the responses to the question of whether students have ever been absent from school due to fear or shame caused by their peers. While 93.6% of students who had not been victimized reported that they never missed school due to fear or shame, 27% of victimized students indicated that they sometimes or often avoided school for these reasons.

The findings are further supported by the results of the linear regression presented in Table 5, which, although explaining only 1.6% of the variance, still indicate that victimization from bullying is a significant predictor of school absence.

Table 5: ANOVA results for the regression model: Victimization as a predictor of school absence

ANOVA ^a						
	Model	Sum of Squares	Df	Mean Square	F	Sig.
1	Regression	3.328	1	3.328	9.786	.002 ^b
	Residual	202.331	595	.340		
	Total	205.658	596			
a. Dependent Variable: <i>Absence from school due to fear or shame</i>						
b. Predictors: (Constant), <i>Have you ever been a victim of violence at school (bullying)?</i>						

The study also considered students' victimization in relation to peer relations.²

Table 6: Correlation of victimization and relations with peers

Correlations			
		<i>Have you ever been a victim of violence at school (bullying)?</i>	Peer relationship
Pearson Correlation	<i>Have you ever been a victim of violence at school (bullying)?</i>	1.000	-.178
	Peer relationship	-.178	1.000
Sig. (1-tailed)	<i>Have you ever been a victim of violence at school (bullying)?</i>	.	.000
	Peer relationship	.000	.
N	<i>Have you ever been a victim of violence at school (bullying)?</i>	595	595
	Peer relationship	595	595

Table 7: ANOVA results for the regression model: peer relationships as a predictor of victimization

ANOVA ^a						
	Model	Sum of Squares	Df	Mean Square	F	Sig.
1	Regression	5.686	1	5.686	19.311	.000 ^b
	Residual	174.606	593	.294		
	Total	180.292	594			
a. Dependent Variable: <i>Have you ever been a victim of violence at school (bullying)?</i>						
b. Predictors: (Constant), Peer relationship						

² Students rated their relationships with classmates on a scale from 1 to 5.

Table 8: Regression coefficients of the model: peer relationships as a predictor of victimization

Coefficients ^a						
Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	2.007	.049		40.740	.000
	Peer relationship	-.113	.026	-.178	-4.394	.000
a. Dependent Variable: <i>Have you ever been a victim of violence at school (bullying)?</i>						

Correlation analysis shows a negative relationship between victimization and the relationship with peers ($r = -0.178$, $p < 0.001$), indicating that students with better relationships with their peers are less likely to be victims of peer violence. Regression results further confirm that the relationship with peers is a significant predictor of victimization. The model is statistically significant ($F = 19.311$, $p < 0.001$), meaning that the relationship with classmates as a predictor is important and is not a chance finding. The regression coefficient for the relationship with classmates is -0.113 ($Beta = -0.178$, $p < 0.001$), indicating that better relationships with classmates reduce the risk of being a victim of violence.

The following tables reflect our findings on the relationship between victimization and the frequency of social interactions among students (i.e., how often they socialize).

Table 9: Personal victimization according to students' friendship with peers

		Have you ever been a victim of violence at school (bullying)?			Total
		Yes	No	I don't know	
<i>Relationships with peers</i>	Often	112	341	33	486
	Sometimes	30	40	6	76
	Rarely	12	10	3	25
	I don't spend time with peers	2	3	1	6
Total		156	394	43	593

Table 10: χ^2 test: Relationship between victimization and friendship with peers

Chi-Square Tests			
	Value	Df	Asymptotic Significance (2-sided)
Pearson Chi-Square	613.358 ^a	12	.000
Likelihood Ratio	32.904	12	.001
Linear-by-Linear Association	3.915	1	.048
N of Valid Cases	593		
a. 12 cells (60.0%) have expected count less than 5. The minimum expected count is .00.			

Table 11: Relationship between victimization and friendship with peers

Symmetric Measures					
		Value	Asymptotic Standard Error ^a	Approximate T ^b	Approximate Significance
Interval by Interval	Pearson's R	-.081	.050	-1.983	.048 ^c
Ordinal by Ordinal	Spearman Correlation	-.109	.048	-2.669	.008 ^c
N of Valid Cases		594			
a. Not assuming the null hypothesis.					
b. Using the asymptotic standard error assuming the null hypothesis.					
c. Based on normal approximation.					

The most common form of social connection, 'I often socialize with children from my class,' is significantly more pronounced among students who were not victims of violence than among victims, with a difference of approximately 14.7%. Among victims, instead of regular socialization, responses in the categories 'sometimes' (19.2% vs. 10.2% among non-victims) and 'rarely' (7.7% vs. 2.5%) are more frequent. These differences clearly indicate that students exposed to violence have less stable and frequent peer contacts.

Statistical tests confirm this connection: Pearson χ^2 with $p < .001$ indicates a significant association between victimization and the intensity of socialization. Additionally, symmetric measures show a small but statistically significant negative correlation (Pearson $R = -0.08$, $p = .048$; Spearman $\rho = -0.11$, $p = .008$), meaning that more intensive friendship relations are associated with a reduced risk of victimization.

This confirms the finding that peer violence leads to a significant disruption of social ties, victims socialize less frequently and are lonelier within the group, which is an important risk factor for children's psychosocial health.

The aim of this study was to examine the emotional well-being of students in primary and secondary schools in the Municipality city of Bitola who identify themselves as victims of peer violence, as well as to determine whether such victimization leads to changes in peer relationships and their dynamics. Additionally, the research aims to determine whether peer violence is a factor contributing to increased student absenteeism from school.

Students who have been victims of peer violence at school reported feeling happy less frequently and more often experience feelings of loneliness, sadness, fear, or other predominantly negative emotions compared to their peers who have not had such experiences. Previous research has consistently shown that adolescents who experience bullying victimization are at a significantly higher risk of developing various mental health problems, including loneliness, anxiety, depression and lower levels of happiness (Ye et al., 2023; Liu et al., 2020; Bernasco et al., 2022; Gomez-Baya et al., 2022).

Feelings of loneliness and unhappiness are also directly linked to disrupted social contacts. In line with our findings, students who experience victimization tend to have less stable and less frequent peer relationships, which increases their vulnerability. Results from other studies also reveal that victimization contributes to increases in peer rejection and low peer acceptance in preadolescence and adolescence (Hodges et al., 1999; Maneiro et al., 2023; Kochel et al., 2012).

The results also showed that victimized students often or sometimes avoid attending school due to fear or embarrassment from their peers. Our findings are consistent with prior studies that showed risk associations between having been bullied and missing school (Beran & Li, 2007; Dake et al., 2003; Steiner et al., 2022).

General strain theory (Agnew, 1992) suggests that bullying victimization introduces negatively valued/noxious stimuli into the victim's life, which in turn creates intense levels of stress or strain. The youth who experience these stressors then require a means of coping. Although children may rely on adaptive methods, such as seeking

help from a trusted adult, coping strategies may also manifest as maladaptive behaviors. Specifically, victimized children may attempt to escape from future victimization by avoiding peers, school or the classroom (Torres et al., 2020). However, this can lead to further social isolation and deterioration of emotional well-being, through the emergence of depression and anxiety, poor academic performance and school dropout. Accordingly, it is imperative to find methods to deal with these effects in order to reduce the frequency of this problem (Sobba, 2019).

The school is the agent responsible for socializing groups of children and young people on specific skills and values in society (Saldana, 2013). Unfortunately, the bullying problem turns school into a source of stress and pain for student victims, instead of a space of safety and belonging. Research shows that the negative effects of victimization often extend far beyond childhood. Victimized children tend to achieve long-term psychological difficulties, lower educational qualifications, experience greater difficulties in financial management, and earn less than their peers in later adulthood (Wolke et al., 2015). In addition to these economic consequences, victims frequently report long-term social difficulties, including problems with making or maintaining friendships. They are also less likely to live with a partner and often lack strong social support networks (Armitage et al., 2023).

Limitations

Whereas the sample in the present study is locally representative, covering all primary and secondary schools in the Municipality of Bitola, it is not representative of the national population. All data were based on self-report, which may introduce bias, as participants could underreport or overreport their experiences. However, because our study ensured confidentiality and anonymity, self-report measures are generally considered reliable and valid (Sigurdson et al., 2015). Additionally, the cross-sectional design does not allow for causal conclusions, and a larger, more diverse sample would improve external validity and increase statistical power to detect significant effects.

Implications

The results highlight the complexity of the problem at the local level, emphasizing that the consequences of victimization are not always immediately visible. While physical effects may subside over time, psychosocial consequences often persist, potentially affecting the long-term well-being of victimized individuals. These findings should encourage stakeholders at both local and national levels to prioritize the creation of safe and supportive school environments, where schools are recognized once again as spaces for learning, social connection, and personal development.

Additionally, despite the local nature of the sample, the present findings align with results from large-scale longitudinal studies conducted in major cities and countries worldwide. This correspondence supports the notion that the observed patterns may reflect broader, potentially universal trends, providing a basis for cautiously extrapolating the conclusions beyond the immediate study context.

5 Conclusions and Recommendations

Bullying is a widespread global issue, with serious consequences for victimized individuals. Victims are the target of physical, verbal, relational, or psychological aggression carried out by some of their classmates with the aim of causing them harm. Therefore, based on the findings of previous literature, peer victimization is a stressor that could adversely impact the psychosocial functioning and adjustment of students as well as the physical and mental health of these individuals.

The results of the present study demonstrated that victims of bullying do not experience positive emotional feelings within the school environment and that students exposed to violence also have less stable and less frequent peer interactions. The findings highlight the complexity of the issue at the local level and resonate with international research, suggesting that these patterns may reflect broader trends.

Although the present study focuses on current attitudes and experiences, longitudinal research indicates that these seemingly invisible consequences leave lasting traces in the later lives of victimized individuals. However, research shows that peer victimization is considered a modifying risk factor (Moore et al., 2017).

For this reason, the issue of bullying should be approached with a high level of seriousness, according to the fact that prevention is not only an ethical task, but also a necessary condition for creating a safe and supportive educational environment.

Schools should adopt a comprehensive prevention framework that incorporates primary, secondary, and tertiary strategies. Primary (universal) prevention programs should aim to reduce risks and strengthen social, emotional, and behavioral skills for all students within the school, enhancing overall school climate and awareness about bullying (Rivara et al., 2016). Secondary prevention should strive to identify at-risk students or classrooms early and to provide timely interventions to prevent escalation and repetition of victimization. Tertiary interventions should offer personalized support and rehabilitative services for victims, helping to reduce long-term harm and vulnerability (Edmondson et al., 2011).

This consistent and comprehensive approach would demonstrate the resolve to tackle the insidious harms caused by bullying.

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Povzetek v slovenskem jeziku

Nasilje med vrstniki, ki se običajno pojmuje kot ustrahovanje, predstavlja razširjen izziv, ki prizadene učence po vsem svetu kot tudi v Severni Makedoniji. Poleg neposrednega psihološkega in čustvenega vpliva na žrtve ustrahovanje oblikuje splošno šolsko klimo ter vpliva na varnost, vključenost in dobro počutje učencev. Viktimizacija je povezana s povečanim strahom, socialnim umikom in motenimi odnosi z vrstniki, kar lahko okrepi cikle agresije. Empirične analize kažejo, da podporne interakcije z vrstniki zmanjšujejo verjetnost, da bo nekdo postal žrtev ustrahovanja. Študija nadalje poudarja, da sta ozaveščenost o ustrahovanju in čustvene izkušnje učencev ključnega pomena za razumevanje dinamike viktimizacije med vrstniki. Ti izsledki poudarjajo večfaktorsko in sistemsko naravo ustrahovanja ter pomen spodbujanja odpornosti in negovanja pozitivnih odnosov med vrstniki za zagotovitev varnega, vključujočega in podpornega izobraževalnega okolja.

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