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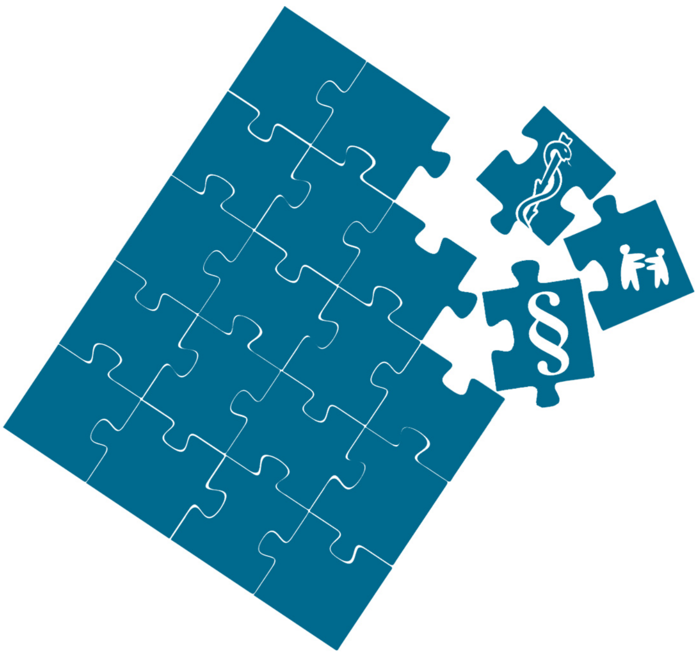

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RULE-OF-LAW CRISIS DURING THE COVID-19 EPIDEMIC: THE CASE OF SLOVENIA

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Abstract This article examines the Constitutional Court of Slovenia's rulings on the government's COVID-19 measures between 2020 and 2022. During the pandemic, the Slovenian government imposed lockdowns, curfews, and school and business closures, and required a "COVID pass" for access to services. These restrictions significantly interfered with fundamental rights, leading to numerous legal challenges. The Constitutional Court found several of these decrees unconstitutional, revealing serious tensions between public health governance and constitutional democracy. The article has two main goals: to evaluate the extent of rights violations and to assess whether rule-by-decree is aligned with democratic principles. The findings show that the rule of law was often undermined, with pandemic-related legal tools at times used to pursue authoritarian political aims. Slovenia's case demonstrates the fragility of democratic institutions in emergencies. It highlights the vital role of constitutional courts in defending the constitutional order, especially when they themselves face political attacks in increasingly illiberal environments.

Keywords
Rule of law, constitutional democracy, COVID-19 epidemic, constitutional court, Slovenia

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1 Introductory Explanation

This article addresses the impact of the decisions of the Constitutional Court of the Republic of Slovenia (hereinafter: CCtRS) related to COVID-19 measures. The Government of the Republic of Slovenia managed the COVID-19 epidemic by issuing decrees ordering lockdowns, including closures of schools and businesses, prohibiting public gatherings, imposing curfew, and conditioning access to goods and services with the so-called "COVID-pass". These measures severely impacted individuals' fundamental rights and freedoms. Consequently, many people turned to the CCtRS to determine whether these measures conformed to the Constitution. During the epidemic from 2020 to 2022 and beyond, the CCtRS issued several decisions, finding that the legislative measures and the decrees designed to prevent the spread of infections failed to conform with the Slovenian Constitution. The purpose of this article was twofold. First, it will examine the extent to which the legislative and executive branches of the government interfered with individuals' rights during the epidemic, and second, it will explore whether such governance by decree still retains the characteristics of a constitutional democracy. The numerous CCtRS decisions issued on this matter during and after the epidemic raised questions on the role of the law in a constitutional democracy. The fact that many decrees and laws were declared unconstitutional in this period triggered a question about whether the options that the authorities had at their disposal were instrumental in achieving political objectives that were not democratic. Another question that arose was whether the CCtRS appropriately performed its function as a guardian of the Constitution.[1] Notably, this function is crucial for maintaining constitutional democracy, particularly in times marred by crises such as economic or financial turmoil, epidemics, natural or ecological disasters, wars, civil unrest, as well as internal or international conflicts. During a period when countries worldwide were compelled to manage an epidemic of a global scale, which posed a significant health risk not only to immunocompromised individuals and older people, but also to the wider population, the significance of the CCtRS, alongside other control mechanisms[2] limiting the powers of the executive and legislative branches of government, was indispensable.

[1] CCtRS has a power to decide, *inter alia*, on the conformity of laws with the Constitution, on the conformity of regulations (which also include government ordinances) with laws and the Constitution, and on constitutional complaints stemming from the violation of human rights and fundamental freedoms by individual acts.

[2] For example, various state institutions responsible for the control and observance of legal regulations in various areas of legal regulation, for example, courts, the Ombudsperson, the Information Commissioner, the Court of

In this paper, I set aside the question of which intensity of state intervention during the COVID-19 epidemic was optimal, i.e., which states had a better approach, those that adopted highly restrictive measures and shut down public life, or those that implemented policies based on recommendations and less stringent social controls. Some level of state intervention to control the spread of the infections was undeniably necessary to protect the health and lives of the population, in line with the constitutional provisions of Articles 51 (right to healthcare) and 17 (inviolability of life). However, the question was whether the measures of intervention were appropriate, necessary, and proportionate to the aims they were pursuing. Legislatures, executives, and courts had a difficult task of balancing the right to life and healthcare on one hand and all other rights that the measures affected on the other hand. Stricter protection of the former very often disproportionately affected the latter. Some commentators observed that in some countries, e.g., France, their responses to the epidemic were becoming "increasingly authoritarian" (Golia et al., 2021, p. 284). Across many nations, constitutional and supreme courts have scrutinized the extent to which authorities may infringe upon the rights and freedoms of their citizens. As several authors point out, where interventions were deemed excessive, courts in various countries abrogated measures that lacked legal grounding, were indefinite, overly broad, disproportionate, unjustified, or unsubstantiated by scientific evidence (Tzifakis, 2020, p. 201; Milinković, 2021, p. 449; Renders, 2021, p. 432; Dobrovičová, 2022, p. 29; Flander, 2022). Tzifakis (2020, p. 201), however, points out that in some Western Balkan countries, particularly Serbia and Albania, the constitutional courts were not even operational, while the political leaders disregarded domestic institutional procedures, ignored the system of checks and balances, and sidelined the legislatures. Some authors have pointed out that in Bosnia and Herzegovina and in Slovakia. At the same time, the constitutional courts in those countries continued to operate throughout the health crisis, their decisions were delayed and limited in scope (Milinković, 2021, p. 449; Dobrovičová, 2022, p. 29). Piotrowski (2024) underlines that in Poland, the measures tackling the epidemic could pass constitutional scrutiny only if a state of emergency had been declared - but no such emergency was officially declared. For some other countries, the academic criticism of both the management of the epidemic and the response of the courts is not that severe. In Belgium, for example, according to Renders (Renders, 2021, p. 432), the Council of State was indeed

Auditors, the Advocate of the Principle of Equality and others.

"seized" by a high number of judicial reviews against the measures related to epidemic, claiming an infringement of fundamental rights, but it has confirmed most of these measures as being consistent with the Belgian Constitution. This corresponds to the finding of Iamiceli & Cafaggi (2023), that generally the role of the courts during the epidemic was seen to be constructive and not disruptive.

2 Methodology

There is extensive literature already available for both individual countries as well as on the comparative level concerning the legality and constitutionality of the epidemic's management. The aim of this article was to complement this literature by a normative dogmatic method, comparative method, as well as by critically assessing the situation in Slovenia, where the authoritarian tendencies were, in my view, particularly visible, and to carry out this assessment from a certain time distance. For this purpose, I analysed the decisions of the CCtRS to explore key constitutional aspects of managing the COVID-19 epidemic in Slovenia and examine where these authoritarian tendencies are most visible. I aimed to explore whether the CCtRS was constructive or disruptive, and if it was disruptive, was it towards the management of the epidemic or the authoritarian tendencies? The research conducted for this article focused on all COVID-19-related CCtRS decisions issued between 2020 and 2024. The analysis examined the outcomes of the key decisions, focusing on key legal issues emerging from these decisions, and the types of constitutional scrutiny applied to the regulations the Court reviewed. The analysis tested the main hypothesis that was set before the research began, which was, as indicated, that the governmental management of the epidemic in Slovenia unveiled authoritarian tendencies that have manifested themselves in increased social control. The starting point of the research was to verify whether the measures passed to prevent the spread of the virus also served to discipline the population (Završnik & Šarf, 2021). In this context, another goal was to examine what role the system of checks and balances played in this situation (Bardutzky & Zagorc, 2021). The research examined whether the crisis posed a danger to public health caused by insufficient and inadequate medical capacities to handle the spread of the infections, and whether it constituted *a crisis of the rule of law*. Due to the limited scope of this article, the research and the conclusions have focused on legal aspects (i.e., conformity with the constitution and checks and balances among different branches of power), as opposed to the wider social aspects, as the latter would require additional and wider research methods.

3 Results

Having analysed the legal developments during the epidemic and CCtRS decisions from the stated period, I assert that what has been witnessed was in fact a rule-of-law crisis. I define *a crisis of the rule of law* in this context as a systematic dismantling of the legal framework by eroding the hierarchy of legal acts, with an aim of social control during the epidemic, which was achieved through the misuse of decrees (ordinances, also by-laws) by the authorities. Predominantly, the measures to curb the epidemic were enacted through government decrees, which, by fundamental legal principles, should have a clear legal basis (a basis in the legislative act adopted by the parliament). These decrees were often hastily adopted, coming into force the day after their publication in the official gazette, if they were published at all. They were in constant flux, frequently unclear, and interpreted inconsistently by different state authorities. The intended addressees, both the populace and legal entities, much too often either misunderstood the rules or were completely unaware of their real meaning. Revelations of such problems eroded public trust in the state management of the epidemic (G.C. & L.Š., 2021). Often, the new rules appeared senseless and unfair, exemplified by the incident where food delivery workers were fined for not wearing masks while eating lunch in central squares, despite being alone (Dnevnik, 2020). The ambiguity of the ordinances, coupled with extremely short notices and inconsistent methods of public communication regarding newly adopted measures, compounded the confusion. Legal entities such as shops and service providers were often forced to open or close with little or no advance notice, many times learning about changes in rules through late-evening news broadcasts. This approach severely undermined legal certainty and trust in the government's ability to manage the epidemic effectively. We now know that this erratic approach reflected the combination of factors, namely global lack of preparedness for a pandemic, lack of national medical capacities, lack of equity among states regarding access to vaccines, and other factors (Maccaro et al., 2023).

Various authors have characterised this period distinctly, including terms like "erosion of law" (Flander, 2021) and "legal hooliganism" (Al. Ma., 2021), indicating the situation indeed amounted to a *crisis* (Koselleck, 2000; Jalušič et. al, 2024). CCtRS also contributed to this crisis, particularly considering its initial deliberations, due to its reluctance and hesitation to abrogate clearly unconstitutional decrees. In this initial period, we may conclude that CCtRS was not disruptive but played a similar enabling role as in most other jurisdictions. Gradually, this changed. For over three years, the epidemic provided a relentless source of materials for the CCtRS's abstract constitutional review. Many individuals affected by the new slew of rules and measures felt these infringed upon their rights and freedoms and sought redress from CCtRS in large numbers (CCtRS, 2020, p. 83, 2021, p. 76). This offered CCtRS numerous opportunities for constitutional decision-making. This paper analyses the key CCtRS judgments from this period, underlining key legal issues and exploring how the court addressed the constitutional challenges posed by the executive and legislature. Through this analysis, I highlight the instances where the Court's response effectively met these challenges and, crucially, where it fell short.

3.1 The Importance of Constitutional Conformity of Regulations While "Ruling by Decree"

During the epidemic, the executive branch of government ruled by decree for an unacceptably long period of time. Rule by decree is a method of governance that has been deemed problematic at least since the era of Nazi Germany (Fraenkel, 1941; Schupmann, 2017). Many of the anti-COVID ordinances and decrees included problematic provisions or lacked a sufficient legal foundation, rendering review by CCtRS essential. The first decision, in which CCtRS addressed one such measure, pertained to the prohibition on crossing municipal borders, which was aimed at restraining the spread of the disease.[3] The CCtRS decision was issued on 27 August 2020, that is, five and a half months after the Minister of Health declared an epidemic.[4] In the first year of the epidemic, the government issued multiple ordinances prohibiting the population from moving beyond the borders of their

[3] CCtRS, Decision No. U-I-83/20-36, 27 August 2020. The petition for the review of constitutionality in the case of the Constitutional Court No. U-I-83/20-36 encompassed several ordinances, all of which shared the common feature of prohibiting movement outside municipal borders for the general population, except for individuals who could demonstrate that they fell under the exceptions specified in the ordinances. Although some of the challenged ordinances were no longer in effect at the time of the Court's decision, the Constitutional Court accepted the petition for the review of certain provisions. This review was deemed essential as it raised significant constitutional questions with precedential value and directly impacted the legal standing of the petitioner.

[4] Republic of Slovenia (2020) Odredba o razglasitvi epidemije nalezljive bolezni SARS-CoV-2 (COVID-19) na območju Republike Slovenije [Order on the Declaration of an Epidemic of the Infectious Disease SARS-CoV-2 (COVID-19) in the Territory of the Republic of Slovenia], Official Gazette RS, No. 19/20, 12 March 2020, https://pisrs.si/pregledPredpisa?id=ODRE2550.

municipality of residence,[5] to restrict the increase in infections. The CCtRS concluded, with a weak majority of five judges out of nine, that the ban was not inconsistent with the Constitution. The restriction of movement was assessed from the perspective of Article 32 of the Constitution, which guarantees freedom of movement.[6] CCtRS concluded that the provisions of the ordinances undoubtedly interfered with the right to freedom of movement within the country. According to Article 15(3) of the Constitution, interference with human rights is permissible only if the Constitution expressly allows for it or to protect the human rights of others. The latter condition means that an intervention is permissible if it meets the strict test of proportionality, which is derived from the principles of the rule of law as per Article 2 of the Constitution. The court majority held that the intervention was permissible because it pursued the constitutionally permissible goals of controlling the epidemic and simultaneously characterized it as appropriate, necessary, and proportionate. As the reasoning reveals, the majority opinion was significantly influenced by the fact that the epidemic was still in its early stages and involved an infectious disease that was "unknown to the population, especially at the beginning of its appearance, and above all it was scientifically and medically unresearched".[7] Furthermore, it was described as a "severe infectious disease" that "broke out for the first time in the country".[8] The court majority in this decision emphasized that even the scientific community was not unanimous on which measures were most suitable for protecting public health. Consequently, it recognized that the authorities, charged with the duty to protect public health, should be afforded a wide margin of discretion in choosing the measures to apply for this purpose. CCtRS considered that limiting contact between people reduces the potential spread of the virus and

[5] Republic of Slovenia (2020) Odlok o začasni splošni prepovedi gibanja in zbiranja ljudi na javnih mestih in površinah v Republiki Sloveniji ter prepovedi gibanja izven občin [Ordinance on the Temporary General Prohibition on the Movement and Gathering of People in Public Places and Areas in the Republic of Slovenia and the Prohibition on Movement Outside Municipalities], Official Gazette RS, No. 38/20 and 51/20, 14 April 2020, https://pisrs.si/pregledPredpisa?id=ODLO2041; Republic of Slovenia (2020b) Odlok o začasni splošni prepovedi gibanja in zbiranja ljudi na javnih krajih, površinah in mestih v Republiki Sloveniji ter prepovedi gibanja izven občin [Ordinance on the Temporary General Prohibition on the Movement and Gathering of People in Public Places, Areas and Cities in the Republic of Slovenia and the Prohibition on Movement Outside Municipalities], Official Gazette RS, Nos. 52/20 and 58/20, 24 April 2020, https://pisrs.si/pregledPredpisa?id=ODLO2049.

[6] Article 32(1) and (2) of the Constitution: *"Everyone has the right to freedom of movement, to choose his place of residence, to leave the country and to return at any time. This right may be limited by law, but only where this is necessary to ensure the course of criminal proceedings, to prevent the spread of infectious diseases, to protect public order, or if the defense of the state so demands."*

[7] Republic of Slovenia (2020) Odlok o začasni splošni prepovedi gibanja in zbiranja ljudi na javnih mestih in površinah v Republiki Sloveniji ter prepovedi gibanja izven občin [Ordinance on the Temporary General Prohibition on the Movement and Gathering of People in Public Places and Areas in the Republic of Slovenia and the Prohibition on Movement Outside Municipalities], Official Gazette RS, No. 38/20 and 51/20, 14 April 2020, https://pisrs.si/pregledPredpisa?id=ODLO2041.

[8] Ibid.

that the spread varies by municipality. Therefore, prohibiting residents from leaving their own municipality was seen to prevent the introduction of infections into less affected areas. These considerations led a narrow CCtRS majority to conclude that the measure restricting movement to the municipality of residence was not considered disproportionate or excessive. In this decision, CCtRS extensively quoted the speeches of leading representatives of the authorities at press conferences, indicating that their cautious public appearances strongly influenced the majority opinion.[9]

What is unusual about this decision is that the majority focused solely on the constitutionality of the ordinance itself, without addressing the constitutionality of the Communicable Diseases Act[10] upon which the ordinance was based, relative to the Constitution. Thus, CCtRS directly proceeded to review the ordinance, bypassing the evaluation of the conformity of the law (on which the ordinance was based) with the Constitution. This was despite many of the petitions for constitutional review, including arguments that the legal basis itself was unconstitutional. This deficiency of the approach was highlighted by the minority of constitutional judges who were outvoted, as evidenced in the dissenting opinions.[11]

Today, we can conclude that this CCtRS decision demonstrated an overly deferential approach towards government actions, meaning that it can be seen as constructive and not disruptive. Early on, the government was broadly trusted by CCtRS to make decisions based on scientific expertise, to act cautiously with respect to other rights and freedoms of the population (the right to life, the right to health), while also ensuring a balance that would allow the economy to continue functioning despite some encroachments on individual freedoms. From today's perspective, understanding that the legal system was in a severe crisis at the time the anti-epidemic ordinances were adopted, the decision appears as a naive endorsement of the practices of the authorities. It was only later that CCtRS acknowledged the presence of serious systemic flaws in the governance. The excessive leniency of the Court was criticized in separate opinions by judges who dissented, warning that facilitating the executive's governance through these ordinances would lead to

[9] Ibid.

[10] Republic of Slovenia (2006) Communicable Diseases Act. Official Gazette RS, No. 33/06, http://www.pisrs.si/Pis.web/pregledPredpisa?id=ZAKO4833.

[11] Mežnar, Š. (2020) Dissenting separate opinion of judge Dr Špelca Mežnar to Decision No. U-I-83/20 of 27 August 2020 of the Constitutional Court RS.

further encroachments on rights and freedoms.[12] This situation showed us that, under challenging conditions, the CCtRS majority was prepared to permit clearly unconstitutional measures if they could potentially contribute to curbing the spread of infections (Flander, 2021, p. 61).

Early in the epidemic, CCtRS imposed one significant limitation on the executive. In April 2020, before deciding on the merits concerning the prohibition of leaving one's own municipality, CCtRS temporarily suspended the enforcement of the ordinance provision that prohibited the crossing of municipal borders until explicitly revoked. Upon this temporary suspension, the Court mandated that the government must *"check every seven days, based on expert opinion, whether epidemiological measures are still necessary to achieve the goal of preventing the spread of COVID-19, and that it must accordingly extend, modify, or eliminate these measures, and must inform the public about its decisions"*.[13] This mandate signified that the government was instructed not to establish measures as permanent fixtures to be lifted at its discretion, but rather to initially set them as temporary, with a possibility of extension. This decision was significant as it established the rules relatively early in the epidemic and was in this sense disruptive for the authoritarian aspirations of the authorities. It curbed the tendency for governmental measures to become indefinite, thereby facilitating easier judicial review and limiting the potential for prolonged, unchecked governmental rule by decree.

3.2 The Importance of Official Publication of General Legal Acts

The CCtRS acknowledged in its next important decision that the legal system was becoming chaotic. This recognition came through a decision in which CCtRS declared the closure of schools for children with special needs unconstitutional.[14] This decision was issued nine months after the declaration of the epidemic, when schools were closed already for a second extended period. When CCtRS evaluated the constitutionality of school closures, it noted that the initial decision on school closure was based on an ordinance that had been duly adopted and published in the Official Gazette. However, subsequent ministerial decisions to extend the

[12] Čeferin, R. (2020) Dissenting separate opinion of judge Dr Rok Čeferin to Decision U-I-83/20 of 27 August 2020 of the Constitutional Court RS.
[13] CCtRS, Decision No. U-I-83/20-10, 16 April 2020.
[14] CCtRS, Partial Decision and decision No. U-I-445/20-13, 3 December 2020.

ordinance's validity were not published in the Gazette. The Court determined that these decisions were general legal acts that affected an unspecified group of individuals, thereby permitting an abstract review of their conformity with the Constitution. CCtRS emphasised that the absence of publication of the acts prevented their entry into force and, consequently, their conformity with the rule of law principles. In this decision, CCtRS reiterated:

"The regulations must be published prior to entering into force. A regulation enters into force on the fifteenth day after its publication unless otherwise determined in the regulation itself. State regulations are published in the official gazette of the state (see Article 154 of the Constitution). Since the Government decisions in question were not published in the Official Gazette of the Republic of Slovenia, they could not enter into force."[15]

Therefore, the ministerial decisions on the grounds of which the schools were closed could no longer be applied, and there was no legal basis for closing schools beyond the initial seven days. Concurrently, it needs to be recalled that the Minister of Education also issued a decision to introduce distance learning, which, however, was also not published in the Official Gazette, despite being a general legal act. Since this decision by the Minister was not published, it legally did not come into effect and should not have been enforced. A few weeks later, in a subsequent ruling on the same case, CCtRS also suspended the ordinance regarding the closure of educational facilities for children with special needs. It ordered that these institutions must reopen immediately.[16] The constitutionality of closing schools in general was, however, never adjudicated by CCtRS, because by the time the discussion on the merits concerning school closures was raised, the relevant ordinances had already expired. It could be assessed that, concerning the closure of schools in general, CCtRS was constructive, while its ruling regarding the schools for children with special needs was disruptive.

Decision-making in the case of closed schools for children with special needs carries dual significance. First, the CCtRS decision facilitated the reopening of schools with programmes adapted for the most vulnerable groups of children. Second, it exposed the authorities' dismissive attitude towards utilising the instruments of normative

[15] Ibid.
[16] CCtRS, Decision No. U-I-83/20-36, 27 August 2020.

activity, contrary to the procedures foreseen within the constitutional legal framework. The revelation that ordinances were not published in the Official Gazette, and that modifications to the content of these ordinances were only posted on government websites—a practice some authority representatives deemed entirely sufficient, as evidenced by their public statements in reaction to the CCtRS decision—highlighted a startling lack of awareness among political actors about basic constitutional norms (G.C., L.Š., 2021). At that moment, the perception of both the crisis of the law and the crisis of governance was profoundly palpable.

3.3 The Importance of an Appropriate Legal Basis for Adopting By-Laws

As we have shown, in the first year of the epidemic (2020), CCtRS exhibited some degree of deference towards the executive and legislative branches, considering the sudden outbreak of an unknown disease for which the authorities had no time to prepare. However, as time progressed, this deference began to wane, and CCtRS became less tolerant towards the executive and more disruptive. With the substantial influx of petitions to review the constitutionality of the ordinances and the increasing scrutiny over the legal bases for their adoption, critical questions emerged: Was the Slovenian Communicable Diseases Act, which was intended to provide the legal basis for *all* anti-COVID-19 measures, even consistent with the Constitution? And, consequently, was it still legally permissible to adopt ordinances and decrees that interfered with freedom of movement and access to goods and services, with new information showing that COVID-19 was no longer viewed as a novel and hazardous disease? A negative answer to these questions in the early phase of the epidemic could lead to additional dimensions of the rule-of-law crisis, if CCtRS abrogated the only law that allowed for adopting measures to combat the virus. It is therefore unsurprising that the time to assess these questions came only in the second year of the epidemic.

That is when CCtRS held that the main provisions of the Communicable Diseases Act, which defined the measures that the government can take in the event of an epidemic, were inconsistent with the Constitution.[17] The provisions granted the executive a broad authority to implement measures to prevent the spread of communicable diseases, including restrictions on movement and prohibitions on

[17] CCtRS, Decision No. U-I-79/20-24, 13 May 2021.

assembly and association. However, the level of discretion given to the government for drafting the measures was deemed excessively vague, giving the government the discretion to "select at its own discretion the methods (types), extent, and duration of restrictions that could (even very intensively) interfere with the freedom of movement of (potentially all) residents" as well as freedoms of assembly and association. This provision allowed for arbitrary interference with individual rights through ordinances, fundamentally conflicting with the principle of legality and the constitutional principles of predictability and legal certainty. Consequently, CCtRS ruled that ordinances based on these unconstitutional provisions were themselves inconsistent with the Constitution.[18] This was the point of a decisive and disruptive constitutional response to the dangers to the rule of law caused by the executive's negligent adoption of decrees and their instrumentalization.

Despite finding certain legal provisions of the Communicable Diseases Act unconstitutional, CCtRS did not opt for its abrogation, and the problematic legal provisions continued to be applied. This decision was made to ensure that there is at least *some* legal basis for further adoption of ordinances, as opposed to none. Indeed, it is never entirely certain whether the legislature will respond in a timely manner and enact appropriate regulations following the guidelines set by CCtRS within the timeframe specified in its decision. Thus, abrogating parts of Article 39 of the Communicable Diseases Act could have exacerbated the existing legal crisis.

The decision established a precedent suggesting that additional measures contained in the ordinances were likewise susceptible to invalidation, a development that was later confirmed by subsequent CCtRS decisions. Among the more significant measures were those in which the executive interfered with the freedom of assembly and association guaranteed by Article 42 of the Constitution. Namely, the ordinances prohibited gatherings during certain periods of the epidemics. In this context, CCtRS effectively fulfilled its role as the guardian of the Constitution. On 15 April 2021, it first temporarily suspended the implementation of the ordinance that temporarily prohibited events, meetings, and gatherings,[19] and in June 2021, it also found that the part of the government ordinances on the restriction of movement and assembly to prevent the spread of COVID-19 that prohibited gatherings or limited them to

[18] Ibid.
[19] CCtRS, Decision No. U-I-50/21-19, 15 April 2021.

up to ten participants was inconsistent with the Constitution. The Court held that there was insufficient evidence that such a restriction was necessary.[20] In this landmark decision, CCtRS, for the first time, defined the content of the right to assembly and association under Article 42 of the Constitution, rendering the decision historic. This ruling not only clarified the constitutional rights during emergency measures but also set a significant precedent for future governance and legal interpretations in times of crisis.

3.4 Failure to Decide on the Conformity of Curfew with the Constitution

As of now, CCtRS has not yet issued a ruling on the constitutionality of the ordinances that imposed a curfew, i.e., restrictions of free movement in public spaces during nighttime. The COVID-19 curfew, lasting 174 days or approximately six months, was among the longest in Europe (Demšar, 2021). Notably, curfew was reintroduced for the first time since World War II occupation. CCtRS had its first opportunity to deliberate on this matter just a few weeks after the curfew ordinance was implemented. However, initially, it dismissed[21] the motion for a temporary suspension of the relevant ordinance without any explanation (G.C. & L.Š., 2021). In September 2022, the Court also rejected a petition for a constitutional review of the curfew on the merits.[22] CCtRS acknowledged that the introduction of curfew and its alignment with the Constitution represented a particularly significant constitutional question with precedential value. However, following the abolition of curfew, CCtRS perceived it as unlikely that such measures would be reintroduced in the future. In March 2023, CCtRS once again rejected a petition challenging the constitutionality of the ordinances that had established and maintained curfew.[23] It could be assessed that on the issue of curfew, the Court was constructive and not disruptive.

In my opinion, the primary contention was that the assumption underpinning the original measures, that their reintroduction could be reasonably anticipated, was not convincingly repudiated. This assumption is questionable, given that the probability of reintroducing such measures persists considering past, present, and anticipated

[20] Ibid.
[21] CCtRS, Decision No. U-I-427/20-21, 5 November 2020.
[22] CCtRS, Decision No. U-I-426/20-57, 15 September 2022.
[23] CCtRS, Decision No. U-I-178/22, 16 March 2023.

future crises, particularly in an era characterised by the strengthening of authoritarianism and the illiberal tendencies of authorities (cf. Pap, 2018; Sajó, 2021; Sajó et al., 2022). Therefore, in my view, a judicial review of these measures would be prudent and justified. By contrast, the German Federal Constitutional Court delivered a ruling on the constitutionality of curfew in May 2021,[24] affirming its compliance with the Constitution. This decision considered factors such as the German legal framework, established case law, the legislator's thorough justification supported by scientific research, a comprehensive range of exceptions to curfew, the restriction of curfew to specific regions, and the linking of the prohibition of nighttime movement to the infection growth rate within the community (Gračar, 2021). In Slovenia, however, where none of these elements were provided for during curfew, there remains a legitimate concern regarding whether the ordinances imposing curfew were consistent with the Constitution. This is particularly pertinent given that the Article upon which they were based was later found to be inconsistent with the Constitution. Moreover, several legal experts have raised alarms about its unconstitutionality (Flander, 2021; Teršek, 2020).[25] Curfew in Slovenia was not only protracted but also imposed extensive daily restrictions, lasting up to nine hours at its peak, two hours longer than curfew in Germany. Additionally, it allowed for only a very limited set of exceptions, which excluded contacts with loved ones, such as non-married partners, and completely barred harmless outdoor recreational activities. Moreover, these measures contradicted the recommendations of epidemiologists (G.C. & L.Š., 2021).

Implementing curfew also prompts a range of significant constitutional and legal questions, such as the legality of imposing it without first declaring a state of emergency, as envisaged by Article 16 of the Constitution. This article stipulates the conditions under which it is permissible to temporarily suspend or restrict rights and freedoms, specifying that such actions are only constitutional in the event of war or a declared state of emergency, and even then, only to the extent required by such circumstances. Moreover, there is the question of whether an epidemic justifies the

[24] Constitutional Court of the Federal Republic of Germany (2021), BvR Decision No. 781/21 of 5 May 2021.
[25] The Constitutional Court judge Špelca Mežnar, in her separate opinion accompanying the decisions U-I-426/20 and U-I-427/20 to reject the petition evaluating curfew's compliance with the Constitution, stated unequivocally that curfew contravened the Constitution. This ruling was based on ordinances that stemmed from an unconstitutional legal provision within the Communicable Diseases Act (2006), as previously determined by CCtRS in decision No. U-I-79/20-24. Mežnar, Š. (2022) Dissenting separate opinion of Judge Špelca Mežnar to decisions U-I-426/20 and U-I-427/20 of the Constitutional Court RS.

declaration of a state of emergency and whether such a declaration might inadvertently open "Pandora's box," enhancing the potential for authorities with authoritarian inclinations to misuse the state of emergency framework in the future (Haack, 2022, p. 87). From the perspective of the continuous development of democratic standards in the country, as well as in law and politics, and to prevent future crises of law, it becomes imperative to address these issues at the constitutional level.

3.5 Encroachment Upon General Freedom of Conduct – Masks and Hand Disinfection

During the final phase of the epidemic in 2022, CCtRS annulled measures mandating hand disinfection and the wearing of masks. The annulment was not because these measures were deemed pointless, but because the legislature had failed to establish an adequate legislative basis for these measures throughout the two years of the epidemic.[26] CCtRS specifically (and constructively) deferred the decision on the legal bases for the mandatory wearing of masks and hand disinfection to a later date, choosing not to address these issues when it was evaluating the adequacy and precision of the definitions within the Communicable Diseases Act in general.[27]

In its decision, the court relied on the fundamental principle of legality, as outlined in Article 120 of the Constitution.[28] The principle of legality means that by-laws and individual acts of the executive power, including those of both the government and administrative bodies, can only be adopted based on the law (a legislative act adopted by the parliament). This requires that they have a sufficiently specific substantive *basis within the law*. Additionally, the content of these acts must remain *within the framework of the law*, ensuring they do not exceed its possible meaning.[29] In this context, CCtRS asserted that the obligation to disinfect hands and wear masks in enclosed public spaces infringes upon the general individual's freedom of conduct enshrined in Article 35 of the Slovenian Constitution. By extension, this provision

[26] CCtRS, Decision No. U-I-132/21-25, 2 June 2022. The omission shows particularly serious negligence on the part of the authorities, which are obliged to protect the rule of law, and to respect its key constituent element, the principle of legality.
[27] CCtRS, Decision No. U-I-132/21-25, 2 June 2022, paragraph 40.
[28] Article 120 (2) of the Constitution reads: *"Administrative authorities perform their work independently within the framework and on the basis of the Constitution and laws."*
[29] CCtRS, Decision No. U-I-132/21-25, 2 June 2022, paragraph 20.

reasonably allows individuals to decide whether to protect themselves from infection. The general freedom of conduct, like any other human right or freedom, may only be encroached upon if it is legally mandated and if such encroachment satisfies a strict proportionality test. CCtRS found that the Communicable Diseases Act, which the executive authority cited when formulating the measures, lacks clear legal provisions that could serve as a basis for mandating hand disinfection and mask-wearing. CCtRS also clarified that the government, while allowed to restrict movement in public places during an epidemic based on legal provisions, cannot implement measures unrelated to movement restrictions, such as mask mandates.[30]

The principle of legality, which the CCtRS employed in its adjudication, is a fundamental constitutional principle mandating that executive actions must always have a legal basis. This principle is universally recognized within the legal profession as central and foundational; without it, a hierarchical structure of legal norms in a rule-of-law-based country would be inconceivable. To safeguard the legal system, which has been thrust into crisis by the issuance of ordinances lacking a legal basis- an action that cannot remain without consequences- CCtRS utilized its primary tool: the principle of legality. This was despite the possibility of also assessing the constitutional conformity of the ordinances on other grounds, given that they impinged on individual human rights and freedoms.

It is also noteworthy that by delaying its decision on this issue, CCtRS provided the authorities with sufficient time to legally justify basic non-invasive measures, such as mask mandates and mandatory hand disinfection. The decision was issued more than two years after the declaration of the epidemic, despite individuals having raised objections to these measures from the outset. In its deliberations, CCtRS avoided a formalistic approach that would have ignored real social needs. Instead, it took into consideration the actual health risks and the social context, recognizing the epidemiological value of preventive measures like hand disinfection and indoor mask-wearing. CCtRS acknowledged that the legislative and executive branches had not acted with the intent to provide a legal basis for their actions, despite the long-standing clarity about the absence of such bases. In its decision, CCtRS also constructively avoided instigating new levels of legal crisis by not invalidating the existing legal foundations for epidemiological measures within the law. Instead, by

[30] Ibid., paragraph 32.

issuing its decision after the ordinances mandating hand disinfection and mask mandates had expired, it provided the legislative and executive branches with clear guidance on how to amend the legal framework for any future measures, without dismantling the existing ones.

The role of CCtRS during this period is characterised by its recognition of the public health risks posed by a new infectious disease. While granting the authorities flexibility and time to respond, CCtRS made it clear that they were expected to establish appropriate legal foundations for their measures. Another noteworthy aspect of this specific assessment of regulatory compliance with the Constitution, and of other constitutional evaluations, is the CCtRS' broad acknowledgment of petitioners' legal interests.[31] This acknowledgment of their legal interest (which is a procedural precondition for abstract review of conformity) allowed petitioners to challenge the substance of the regulations they contested. In assessing legal interest, CCtRS normally verifies whether a regulation directly impacts individuals' legal standing and whether they have exhausted all other available legal avenues. However, in the case of the obligation to wear masks, this scenario would only arise if petitioners violated the ordinance's rules and were fined for the minor offence. Only then could they pursue legal remedies, including a constitutional complaint. For such cases, CCtRS determined that compelling individuals to commit minor offences to demonstrate legal interest before CCtRS was inappropriate, and that their legal interest should be recognised even if the law did not yet affect them directly. This rationale can be assessed as adequate for the recognition of petitioners' legal interests in the case of mask mandates.

3.6 The Importance of the Principle of Legality for Determining New Types of Compulsory Vaccination

With the widespread availability of COVID-19 vaccination, access to goods and services became contingent upon adherence to the "recovered/vaccinated/tested" requirement (also known as COVID-pass). This rule mandated that individuals possess a certificate demonstrating recovery from COVID-19, vaccination against it, or a negative result from a rapid antigen test to access most goods and service providers, as well as workplaces. Towards the end of the epidemic, discussions

[31] CCtRS, Decision No. U-I-427/20-64, 15 September 2022.

intensified regarding the potential necessity of implementing vaccination mandates for certain professions or types of employment. These discussions culminated in the adoption of an ordinance stipulating that civil servants could only access their workplace with a medical certificate confirming recovery or vaccination.[32] For civil servants unable to demonstrate recovery from COVID-19 and whose work could not be conducted remotely, this ordinance effectively amounted to mandatory vaccination. Consequently, it became imperative to assess the compliance of this ordinance with the legislation governing mandatory vaccination under national law. A trade union challenged the provision of the ordinance before CCtRS, resulting initially in a temporary suspension of its enforcement. Subsequently, CCtRS concluded that the relevant provision of the ordinance was inconsistent with the Constitution.[33] CCtRS again revisited the fundamental principle of legality when deliberating on the issue and examined whether a legal basis existed for such an obligation. It determined that this was not the case, as the vaccination programme applicable to employees, adopted under the Communicable Diseases Act (2006), did not designate mandatory vaccination against COVID-19. Although these conclusions may seem self-evident today, they highlight the extent of the legal and institutional crisis faced by the country during the epidemic. The fact that there were plans to introduce compulsory vaccination for a specific group of people without legal grounds underscores the gravity of the situation.[34] It could be assessed that on this issue CCtRS acted in a way that was disruptive for the authorities.

3.7 The Principle of Protection of Legal Certainty and the Principle of Separation of Powers

In 2024, CCtRS continued to consider issues related to epidemic control and management. Two primary factors contributed to this ongoing process. The first one was the protracted duration of judicial decision-making within CCtRS. Second, the effect of certain measures from COVID times continued to resonate in various regular court proceedings due to judicial actions filed against them.

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[32] Republic of Slovenia (2021) Ordinance on the Method of Meeting the Recovered/Vaccinated/Tested Rule to Contain the Spread of the SARS-CoV-2 Virus Infections, adopted by the Government of the Republic of Slovenia, in force since 15 September 2021, http://pisrs.si/Pis.web/pregledPredpisa?id=ODLO2600.
[33] In the meantime, the ordinance ceased to be valid, as it was replaced by another ordinance, which did not contain this provision. Republic of Slovenia (2021), Ordinance on Temporary Measures for the Prevention and Control of Infections with the Infectious Disease COVID-19, adopted by Government of the Republic of Slovenia, in force since 8 November 2021, http://www.pisrs.si/Pis.web/pregledPredpisa?id=ODLO2622.
[34] CCtRS, Decision No. U-I-210/21-25, 29 November 2021.

In response to these ongoing issues, CCtRS addressed the question of whether it was permissible to reduce the salaries of prosecutors to allocate funds necessary for state epidemic control. Specifically, one of the intervention laws adopted by the parliament mandated a 30% reduction in the salaries of certain officials, including prosecutors, over a period of one and a half months in 2020.[35] The salaries of prosecutors were reduced without any consultation with the prosecutors themselves.[36] Furthermore, the salaries of officials in all independent bodies, except for judges and CCtRS judges, were lowered as well. Prosecutors objected to this reduction, and some initiated individual labour disputes, challenging the constitutionality of the law upon which the reduction was based. CCtRS determined that the arbitrary reduction of salaries was unconstitutional. The regulation was evaluated through the lens of the principle of legal certainty, which emanates from the broader principle of the rule of law as outlined in Article 2 of the Constitution. The principle of legal certainty ensures that individuals are protected from arbitrary detriment to their legal position by the state. Such detriment must be based on genuine reasons rooted in the prevailing and constitutionally permissible public interest.[37] The explanatory notes accompanying the draft law made it evident that the purpose of the salary reduction was to generate funds to address the repercussions of the epidemic, which were unforeseen during the budget preparation. However, due to the National Assembly's lack of response to the request for a constitutional review, CCtRS had no concrete information regarding the amount allocated and its expenditure. In the absence of a clear demonstration of the necessity for these funds, CCtRS determined that the interference with the rights of prosecutors was unjustified.[38]

It is essential to note that the measure also impacted chief officials of independent state bodies, including the Ombudsperson, the Court of Auditors, the Commission for the Prevention of Corruption, the Information Commissioner, the National Commission for Auditing Public Procurement, the Advocate of the Principle of Equality, and others. These bodies are autonomous and independent, occupying a

[35] Republic of Slovenia (2020) Act Determining the Intervention Measures to Contain the COVID-19 Epidemic and Mitigate its Consequences for Citizens and the Economy, OGRS, No. 49/20 and 61/20, 30 April 2020, http://www.pisrs.si/Pis.web/pregledPredpisa?id=ZAKO8190.
[36] Concurrently, the legislature also reduced its own salaries, as well as those of government representatives, who then increased their salaries back.
[37] CCtRS, Decision No. U-I-432/20-10, 2 February 2023.
[38] Ibid., paragraphs 15 and 16.

distinct position within the system of separation of powers. They do not fall neatly within any of the three branches of government, legislative, executive, or judicial. Indeed, while these bodies perform certain executive functions such as inspection or minor offense procedures, they also wield a range of other specific powers not typically associated with any of the three main branches of government. These include drafting opinions on issues within their mandates, investigating human rights violations, and representing clients before courts. Therefore, unilateral interference with their salaries, lacking detailed justification, raises questions from the perspective of the principle of separation of powers as outlined in Article 3 of the Constitution. Moreover, such actions could be interpreted as attempts at intimidation, potentially leading to the subordination of these bodies to ensure approval from the legislative and executive branches of government. Notably, these branches already exert significant influence over the determination of their powers, working conditions, and budgetary allocations.

4 Discussion

A review of key CCtRS decisions on the conformity of epidemiological regulations with the Constitution reveals a stark reality: the response of authorities to the epidemic disrupted several fundamental constitutional principles, many of which were unconstitutionally violated. The state practices observed during the epidemic precipitated a rule-of-law crisis, arguably unparalleled since the country's independence. Throughout its existence, CCtRS encountered various violations of constitutional principles and human rights and freedoms. However, what distinguishes this crisis is the profound nature of these violations of fundamental legal principles and their systemic dimensions, affecting all parts of society. These violations ranged from the failure to publish regulations in the official gazette to the continuous breaches of the principle of legality through the successive adoption of ordinances without a proper legal basis. All these actions disproportionally encroached upon the freedoms of individuals, particularly the general freedom of conduct, freedom of movement, the right to peaceful assembly and association, access to goods and services, and the right to education, among others. In my opinion, the way in which the authorities handled the epidemic profoundly destabilized the existing system of constitutional democracy in Slovenia. Some violations were fundamental, and the reactions to CCtRS invalidations were so surprisingly dismissive that it is difficult to think otherwise.

Furthermore, the content of many adopted ordinances, with their disproportionate and unlawful interference with fundamental rights, not only reflected the low level of democratic culture in the country but also revealed alarming authoritarian tendencies within the authorities. My assessment is that such measures were not mere excesses or oversights but, under the pretext of handling epidemics, deliberate steps towards illiberalism that would undermine the foundations of a constitutional republic (Pap, 2018, Chapter 3). Examples of the escalating and ultimately excessive use of police powers (Flander, 2021, p. 54), including the use of force, which in later official analysis turned out to be excessive and unprofessional (Ministry of the Interior of the Republic of Slovenia, 2022), also indicate this. Other examples that showed authoritarian tendencies are almost complete prohibition of public gatherings and protests, which resulted in arrests of people who were reading the Constitution out loud on one of the main squares (24ur.com, 2021) and arrests of people who peacefully expressed dissent to governmental infringement of rights (PMVD, 2021, 2021a, 2022, 2022a).

Indeed, it cannot be argued that the epidemiological measures were not at least partly meaningful and needed with a view to protecting the constitutional right to health care and inviolability of human life. At the onset of the epidemic, there was deep uncertainty regarding the functionality of the unknown virus. The experiences of certain countries underscored the profound threat the virus posed to people's lives and health, as well as the repercussions of inaction, ineffective measures, or the absence of stringent enforcement of protocols. However, what stood out as an executive's and legislature's act of defiance against the CCtRS decisions was their prolonged inaction in terms of preparation of the new legislation that would be suitably tailored to the evolving circumstances and the unique nature of the epidemic. While it was entirely understandable at the outset that an appropriate legal framework might not exist, given that other types of viruses and diseases primarily informed the expertise of the epidemiological profession, it became increasingly evident over time, especially following the abrogation of the Communicable Diseases Act in May 2021, that the inertia in implementing suitable legal foundations was intentional. Moreover, it became apparent that the CCtRS ruling declaring the Communicable Diseases Act unconstitutional was intentionally disregarded, thereby deliberately precipitating a legal crisis. By contrast, in Germany, for instance, the legislation governing responses to outbreaks of communicable diseases was amended as early as March 2020, facilitating more effective management of the epidemic (Gračar, 2021, p. 31). However, such proactive measures were not undertaken in Slovenia. Following the CCtRS' declaration of the law's unconstitutionality, a two-month deadline was set for the legislative branch to rectify the identified flaws. However, this deadline was significantly surpassed due to delays in the amendment process. The amendment to the Communicable Diseases Act was adopted only on 27 September 2022,[39] a year and two months after the stipulated deadline. In a nation founded on the tenets of constitutional democracy, authorities entrusted with upholding constitutional principles should have prioritized the formulation of appropriate legal frameworks for implementing measures much earlier, ideally at the outset of the epidemic, but no later than the deadline set by CCtRS. For the future, it is hoped that the new international legal framework – namely the Pandemic Agreement adopted by the member states of the World Health Organization – will provide for additional guidelines for a more constitutionally acceptable approach.

5 Conclusions

As I have shown in my analysis, the management of the COVID-19 epidemic in Slovenia amounted to a rule-of-law crisis, which was evident from a systematic dismantling of the legal framework by eroding the hierarchy of legal acts. Decrees imposing anti-COVID measures became the main governing tool while the legislature was sidelined and passive. Most of these decrees, as well as the law on which the decrees were based, were declared unconstitutional by the CCtRS. The hastily and unpredictably way in which the decrees were adopted and announced, the (occasional) lack of their official publication, the tendency to establish decrees with permanent and not temporary validity, and the extent to which the executive branch went to punish and intimidate other state bodies and individuals point to the authoritarian tendencies. The experience of constitutional challenges during COVID-19 showcases that constitutional courts must be vigilant regarding such authoritarian inclinations that threaten the rule of law. Constitutional courts must be particularly mindful of this, as they are often targeted for dissolution, court-packing, or other attacks in the event of the proliferation of illiberal democracy and authoritarianism (Sajó, 2021, p. 66). Authoritarianism is not exclusive to foreign

[39] Republic of Slovenia (2022), Act on Amendments to the Communicable Diseases Act – ZNB-D, Official Gazette RS, No. 125/22, https://pisrs.si/pregledPredpisa?id=ZAKO433.

countries (Sajó, 2021, p. 4); it can emerge anywhere. The fact that the judiciary may not always be fully cognizant of this reality is exemplified by certain instances, including some lenient and constructive rulings by CCtRS. In this regard, CCtRS has rightfully faced criticism for appearing overly "restrained" (G.C. & L.Š., 2021). While it is understandable that CCtRS may not have fully accounted for the realities of the epidemic, which likely influenced its leniency, it failed to fully recognize the potential misuse of legal mechanisms to realize authoritarian ambitions for increased social control, a phenomenon not unfamiliar even in "mature democracies" (Sajó, 2021, p. 1). Authorities exploited the epidemic to instigate, initially perhaps inadvertently, and later intentionally, a rule-of-law crisis, consequently bolstering authoritarian elements within the political and legal framework. Amidst the rapid spread of a novel and unfamiliar virus, detecting these trends was sometimes challenging, compounded by the dense fog created by an array of intervention laws and ordinances. In such tumultuous periods, the paramount importance of the system of checks and balances, as well as the separation of powers, becomes apparent. Each branch of government bears its responsibility, and by honouring the decisions of other branches, constitutional democracy operates in a manner that closely aligns with the ideal.

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Povzetek v slovenskem jeziku

Članek obravnava odločitve Ustavnega sodišča Republike Slovenije glede ukrepov vlade med epidemijo covida-19 v letih 2020–2022. Vlada je sprejela številne odloke, ki so uvedli zaprtje javnega življenja, policijsko uro, prepoved zbiranja, zapiranje šol in podjetij ter pogoj PCT za dostop do storitev. Ti ukrepi so močno posegli v temeljne pravice, kar je sprožilo številne ustavne presoje. Ustavno sodišče je več teh ukrepov razglasilo za neustavne, kar kaže na resne napetosti med varstvom javnega zdravja in načeli ustavne demokracije. Članek zasleduje dva cilja: oceniti obseg posegov v pravice ter preveriti, ali je vladanje z odloki ostalo v okviru demokratičnih načel. Ugotovitve kažejo, da je bila vladavina prava večkrat ogrožena, pravni instrumentarij pa zlorabljen za avtoritarne cilje. Slovenska izkušnja poudarja krhkost demokratičnih institucij v kriznih časih in ključno vlogo ustavnih sodišč pri obrambi ustavne ureditve, zlasti ko postanejo tarča političnih pritiskov v režimih z neliberalnimi elementi.

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LEGAL FRAMEWORK FOR DRUG OPTIMIZATION IN VIETNAM: ALIGNING WITH INTERNATIONAL BEST PRACTICES

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Abstract This study investigates legal and policy reforms to strengthen Vietnam's drug control system through a holistic approach integrating public health, legal foundations, political will, and international cooperation. Using mixed-methods, legal analysis, literature review, and comparative case studies, it assesses Vietnam's laws against global frameworks, identifying key areas for reform. Insights from Germany and Singapore offer practical governance models. Grounded in empirical data and legal scholarship, the study proposes context-sensitive recommendations tailored to Vietnam's institutional landscape. It contributes to global discourse on drug policy and urges policymakers to adopt integrated, adaptive strategies that reduce harm and align with international standards.

Keywords
adaptive policy strategies, drug control policies, international drug policies, evidence-based policies, public health policy, legal compliance

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1 Introduction

Managing and administering drugs in Vietnam is the responsibility of the Ministry of Health (MOH) and the Drug Administration of Vietnam (DAV). In contrast, the Department of Medical Equipment and Health Works (DMEHW) regulates medical devices (Nguyen & Scannapieco, 2008). According to Luong (2021), the responsibility for administering drugs is considered crucial, especially given the increasing number of drug-related violations in recent years. The DAV and the MOH oversee the drug management system, regulating both medicinal and illicit drug products. Their responsibilities include developing policies to standardize medical products, licensing, and to establish drug mitigation procedures. Within this framework, the DAV is critical in analyzing, verifying, and approving pharmaceutical information before processing and distributing drugs. Once a drug is reviewed and meets the necessary standards, the DAV issues an approval statement for its distribution.

However, if a drug already on the market fails to comply with set consumption or content requirements, the institution issues a warning and withdraws the product. Effective drug management remains a primary responsibility of the DAV, ensuring that medicinal products meet key criteria. A qualified drug must demonstrate effectiveness in disease prevention and treatment, have minimal or no harmful side effects, maintain stable quality throughout its shelf life, and be practical for use and storage.[1] Achieving these objectives requires rigorous control and oversight by competent state agencies, emphasizing the importance of regulatory enforcement in safeguarding public health. One of the biggest challenges exposed is the weak supply chain management, which has led to the distribution of substandard medication and shortages in necessary medical supplies. According to a study by Do (2024), the COVID-19 pandemic posed the biggest challenge encountered by the MOH, especially given the fast spread of the disease and the limited medical resources within the country. Consequently, the pandemic imposed numerous threats to the healthcare system, bringing to light the necessity to develop a holistic and more diverse healthcare system, especially regarding drug management. During the pandemic, the role of the DAV came to light as the institution was tasked with drug

[1]Drug Administration of Vietnam, *Function & Assignment*. Retrieved from https://dav.gov.vn/function-amp;-assignment-ce1.html (July 29, 2025).

registration, receiving drug information, and declaring drug prices. These responsibilities allowed the institution to analyze the drugs developed and distributed in the country to curb the spread of the pandemic. Additionally, it is necessary to overcome existing shortcomings to improve Vietnam's law on drug management and fulfill the goal of protecting and caring for people's health (Do, 2024). This current study examines methods to optimize drug regulation in Vietnam by analyzing its national legal framework considering international best practices. Furthermore, the author approaches the terminology of drugs and analyzes the shortcomings in managing medications for human use within the scope of the Law on Pharmacy 2016.

2 Conceptual Framework

This study's conceptual framework is grounded in the principle of optimizing drug regulation in Vietnam through the alignment of its national legal framework with international best practices. Drawing from a wide variety of studies, the conceptual framework for the current study is anchored on the premise that effective drug regulation necessitates a comprehensive approach encompassing legal structures, enforcement mechanisms (Duc, 2020), public health considerations, and international cooperation (Feng et al., 2024). The framework is built upon several interconnected concepts.

First, International Drug Control Standards, articulated by the World Trade Organization,[2] form a crucial pillar. This encompasses the body of treaties, conventions, and guidelines developed by international organizations, notably the United Nations (UN) and the World Health Organization (WHO). These standards provide a blueprint for national drug control laws, striving to balance the imperative of preventing drug abuse and trafficking with ensuring access to essential medicines. Second, the National Legal Framework of Vietnam, which encompasses the country's domestic laws, regulations, and policies about drug control, is a key component. The framework analyzes the existing legal instruments, who they are implemented, and their effectiveness in achieving desired outcomes. It critically

[2] World Trade Organization, *International export regulations and controls: Navigating the global framework beyond WTO rules*. Retrieved from https://www.wto.org/english/res_e/booksp_e/int_exp_regs_part2_1_e.pdf (July 29, 2025).

examines the strengths and weaknesses of the current system, pinpointing areas ripe for reform.

Third, the "Best Practices" concept is central to this study. This refers to the most effective and efficient approaches to drug regulation, identified through rigorous research, practical experience, and thorough evaluation. The study investigated best practices in other countries, focusing on Germany and Singapore. These nations were selected for comparative analysis due to their divergent approaches, Germany with a harm reduction emphasis in certain areas, and Singapore with a stricter, zero-tolerance stance, offering a spectrum of perspectives on drug control. Fourth, policy optimization is the dynamic process of adopting and implementing best practices within the specific context of Vietnam (Feng et al., 2024). It acknowledges that a universally applicable solution is unrealistic and that effective drug regulation requires tailoring policies to the country's unique social, cultural, and economic realities. The framework underscores the importance of evidence-based policymaking, meaningful stakeholder engagement, and continuous evaluation to ensure policy effectiveness.

Finally, "public health and safety" constitute the overarching goal of effective drug regulation (Luong, 2024). The framework recognizes that drug control policies should aim to minimize the harms associated with drug abuse and trafficking while simultaneously ensuring access to necessary medications and promoting public health. It considers the wide-ranging impact of drug policies on individuals, families, and communities. This framework proposes that by systematically comparing Vietnam's national legal framework with international standards and best practices in other countries, and through careful consideration of public health and safety, pathways for optimizing drug regulation in Vietnam can be identified. This optimization involved developing and implementing evidence-based policies tailored to the specific needs and context of the country while adhering to international obligations.

3 Materials and Methods

This study adopted a mixed-methods approach, integrating legal research, a systematic literature review, and comparative analysis. The legal literature review comprehensively examined relevant legal documents within Vietnam and internationally. This review encompassed Vietnamese drug laws and regulations, including an analysis of the existing legal framework for drug control in Vietnam, encompassing relevant statutes, regulations, and policies. It also examined international drug control treaties and conventions to which Vietnam is a signatory to identify Vietnam's international obligations and commitments. Finally, relevant academic articles, books, and drug law and policy reports were reviewed to provide context and inform the analysis.

The systematic literature review involved a rigorous search of scientific journals to identify evidence-based best practices in drug regulation. This entailed searching relevant databases such as PubMed, Scopus, and Google Scholar using keywords related to drug policy, drug regulation, and international best practices in Vietnam. Studies were screened based on pre-defined inclusion criteria, focusing on research that evaluated the effectiveness of different drug control policies affecting Vietnam. Relevant data from included studies were extracted and synthesized to identify key findings and best practices.

The comparative analysis involved a detailed comparison of Vietnam's drug regulatory framework with those of Germany and Singapore. These countries were selected for their diverse approaches to drug control. The analysis focused on legal frameworks, comparing the legal frameworks for drug control in the three countries, including relevant legislation, regulations, and enforcement mechanisms. It also examined policy approaches, analyzing the different policy approaches adopted by the three countries, including harm reduction strategies, law enforcement approaches, and public health initiatives. Finally, it compared the outcomes and effectiveness of drug control policies in the three countries, considering indicators such as drug use prevalence, drug-related crime rates, and public health outcomes. The legal literature review, systematic review, and comparative analysis findings were synthesized to develop a framework to optimize drug regulation in Vietnam. This framework included specific recommendations for legal and policy reforms, considering the unique context of Vietnam and its international obligations.

4 Findings and Discussion

4.1 Legal Provisions of Vietnam on Drug Management

4.1.1 The Concept of Drug - an Object of Regulation by the Law on Pharmacy 2016

According to the provisions of Clause 2, Article 2 of the Law on Pharmacy 2016, "Drug means a preparation containing a pharmaceutical ingredient or medicinal materials for prevention, diagnosis, cure, treatment or mitigation of human diseases or modification of physiological functions of the human body. Drugs include pharmacochemical drugs, drugs made from medicinal materials, traditional drugs, vaccines, and biological products." Thereby, some of the following characteristics can be drawn:

First, a drug is a preparation containing pharmaceutical or medicinal ingredients. Specifically, the pharmaceutical or active ingredient may consist of a single substance or a mixture of substances, while medicinal materials are derived from plant, animal, or mineral sources.[3] The Law on Pharmacy (2005) defined drugs as substances or mixtures, implying that drugs encompass only pharmaceutical substances. At that time, two distinct concepts of drugs existed: material medical and traditional medicaments (Clauses 8 and 9, Article 2 of the 2005 Law on Pharmacy) and the general concept of drugs. Consequently, the definition of drugs primarily referred to Western medicine products, excluding traditional medical products.

Second, a drug is intended for the prevention, diagnosis, treatment, or mitigation of human diseases and for modifying physiological functions within the human body. In this context, drugs are strictly for human use. They are distinct from veterinary medicines, regulated under the Law on Veterinary Medicine (2015),[4] and pesticides, which fall under the Law on Plant Protection and Quarantine (2013).[5] This distinction ensures that pharmaceutical regulations and safety standards are

[3]National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016*. Clause 4, Article 2.
[4] National Assembly of the Socialist Republic of Vietnam. (2015). *Law on Veterinary Medicine (No. 79/2015/QH13), dated June 19, 2015*.
[5] National Assembly of the Socialist Republic of Vietnam. (2013). *Law on Plant Protection and Quarantine (No. 41/2013/QH13), dated November 25, 2013*.

appropriately tailored to human health needs, separate from those governing animal or agricultural treatments.

Third, a drug must fall into one of five specific categories: pharmacochemical drugs, drugs derived from medicinal materials, traditional drugs, vaccines, or biological products. While current regulations no longer explicitly exclude functional foods, as was the case under the Law on Pharmacy (2005), it is essential to note that certain products with drug-like properties, such as cosmetics (regulated under Circular 06/2011/TT-BYT, issued on January 25, 2011, by the Minister of Health) and functional foods (governed by the Law on Food Safety (2010)), are not classified as drugs. This distinction ensures that only substances meeting strict pharmacological criteria are subject to drug-specific regulatory oversight, maintaining the integrity of drug safety and efficacy standards.

In addition, the Law on Pharmacy 2016 and related legal documents only regulate issues related to pharmaceutical products such as drugs and drug materials in the context of human beings.[6] On September 5, 2022, the Government of Vietnam, through the MO H, issued Circular No. 08/2022/TT-BYT, introducing new guidelines for the registration of drugs and drug materials. This Circular, which took effect in October 2022, replaced Circular No. 32/2018 and introduced significant amendments aimed at streamlining the drug registration process.[7] One of the key changes involved modifying the requirements for granting a Certificate of Pharmaceutical Products (CPP), making the criteria less restrictive to facilitate access to essential medicines. Additionally, the revised regulation allowed manufacturers to submit legal documents demonstrating compliance with Good Manufacturing Practice (GMP) standards before obtaining a license to operate or manufacture pharmaceuticals. The current study acknowledges that such drug regulation updates reflect the government's commitment to enhancing regulatory efficiency while ensuring the quality and safety of pharmaceutical products.

[6] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016.* Clause 1, Article 2.

[7] Ministry of Health of the Socialist Republic of Vietnam. (2022). *Circular No. 08/2022/TT-BYT dated September 5, 2022, on marketing authorization of drugs and medicinal materials.*

4.1.2 Regulations on the Registration of Free Sale of Drugs

One form of drug registration, known as drug circulation registration, involves issuing a certificate of free sale. Rama Kishore et al. (2022) observes that this certificate is granted for drugs that either lack or possess an existing certificate that has changed various aspects. These changes may include alterations in pharmaceutical ingredients or medicinal materials, variations in the content, concentration, or quantity of active pharmaceutical ingredients, modifications to the form of preparation, changes in the route of administration, or a shift in the manufacturer. However, changes related to secondary packaging establishments or manufacturing locations do not necessitate a new certificate. According to regulatory requirements, establishments engaged in the manufacturing, wholesaling, exporting, or importing of drugs or drug materials, whether located in Vietnam or foreign entities with representative offices in Vietnam, must register their drugs with the appropriate state management agencies before their circulation within the Socialist Republic of Vietnam.[8]

Drugs may be allowed for circulation in Vietnam without prior registration under specific exclusive circumstances, ensuring essential medicines remain accessible for urgent medical needs while maintaining regulatory oversight.[9] One such case involves prescription drugs prepared at drugstores, where retail, and pharmaceutical establishments produce medications on-site using approved drug materials. These preparations are permitted exclusively within the same establishment where they are produced.[10]

Another exception applies to drugs manufactured and prepared within medical examination and treatment facilities. These drugs are produced to meet the facility's internal treatment needs. However, an exception exists for radioactive drugs,[11] which may be supplied to other healthcare institutions if the quantity produced

[8] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016.* Points a and b, Clause 2, Article 55.

[9] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016.* Clause 1, Article 54.

[10] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016.* Point b, Clause 1, Article 47.

[11] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016.* Clause 2, Article 85.

exceeds the facility's actual treatment demand[12] and if the MOH, specifically the Drug Administration, grants written approval.[13]

Additionally, certain imported drugs that lack certificates of free sale in Vietnam may be imported in restricted quantities based on import permits. This applies to drugs containing pharmaceutical ingredients that are not yet registered for free sale in Vietnam or are registered but in insufficient supply to meet treatment demands. It also includes drugs containing pharmaceutical ingredients introduced in Vietnam or those previously available but now in limited supply. Medications required for urgent national defense, security needs, epidemic control, disaster response, or exceptional treatment cases also fall under this exemption. Furthermore, rare drugs, which are not commonly available but are essential for treating specific medical conditions, may be imported without prior registration.

In cases where drugs are identical to brand-name pharmaceuticals already registered in Vietnam, including those with the same trade name, active ingredient, concentration, or dosage form, they may be imported if they are manufactured either by the original producer or an authorized manufacturer and are priced lower than the brand-name equivalent. The MOH must request such importation. Additionally, medications designated for national health programs are permitted to ensure widespread public health initiatives are met. Drugs provided as aid or humanitarian donations also qualify under these exemptions, as they support healthcare initiatives and disaster relief efforts. Another category includes drugs imported for non-commercial purposes, such as those used for clinical trials, bioequivalence and bioavailability studies, scientific research, exhibitions, registration samples, or testing.[14] These exemptions reflect the Vietnamese government's commitment to balancing drug accessibility, public health needs, and regulatory control. By allowing unregistered drugs in exceptional cases, the system seeks to meet urgent and critical medical needs while upholding safety and quality standards.

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[12] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016.* Clause 3, Article 85.

[13] Article 9 of Circular No. 20/2017/TT-BYT dated May 10, 2017 of the Minister of Health detailing a number of articles of the Law on Pharmacy and Decree No. 54/2017/ND-CP dated May 8, 2017 of the Government on drugs and drug materials subject to special control.

[14] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016.* Clause 2, Article 60.

Traditional drugs refer to medicinal products processed, prepared, and dispensed based on traditional medical prescriptions or formulations. These drugs are produced within medical examination and treatment establishments that apply traditional medicine and are used internally within the facility or sold under prescription at the same establishment.[15] Additionally, traditional drugs prepared by hospitals at the provincial level or higher, incorporating traditional medicine practices, may be distributed to other medical facilities specializing in traditional medicine within the same province or centrally governed city.[16] This distribution ensures that patients receiving treatment at these facilities have access to standardized traditional medicinal products.

The authority to grant a certificate of free sale (CFS) for drugs rests with the MOH. This certification is issued following an appraisal and consultation process conducted by the Advisory Council for the Grant of Certificates of Free Sale of Drugs and Drug Materials. The certificate of free sale serves as an official approval for drug circulation, affirming that the product meets safety, efficacy, and quality standards. A certificate of free sale for drugs remains valid for five years from the date of issuance. However, suppose a drug is subject to continued safety and efficacy monitoring. In that case, the certificate's validity is limited to three years from the date of issuance, as stipulated in Clause 6, Article 56 of the Law on Pharmacy 2016.[17] This regulatory framework ensures that traditional drugs adhere to national safety and efficacy requirements while supporting the integration of traditional medicine into Vietnam's healthcare system.

Under the Law on Pharmacy 2005, the only option for maintaining the validity of a certificate of free sale (CFS) for drugs was re-granting rather than extending the certificate. This process was unnecessarily costly and imposed administrative burdens on businesses, negatively impacting their operations.[18] Although regulatory changes have since been introduced, the extension of a CFS remains a form of drug registration rather than a streamlined renewal process. To apply for an extension,

[15] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016*. Clause 1, Article 70.
[16] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016*. Clause 1, Article 70.
[17] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016*. Clause 1, Article 56.
[18] Report No. 562/TTr-CP dated October 22, 2015 of the Government on the Pharmaceutical Law Project (amended).

the submitted dossier must remain unchanged from the originally approved application and be filed within 12 months before the certificate's expiration. Additional procedures must be followed if there are any modifications to the drug at the time of extension registration. In cases where significant changes occur, a new CFS or supplementary registration must be obtained rather than a simple extension.[19]

The authority and procedures for extending a CFS mirror those required for its initial issuance. Once expanded, the certificate remains valid for five years from the extension date, ensuring continuous authorization for drug circulation.[20] The standard five-year validity period and mandatory extensions were temporarily adjusted in response to the urgent medical needs during the COVID-19 pandemic.[21] Specifically, certificates set to expire between December 30, 2021, and December 31, 2024, have been automatically extended until December 31, 2024. This measure was implemented to prevent drug availability disruptions and support public health efforts during the pandemic.[22]

4.1.3 The issues of Counterfeit Drugs, Substandard Drugs

The current legal framework no longer considers "fraudulent intent," [23] or the subjective will of the drug manufacturer or distributor, as determining factors in identifying counterfeit drugs. Instead, a drug is classified as counterfeit if it meets specific criteria outlined in Clause 33, Article 2 of the Law on Pharmacy. These criteria fall into two main categories: content and form. From a content perspective, a drug is deemed counterfeit if it lacks the declared pharmaceutical ingredients or medicinal materials, contains pharmaceutical ingredients different from those

[19] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016.* Point b, Clause 1, Article 55.
[20] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016.* Clause 4, Article 55.
[21] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016.* Clause 6, Article 56.
[22] See Resolution No. 12/2021/UBTVQH15 dated December 30, 2021 of the National Assembly Standing Committee on allowing the implementation of a number of mechanisms and policies in the health sector to serve the prevention and control of the COVID-19 epidemic and Resolution No. 80/2023/QH15 dated January 9, 2023 of the National Assembly on continuing to implement a number of policies in the prevention and control of the COVID-19 epidemic and the use of certificates of free sale of drugs and drug materials expiring from January 1, 2023 to December 31, 2024.
[23] National Assembly of the Socialist Republic of Vietnam. (2005). *Law on Pharmacy (No. 34/2005/QH11), dated June 14, 2005.* Clause 24, Article 2.

indicated on its label, or fails to meet the quality standards registered for circulation or stated in its import permit. Additionally, a drug is classified as counterfeit if it contains pharmaceutical ingredients or medicinal materials in concentrations, quantities, or amounts inconsistent with those registered for circulation, except in cases where the quality has degraded due to storage or distribution conditions.

Regarding form and appearance, a drug is considered counterfeit if it is manufactured, presented, or labeled in a way that imitates a genuine manufacturer, misrepresents the country of manufacture, or falsely claims a different country of origin. Since drugs are classified as goods, the production and distribution of counterfeit drugs fall under the broader category of counterfeit goods manufacturing and trading. As such, these activities may be subject to administrative penalties under Decree No. 98/2020/ND-CP, issued on August 26, 2020, which governs sanctions for violations in commercial activities, counterfeit goods production, and consumer protection. In more severe cases, those involved in producing and selling counterfeit drugs may face criminal prosecution under Article 192 of the 2015 Criminal Code, as amended in 2017, for the crime of manufacturing and trading counterfeit goods.

However, different legal provisions apply depending on the counterfeit drug's intended use. For drugs intended for diagnosing, treating, mitigating diseases, or regulating physiological functions, administrative sanctions or criminal liability under Article 192 apply. In contrast, counterfeit drugs specifically meant for disease prevention and treatment are subject to stricter legal consequences, bypassing administrative penalties and directly falling under Article 194 of the Criminal Code, which governs the manufacturing and trading of counterfeit medicines intended for disease prevention or treatment.

"Poor quality drug" is replaced by "substandard drug" with the same meaning. They refer to drugs not satisfying the quality standards registered with competent state agencies.[24] In addition, drugs with pharmaceutical ingredients and medicinal materials are not following registered quality standards, but they are counterfeit drugs if they have not met the standards right before and during registration, and

[24] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016.* Clause 32, Article 2.

drugs that do not meet quality standards are unintended to be changed during storage and circulation.[25]

4.1.4 Regulations on Illicit Drugs

Vietnam's drug enforcement framework, governed by the 2015 Criminal Law[3], is stringent yet nuanced, balancing punitive measures with harm reduction. Vietnam legally defines illicit drugs as narcotic substances with addictive or psychotropic properties, as outlined in Article 2, Clause 1 of the Law on Drug Prevention and Control (No. 73/2021/QH14).[26] These include substances like opium, heroin, cocaine, and amphetamine-type stimulants listed in Annexes I to IV, prohibited for unauthorized use, production, or distribution, except for regulated medical or scientific purposes.[27] This definition underpins the country's regulatory approach, balancing enforcement with harm reduction.

The Penal Code safeguards national security, human rights, and public order while addressing criminal acts, including illicit drug use and trafficking. Over recent decades, Vietnam's drug landscape has evolved due to technological advancements and the emergence of new substances like amphetamine-type stimulants.[28] In 2009, Vietnam decriminalized personal drug use, reclassifying it as an administrative violation rather than a criminal offense (Vuong et al., 2012). This shift aimed to reduce penalties for users while maintaining strict enforcement against trafficking, though it has sparked challenges in balancing decriminalization with effective control.

The United Nations Office on Drugs and Crime reports a global rise in illicit drug use, particularly among youth, driven by low costs and increased availability. Vietnam, with its historical ties to opium production, faces persistent challenges (Windle, 2015). The government has adopted multifaceted strategies, including supply reduction, demand suppression, and harm reduction, such as establishing

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[25] National Assembly of the Socialist Republic of Vietnam. (2016). *Law on Pharmacy (No. 105/2016/QH13), dated April 6, 2016.* Point c, Clause 33, Article 2.
[26] National Assembly of Vietnam. (2021). Law on Drug Prevention and Control No. 73/2021/QH14, Article 2, Clause 1. Hanoi: National Assembly.
[27] National Assembly of the Socialist Republic of Vietnam. (2021). *Law on Drug Prevention and Control (No. 73/2021/QH14), dated March 30, 2021.*
[28] United Nations Office on Drugs and Crime (UNODC), *Viet Nam Office.* Retrieved from https://www.unodc.org/roseap/en/vietnam/overview.html (July 29, 2025).

detox clinics and promoting rehabilitation over punishment (Hieu et al., 2021). However, distinguishing between recreational and habitual users remains problematic, undermining efforts to curb demand (Nguyen, 2008). Critics argue that lenient policies for users, coupled with harsh penalties for traffickers, create enforcement inconsistencies (Hue et al., 2024).

Vietnam's "open door" economic policy, implemented in the late 1980s, has inadvertently facilitated drug trafficking by enhancing cross-border trade.[29] Despite this, the government has reduced domestic poppy cultivation, contributing to a decline in internal drug supply.[30] Vietnam's commitment to international cooperation, including membership in the Greater Mekong Sub-Region Memorandum of Understanding on Drug Control and adherence to UN conventions such as the UN Convention against Illicit Trafficking of Narcotic Drugs of 1988, has strengthened its legal framework (Buddenberg et al., 2003). However, challenges persist, particularly in distinguishing between users, suppliers, and financiers, which complicates enforcement efforts (Reid & Higgs, 2011).

4.2 Comparative Analysis with Singapore and Germany

A comparative analysis of Vietnam's drug regulation landscape alongside those of Singapore and Germany reveals divergent policy architectures, each shaped by distinct legal traditions, public health priorities, and socio-political contexts. While Singapore's drug policy is anchored in a zero-tolerance paradigm, characterized by stringent enforcement, mandatory sentencing, and capital punishment for certain offenses, it has achieved low prevalence rates of drug use through aggressive supply-side interventions such as border surveillance and deterrent policing (Koman, 2019). However, this model has drawn sustained criticism from international human rights bodies for its limited incorporation of harm reduction and its punitive stance toward drug users (Miao & Lai, 2023).

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[29] United Nations Office on Drugs and Crime (UNODC), *Viet Nam Office*. Retrieved from https://www.unodc.org/roseap/en/vietnam/overview.html (July 29, 2025).

[30] United Nations Office on Drugs and Crime (UNODC), *World Drug Report 2020*. Retrieved from https://wdr.unodc.org/wdr2020/index2020.html (July 29, 2025)

Germany, by contrast, has adopted a public health-oriented framework that integrates harm reduction, treatment, and social reintegration. Its decentralized governance structure allows for regional tailoring of drug programs, including supervised consumption sites, opioid substitution therapy, and community-based rehabilitation (Savaskan et al., 2024). The German model reflects a normative shift toward recognizing substance use disorders as health conditions rather than criminal infractions, aligning with WHO and UNODC guidelines on drug policy reform.

Vietnam's regulatory regime occupies a transitional space. Historically rooted in enforcement-heavy strategies, the country has begun to incorporate public health considerations, particularly through methadone maintenance programs and pilot harm reduction initiatives. Nonetheless, enforcement challenges persist, exacerbated by porous borders, fragmented inter-agency coordination, and limited institutional capacity (Thanh-Luong, 2022). Moreover, Vietnam's regulatory scope remains narrowly focused on illicit substances, with limited attention to pharmaceutical governance, access to controlled medicines, and pharmacovigilance, areas where Germany has developed robust oversight mechanisms (Shinde et al., 2025).

Three key insights emerge from this comparative exercise. First, Vietnam's drug policy reform would benefit from adopting a more evidence-based and multi-sectoral approach, integrating epidemiological data, health economics, and legal analysis to inform policy design. Second, the dichotomy between enforcement and public health should be re-framed as a continuum, where strategic integration, rather than substitution, of approaches yields more sustainable outcomes. Third, international collaboration must extend beyond bilateral exchanges to include participation in global monitoring platforms such as the Global Drug Policy Index, which benchmarks national performance across dimensions including access to medicines, proportionality of criminal justice responses, and development-linked drug policy.[31]

While neither Singapore nor Germany offers a universally transferable model, each provides instructive contrasts. Singapore's supply-side efficacy is tempered by ethical concerns and limited scalability, whereas Germany's harm reduction success is

[31] International Drug Policy Consortium (IDPC), *The Global Drug Policy Index 2021: Analytical Report*. Retrieved from https://idpc.net/publications/2021/11/the-global-drug-policy-index-2021-analytical-report (July 29, 2025).

contingent on strong institutional infrastructure and public trust. Vietnam's path forward lies in synthesizing these lessons into a context-sensitive framework that balances enforcement with health imperatives, aligns with international obligations, and reflects the country's evolving socio-legal landscape.

4.3 Inadequacies and Recommendations for Improvement

Vietnam's Law on Pharmacy 2016 faces definitional and procedural challenges that hinder effective drug regulation, necessitating amendments to align with international best practices. The definition of "drugs" in Clause 2, Article 2, while describing characteristics and uses, is undermined by specifying only five substances, creating ambiguity that enables manufacturers to evade registration obligations (Nguyen, 2015). This restrictive approach renders broader definitional elements redundant, complicating enforcement. France's Public Health Code, in contrast, offers a useful alternative model that employs a precautionary principle, classifying ambiguous products as drugs if they meet both drug and other product definitions (Legifrance, 2023). Following the French model, Vietnam could redefine drugs as preparations containing pharmaceutical ingredients or medicinal materials for prevention, diagnosis, treatment, or physiological modification, adopting this principle to ensure public health protection.[32] The absence of cosmetics from the Law on Pharmacy creates a regulatory gap,[33] despite their health impacts and oversight by the Drug Administration under Circular 06/2011/TT-BYT.[34] Codifying cosmetics as substances for external human use to cleanse or enhance appearance, as in Canada's Food and Drugs Act 1985,[35] would streamline governance. The certificate of free sale (CFS) extension process burdens the system, requiring full dossiers even for safe drugs, causing supply disruptions, with 12,896 registrations expiring between 2021 and 2022 (Minh, 2022). Adopting the European Union's model[36] of indefinite renewals after five years with post-market surveillance

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[32] European Medicines Agency (EMA), *Medicinal Product Definitions*. Retrieved from https://www.ema.europa.eu/en/human-regulatory/overview/medicinal-products (July 29, 2025)

[33] Report No. 4360/BC-UBVĐXH13 of the Committee on Social Affairs verifying the Pharmaceutical Law Project (amended).

[34] Clause 1, Article 2 of Circular 06/2011/TT-BYT dated January 25, 2011 of the Minister of Health regulating the management of cosmetics.

[35] *Food and Drugs Act*, R.S.C., 1985, c. F-27 (Canada). Retrieved from https://laws-lois.justice.gc.ca/eng/acts/f-27/ (accessed May 9, 2025).

[36] Full text: "*Lorsque, eu égard à l 'invemble de ses caractéristiques, un produit est susceptible de répondre à la fois à la définition du médicament prévue au premier alinéa du I et au II et à celle d 'autres catégories de produits régies par le droit européen ou national, il*

or China's manufacturer-led safety approach would enhance efficiency (Feng and Li, 2021). Vietnam's limited processing capacity, 500 applications monthly against 14,000 annual extensions, underscores this need (Minh, 2022). The definition of "counterfeit drugs" in Clause 33, Article 2, incorrectly labels them as drugs lacking pharmaceutical ingredients, leading to misapplied criminal convictions, such as smuggling (Nguyen, 2019). Aligning with the World Health Organization's[37] definition of counterfeit drugs as fraudulently mislabeled products and adopting Singapore's[38] stringent penalties would clarify enforcement. These reforms, rooted in global practices, would strengthen Vietnam's pharmaceutical framework, enhancing public health and regulatory efficiency.

5 Conclusion

In conclusion, the Law on Pharmacy ensures that individuals can access quality, safe, and affordable medications. This law must establish a robust framework for regulating drug manufacturing, distribution, and pricing, focusing on consumer protection and patient safety. The COVID-19 pandemic has underscored the need for Vietnam to reevaluate its legal and policy frameworks for drug management. By reflecting on the lessons learned during the pandemic, Vietnam has the opportunity to strengthen its legal provisions and improve drug regulation. This study emphasizes the importance of looking at international models from countries like Germany and Singapore, and Canada, France and the EU, to identify best practices that can be adapted to Vietnam's context. Moreover, it is critical to address the inconsistencies in Vietnam's policies related to counterfeit drugs, aligning them with international standards, especially given the challenges posed by porous borders. Closing these gaps through stronger regulations and fostering international cooperation will enhance Vietnam's drug regulatory framework, help improve public health and safety while meeting global obligations. This research contributes to the ongoing discussion on effective drug control by providing evidence-based recommendations for legal reforms that are contextually relevant and in line with

est, en cas de doute, considéré comme un médicament", Article L5111-1 Code de la santé publique*, see https://www.legifrance.gouv.fr/codes/texte_lc/LEGITEXT000006072665/* (May 10, 2023).

[37] World Health Organization, *Guidelines for the development of measures to combat counterfeit drugs*, pp. 7–8. Retrieved from https://apps.who.int/iris/handle/10665/65892 (May 8, 2025).

[38] *Misuse of Drugs (Amendment) Act 2023*, No. 12 of 2023, Republic of Singapore Government Gazette, Acts Supplement, April 28, 2023. Retrieved from https://sso.agc.gov.sg/Acts-Supp/12-2023/Published/20230424 (July 29, 2025).

international best practices, paving the way for a more resilient and efficient drug regulation system in Vietnam.

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Povzetek v slovenskem jeziku

Ta študija preučuje pravne in politične reforme za krepitev vietnamskega sistema nadzora nad drogami s celostnim pristopom, ki vključuje javno zdravje, pravne temelje, politično voljo in mednarodno sodelovanje. Z uporabo mešanih metod, pravne analize, pregleda literature in primerjalnih študij primerov ocenjuje vietnamsko zakonodajo glede na globalne okvire ter opredeljuje ključna področja za reformo. Spodbudni primeri iz Nemčije in Singapurja ponujajo praktične modele upravljanja. Na podlagi empiričnih podatkov in pravne znanosti študija predlaga kontekstualno občutljiva priporočila, prilagojena institucionalnemu okolju Vietnama. Prispeva k globalni razpravi o politiki glede drog ter poziva oblikovalce politik k sprejemanju integriranih in prilagodljivih strategij, ki zmanjšujejo škodo in se usklajujejo z mednarodnimi standardi.

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LEGAL ASPECTS OF SAFETY IN MEDICAL PROCEDURES: INTERNATIONAL STANDARDS AND PRACTICES

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Abstract This paper examines the legal regulation of medical procedure safety and proposes avenues for legislative enhancement informed by international norms. A comparative legal analysis was performed utilising the cases of Bulgaria, Italy, and Kazakhstan. The study utilised a systematic methodology to evaluate legal efficacy and predictive techniques to delineate potential advancements. The findings reveal that all three countries acknowledge the right to healthcare at the constitutional level, but implementation strategies vary. Bulgaria and Italy utilise insurance-based healthcare systems that incorporate private sector involvement. Bulgaria faces challenges in harmonising its law enforcement with European norms, whilst Italy's decentralised Servizio Sanitario Nazionale results in regional disparities. Kazakhstan upholds a state-centric regulatory framework but lacks comprehensive legal safeguards for patients and medical practitioners, especially concerning liability insurance. No country possesses a comprehensive legal framework for digital medicine. Key proposals include improving insurance protections, harmonising national laws with international norms, and regulating emerging medical technologies.

Keywords
healthcare,
regulatory framework,
state regulation,
licensing,
civil liability

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1 Introduction

Ensuring the safety of medical procedures is an integral part of the enjoyment of the human right to health. States have a legal responsibility to establish a regulatory framework governing the activities of medical institutions, the quality of services rendered, and the protection of patients from possible risks. However, despite the existence of international standards, approaches to the legal provision of safety of medical procedures vary significantly depending on the specific socio-economic, historical, and legal features of particular countries. The need conditioned the relevance of the present study for a comprehensive comparative analysis of legal support for the safety of medical procedures in different countries.

Modern international law recognises the need for patient protection at the legislative level, but the effectiveness of the regulations and control mechanisms continues to be a matter of debate. Some countries, such as Kazakhstan, regulate and license, while others, such as Italy, operate under a universal Servizio Sanitario Nazionale primarily funded through general taxation, with regional health authorities overseeing healthcare delivery and civil liability for medical errors governed by a mixed system of contractual and tort law. These differences raise questions about the extent to which patient rights are protected, the effectiveness of legal mechanisms to prevent medical errors, and liability for violations of medical standards.

In the field of legal provision of safety of medical procedures, there is a significant body of scientific research covering various aspects of this problem. A substantial part of the studies addresses the analysis of international standards, their implementation in national legislation, judicial practice, and mechanisms of legal liability of medical workers. However, these studies demonstrate varying approaches and have their limitations, which necessitate a comparative analysis of legal models of different countries.

Thus, Glushkova et al. (2021) and Liu & Hyman (2020) paid considerable attention to the harmonisation of international and national legal provisions regulating the safety of medical procedures. The researchers noted that EU directives and recommendations of the World Health Organisation (WHO) play a key role in the formation of national legal systems. Still, their implementation in different countries is uneven. Specifically, analyses of EU Member State legislation revealed that some countries (e.g., Germany and France) have a well-developed system of independent monitoring of medical services and compulsory professional liability insurance for doctors, while others (e.g., Bulgaria) face funding problems and insufficient regulatory mechanisms.

Hanganu et al. (2020) and Agarwal et al. (2019) focused on analysing court practices in medical error cases. The researchers compared approaches to such cases in multiple countries. They found that in legal systems with developed case law (e.g., Italy, despite its civil law tradition, where judicial precedents – especially from the Corte di Cassazione – play an increasingly influential role in shaping medical liability standards), court decisions substantially influence the law and practice of medical institutions. At the same time, in countries with a continental legal system, medical liability is more often regulated by strict rules of law, while the role of judicial practice is less significant.

Amir & Damayanti (2022) and Amin et al. (2020) investigated the role of insurance mechanisms in ensuring the safety of medical procedures. Their studies noted that the effectiveness of the health insurance system directly affects the level of legal protection of patients. For example, in countries with developed insurance medicine, doctors usually have professional liability insurance policies, which enable patients to receive compensation without the need for lengthy legal proceedings. In contrast, in countries where the insurance system is underdeveloped, patients are more likely to have to go to court, which increases the burden on the legal system and creates extensive time and financial costs.

Studies analysing the national health protection strategies also made a substantial contribution to the understanding of the legal regulation of the safety of medical procedures. For example, Adu-Gallant et al. (2024) and Seidanov et al. (2024) considered the problems of implementing medical safety standards in the post-Soviet countries. The researchers noted that the principal challenges for these states continue to be the insufficient legislative framework, the lack of effective control over the quality of medical services, and the low level of legal literacy of patients.

Despite the vast amount of research conducted, there are still some gaps in this area. For instance, most studies analyse legal models only within individual countries or regions, which complicates identifying common trends and best practices. Theoretical aspects dominate the existing studies, while empirical analyses (e.g., assessing the factual effectiveness of legislative provisions) are much less common.

The purpose of the present study was to analyse the legal regulation of the safety of medical procedures and identify areas for improving legislation based on international experience. To fulfil this purpose, the following objectives were set: to analyse international legal provisions governing the safety of medical procedures and their influence on national legislation; to investigate the specific features of legal regulation of the safety of medical procedures in Kazakhstan, Bulgaria, and Italy; to identify key problems and legal gaps in the regulation of medical safety at the national level.

2 Materials and Methods

The study of legal regulation of the safety of medical procedures in Bulgaria, Italy, and Kazakhstan was conducted using a set of special legal methods aimed at analysing national legislative systems and their compliance with international standards of medical safety. The principal method of the study was comparative legal analysis, which was employed to determine the best approaches to the legal regulation of the safety of medical procedures by comparing the national legislations of Bulgaria, Italy, and Kazakhstan with international standards. Within the framework of this analysis, the provisions of national legislation were compared with international regulations governing the rights of patients and obligations of medical workers. The selection of international legal instruments for this study was determined by their normative impact, global or regional legal authority, and historical importance in establishing norms for patient rights and medical safety.

The Universal Declaration of Human Rights (1948), the European Convention on Human Rights (1950), the International Covenant on Civil and Political Rights (1966), the International Covenant on Economic, Social and Cultural -Rights (1966), the Nuremberg Code (1947), the Charter of the Hospital Patient (1979) were considered as key international documents. Other significant international documents that were reviewed include: Recommendation of the Committee of

Ministers of the Council of Europe No. R(80)10 on Measures Against the Transfer and the Safekeeping of Funds of Criminal Origin (1980), Declaration on a Promotion on Patients' Rights in Europe (1994), European Charter of Patients' Rights (2002), Convention on Human Rights and Biomedicine (1997), Convention on the Rights of Persons with Disabilities (2006), Convention on the Rights of the Child (1989), Directive of the European Parliament and of the Council No. 2011/24/EU on the Application of Patients' Rights in Cross-Border Healthcare (2011).

The study analysed the regulations of Bulgaria, Italy, and Kazakhstan governing the safety of medical procedures. These included the Constitution of the Republic of Kazakhstan (1995), the Constitution of the Italian Republic (1947), the Constitution of the Republic of Bulgaria (2003), the Law of the Republic of Bulgaria No. 302-01-35 "On Health Protection" (2005), the Law of the Republic of Bulgaria "On Health Insurance" (1998), the Law of the Italian Republic No. 833 "Establishment of the National Health Service" (1978), Law of the Italian Republic No. 24 "Provisions on the Safety of Care and the Assisted Person, As Well As on the Professional Liability of Health Professionals" (2017), the Code of the Republic of Kazakhstan No. 360-VI "On the Health of the People and the Health Care System" (2020), and the State Programme of Development of Health Care of the Republic of Kazakhstan for 2020-2025 (2019). The analysis of these documents allowed us to identify the specific features of law enforcement in different jurisdictions and the legal gaps affecting the level of safety of medical procedures.

We employed the formal-legal method to examine the structure and content of national legislation aimed at regulating medical safety. Specifically, the study examined the regulatory language concerning standards of medical care, including requirements for the quality and safety of medical procedures, as well as medical licensing procedures covering the conditions and procedures medical institutions and practitioners must follow to obtain licences. A systemic approach was used to identify the institutional features of legal regulation of the safety of medical procedures in Kazakhstan, Bulgaria, and Italy. This analysis examined mechanisms of state control in the healthcare sector, models of interaction between the private and public sectors, and the degree of digitalisation of medical services.

Kazakhstan, Bulgaria, and Italy were selected to represent a varied array of legal, political, and healthcare governance frameworks, post-Soviet centralised regulation, an EU member state undergoing legal transition, and a developed Western European decentralised model, respectively. The analysis concentrated on delineating particular characteristics in each nation, encompassing constitutional health protections, medical licensing and accreditation mechanisms, informed consent standards, liability regime structures and effectiveness, and the deployment of digital health technologies.

Furthermore, we employed the SWOT analysis method to identify the strengths and weaknesses of the legal systems of each of the studied countries, to identify potential threats and opportunities for improving the legal regulation of medical safety.

3 Results and Discussion

3.1 Influence of International Legal Provisions on National Legislation in the Field of Safety of Medical Procedures

The formation of international legal provisions regulating the safety of medical procedures is a complex process due to a series of significant changes in the healthcare sector. Social changes include increasing patient demands for quality and safety of medical services, increasing awareness of the rights to healthcare, and legal protection. Economic factors are related to the globalisation of health services, increasing healthcare costs, and the need to optimise financial mechanisms to ensure accessibility and quality of healthcare. Technological changes are manifested in the active introduction of innovative methods of diagnosis and treatment, digitalisation of medical data, and the development of telemedicine, which requires the adaptation of legal regulation to new conditions and risks. This process began with the realisation of fundamental human rights and the need to protect patients from risks associated with medical interventions. The historical evolution of international regulation in this area demonstrates how global changes in medicine and society have influenced the development and adoption of international documents, as well as how these documents have affected the national legislations of different countries (Gerasymchuk et al., 2021).

One of the first steps towards the recognition of patients' rights was the Universal Declaration of Human Rights (1948), which set out the basic principles for the protection of human life, dignity, and health. This was the starting point for the further development of international legal mechanisms aimed at protecting patients. According to these principles, many countries began to form national legislation in the field of medical safety. For example, the USA developed laws regulating patients' rights, such as the Health Insurance Portability and Accountability Act (1996). Subsequently, the European Convention on Human Rights (1950) supplemented these provisions by emphasising the inadmissibility of inhuman treatment, which, specifically, applied to the medical sphere.

The findings of the study coincided with those of Beauchamp & Childress (2019), who noted that the basic principles of humanism and the protection of human rights are crucial for the formation of ethical norms in medicine. However, unlike in some Western countries, where reforms have been faster, in post-Soviet countries, the harmonisation of legislative provisions with international standards continues to be challenging due to a series of institutional and economic barriers.

In the 1960s and 1970s, the rapid development of medical technology, the introduction of new methods of treatment and diagnosis, and the increasing number of medical interventions led to the realisation of the need for more detailed legal regulation of medical activities. The International Covenant on Civil and Political Rights (1966) and the International Covenant on Economic, Social and Cultural Rights (1966) prescribed everyone the right to have access to healthcare, emphasising the significance of fair and safe provision of health services.

Germany and the United States were among the first countries to develop such legal standards. Germany adopted the Nuremberg Code (1947) after World War II and it became a crucial international document governing ethical standards for medical experimentation. USA passed the Patient Protection and Affordable Care Act in 1964, which included strict rules for medical research and established Ethics Committees responsible for overseeing experimental medicine. All these initiatives were part of a broader international movement to protect patients' rights and prevent abuses in medical practice.

The findings of the study were in line with the findings of Hulme (2020), who emphasised that the integration of international standards into national legislation requires a systematic approach that factors in not only the legal but also the technological changes, especially in the era of digitalisation and the introduction of innovative diagnostic and treatment methods.

A significant challenge for the healthcare system in the 1970s and 1980s was the commercialisation of health services and the increasing bureaucratisation of the industry, which increased the imbalance in the doctor-patient relationship. In response, documents such as the Charter of the Hospital Patient (1979) and Recommendation of the Committee of Ministers of the Council of Europe No. R(80)10 "On Measures Against the Transfer and the Safekeeping of Funds of Criminal Origin" (1980) were adopted, which were the first to emphasise the active participation of the patient in decisions about their own care. These initiatives were reflected in the national legislations of Western European countries, which began to introduce relevant provisions on patients' rights, including the right to information, confidentiality, and protection against unwarranted medical interference.

The international community's focus on patients' rights and medical safety came to a head in the 1990s with the adoption of the Declaration on the Promotion of Patients' Rights in Europe (1994) and the European Charter of Patients' Rights (2002). Under their influence, reforms were initiated in various countries to improve the protection of patients' rights and medical safety. In Germany, laws governing patient awareness of treatment and medical research have been strengthened. In France, new laws have been introduced to improve access to legal advice and improve patient awareness (Pajuk et al., 2024). In the UK, the Patients' Rights Act was passed, providing improved communication with healthcare providers. These documents have become significant benchmarks for national healthcare systems, contributing to the revision of approaches to the legal regulation of medical activities.

One of the key aspects of these documents was the expansion of the concept of patient safety and its recognition as a central element of medical law. Specifically, the European Charter of Patients' Rights prescribes principles such as the right to prevention, accessibility of health services, patient awareness, confidentiality, and protection of personal data. These provisions have become the cornerstone for healthcare reforms in many countries, including in Italy and Eastern Europe, where previously patients' rights had often remained on the periphery of health policy.

Notably, the processes of harmonisation of national legislations with international standards have been uneven. Western European countries were quicker to adapt their systems to the new requirements. At the same time, the post-Soviet states, including Ukraine, Kazakhstan, and Kyrgyzstan, faced a series of institutional and economic challenges in implementing international provisions. One of the primary obstacles was the lack of an adequate legal framework, as well as the insufficient preparedness of state authorities to monitor and implementing international standards effectively. For example, in Ukraine, until the early 2000s, outdated Soviet regulations were in force in medical safety, which prevented the full protection of patients' rights. In Kazakhstan, healthcare legislation was fragmented, while implementing international standards was hampered by a weak institutional framework and insufficient funding (Tursynova et al., 2024). In Kyrgyzstan, problems implementing international standards were related to the lack of qualified specialists in medical law and healthcare.

The findings of the present study were in line with the studies conducted by other researchers. For instance, Ruppel et al. (2022) emphasised that the selective application of international standards substantially limits the equality of litigants and respect for human rights. Furthermore, analyses revealed that increased interaction between national judicial systems and international legal institutions is necessary to improve the effectiveness of law enforcement. Many studies, including Millar (2023), pointed out that international organisations substantially influence the reforming of judicial systems, but a lack of domestic politics will often limit their impact.

With advances in technology, increasing volumes of medical data, and growing cross-border cooperation in healthcare, international organisations such as the WHO and the World Medical Association have increased their focus on medical safety (Kachan et al., 2025). One of the key areas has been the introduction of digital technologies such as telemedicine, electronic medical records, and artificial intelligence, which have considerably affected the quality and safety of medical procedures. Telemedicine has increased access to health services, especially in remote regions, which has required the creation of new international standards to protect patient privacy and regulate cross-border consultations (Del Carpio-Delgado et al., 2023; Shevchenko et al., 2023).

Electronic medical records have helped to improve diagnostic accuracy and reduce the risks associated with the loss or distortion of medical information, which prompted the adoption of international provisions on standardisation and protection of digital data. Introducing artificial intelligence into the healthcare system has improved decision-making and minimised medical errors but has also necessitated developing legal regulation concerning liability for algorithm-based decisions (Pētersone et al., 2020; Nowak & Grzybowski, 2013). In response to these challenges, international law has become more active in adapting to the new reality by adopting WHO recommendations on the use of digital technologies in healthcare and developing data protection standards under the General Data Protection Regulation in the EU. Thus, the digitalisation of healthcare has necessitated a revision of international legal provisions aimed at ensuring the safety of medical procedures and protecting patients' rights. The findings of the current study were consistent with the analysis of Bali et al. (2019), who noted that establishing a strong ethical and legal framework for the use of artificial intelligence in medicine is integral to current practice, highlighting the need to synchronise national legislation with international standards in this area.

The movement to actively develop national legislation regulating patients' rights and the safety of medical procedures began in Europe in the 1980s and 1990s. During this period, a series of countries adopted separate laws on patients' rights, which were largely based on international standards and recommendations. The first such act was the Act on the Status and Rights of the Patient, adopted in Finland in 1992. It mandated the basic rights of patients, such as the right to quality medical care, to be informed about their health status, and to be able to make their own decisions regarding medical interventions. A significant innovation was the introduction of a patient ombudsman, an official authorised to protect the interests of patients and consider their complaints. This practice was subsequently borrowed by other countries, including the Netherlands (1994), Israel (1996), Lithuania (1996), Iceland (1997), Denmark (1998), Norway (1999), Georgia (2000), France (2002), Moldova (2005), and others. In many countries, provisions regulating the safety of medical procedures and patients' rights have been incorporated into broad healthcare legislation.

Apart from the legislative acts, patient rights charters play a prominent role in regulating the safety of medical procedures. Government agencies, medical institutions, professional communities, and civil society organisations develop these documents. Unlike legislative acts, charters are often non-binding. Still, they nevertheless contribute to developing a legal culture, raising citizens' awareness of their rights, and creating mechanisms of public control over compliance with medical standards. For instance, in Portugal, the Consumer Charter has been incorporated into national legislation. In Germany, as early as 1975, the Social Code was supplemented by the Patients' Charter, which was a crucial step in developing a system for protecting patients' rights (Agarwal et al., 2019).

The practices of Great Britain deserve special attention, where protecting patients' rights and regulation of the safety of medical procedures is carried out mainly through case law. Unlike the countries of continental Europe, where legal provisions are prescribed in legislative acts, in the UK, the development of patient rights is based on court decisions. This creates a flexible but also less predictable system of regulation, as each new court case can set new legal standards. Such a system has both advantages and disadvantages. On the one hand, it allows the specifics of each case to be considered, ensuring an individualised approach to protecting patients' rights. On the other hand, the absence of a single regulation governing all aspects of medical safety can lead to legal uncertainty and complicate law enforcement practice. An illustrative example is the fact that the National Health Service in the UK must pay out hundreds of millions of pounds annually in patient claims for inappropriate care (Ravshanov et al., 2024).

Regarding the influence of international legal provisions on national legislation, one cannot fail to mention the harmonisation of legal systems, which is actively developing (Hulme, 2020). Within the EU, directives have been adopted to oblige EU member states to implement uniform standards of medical safety and to regulate issues related to patients' rights. The WHO and the Council of Europe have also developed recommendations for quality assurance of health services. These have become the basis for national patient safety strategies in many countries. However, the harmonisation of legislation faces serious challenges. Firstly, a considerable proportion of countries, especially developing countries, have financial constraints that complicate implementing international standards. Secondly, differences in the level of development of healthcare systems lead some states to successfully adopt international provisions, while others only formally adopt laws with no real enforcement mechanism (Beauchamp & Childress, 2019). Thirdly, there is resistance from the medical community, including in Italy, where parts of the medical profession have expressed concerns that increasing legal oversight may hinder clinical discretion and increase the risk of defensive medicine.

Table 1: Influence of International Legal Provisions on National Legislation in the Field of Safety of Medical Procedures

Criterion	International legal provisions	National legislation	Results and trends
Patient's right to the safety of medical procedures	Established in international conventions (Convention on Human Rights and Biomedicine, etc.)	Included in patient rights laws, healthcare laws, codes of medical ethics	Improvement of safety standards, introduction of a patient-centred approach
Informed consent of the patient	Confirmed in international instruments (Declaration of Helsinki)	Regulated in laws on medical activities, acts on the protection of patients' rights	Increased transparency of medical interventions, reduction in the number of lawsuits
Control over the quality of medical services	Defined by the World Health Organisation and international standards (ISO, JCI)	Included in the system of licensing and accreditation of medical institutions	Improvement of the quality of medical care, strengthening of state control
Confidentiality of health information	Prescribed in international documents (General Data Protection Regulation, Council of Europe Convention 108)	Protected by laws on personal data, medical secrecy	Development of digital data protection systems, regulation of access to information
Liability for medical errors	Prescribed in international agreements on medical human rights	Provided for in criminal and civil legislation	Increase in the number of lawsuits, development of pre-trial settlement mechanisms
Protection of vulnerable groups (children, disabled, elderly)	Reflected in the Convention on the Rights of Persons with Disabilities, Convention on the Rights of the Child	Included in specialised laws on the healthcare of certain categories of the population	Development of targeted medical care programmes, strengthening social protection

Source: compiled by the authors based on Convention on Human Rights and Biomedicine (1997), Declaration of Helsinki (1967), Convention on the Rights of Persons with Disabilities (2006), Convention on the Rights of the Child (1989).

An analysis of the influence of international legal provisions on the national legislation of various countries revealed that integrating global standards into the sphere of medical law is taking place in several key areas. Firstly, international documents set general guidelines for ensuring the safety of medical procedures, protecting patients' rights, and regulating the activities of medical institutions. Secondly, countries adopt these standards into their legal system by incorporating them into constitutions, specialised laws, and regulations. In Italy, for instance, the transposition of the European Charter of Patients' Rights and the adoption of Law of the Italian Republic No. 24 "Provisions on the Safety of Care and the Assisted Person, As Well As on the Professional Liability of Health Professionals" (2017) marked a significant step toward aligning national legislation with international principles on patient safety and medical liability Thirdly, implementing international standards is accompanied by changes in the regulation of aspects such as medical liability, protection of patients' personal data, access to health services for vulnerable groups, and healthcare quality control (Komilova et al., 2024). These aspects are systematised in Table 1.

Thus, international legal provisions governing the safety of medical procedures have been shaped by a series of factors: technological advances, ethical debates, social change, and the globalisation of the medical field. National legislation adopting international principles has faced various challenges, including institutional barriers, lack of funding, and the need to change public consciousness. Despite differences in pace and approach, the general trend in the development of medical law shows a desire to improve patient safety, as evidenced by the adoption of new international standards and their implementation in the legal systems of different countries.

3.2 Specific Features of Legal Regulation of Safety of Medical Procedures in Bulgaria, Italy, and Kazakhstan

The right to health protection in Bulgaria is guaranteed by Article 52 of the Constitution of the Republic of Bulgaria (2003). A series of legal acts regulates the safety of medical procedures, the principal ones being the Law of the Republic of Bulgaria No. 302-01-35 "On Health Protection" (2005), the Law of the Republic of Bulgaria "On Health Insurance" (1998). Bulgaria, as a member of the EU, has adapted its legislation to meet the requirements of Directive of the European Parliament and of the Council No. 2011/24/EU "On the Application of Patients' Rights in Cross-Border Healthcare" (2011).

A specific feature of the Bulgarian model is the combination of public and private health services with *strict state* control. For example, medical centres are subject to compulsory licensing by the Bulgarian Ministry of Health. National standards for medical procedures have been introduced, which are in line with WHO recommendations. One of the key areas in the field of legal regulation is the strengthening of the liability of medical professionals for medical errors (Zozulya et al., 2023; David-Tenorio & Torres-Rojas, 2025). The legislation mandates civil and criminal liability in cases of harm caused to a patient because of negligence or improper provision of medical care. However, despite formal compliance with European norms, there is still a series of unresolved problems in practice. Specifically, professional liability insurance for medical workers has not yet become an effective tool for protecting their rights, and patients often face challenges when trying to recover compensation for harm caused.

In their studies on legal aspects of medical safety in Bulgaria, Palm et al. (2021) and Pauliñska (2021) emphasised the active integration of European standards into national legislation, which was also identified in the analysis conducted during the present study. However, in contrast to the findings of Palm et al. (2021) and Pauliñska (2021), the present study emphasised the lack of protection for physicians in the insurance system, which may ultimately reduce the effectiveness of enforcement. In Italy, healthcare is a constitutional right set out in Article 32 of the Constitution of the Italian Republic (1947). The basis of legislation in the field of medicine is Law of the Italian Republic No. 833 "Establishment of the National Health Service" (1978), and Law of the Italian Republic No. 24 "Provisions on the Safety of Care and the Assisted Person, As Well As on the Professional Liability of Health Professionals" (2017).

The specific feature of the Italian system lies in the decentralised approach to regulating medical procedures. The powers in this sphere are distributed between the central government and regional authorities, which allows accommodating the specific needs of the population of different regions. However, this approach leads to some differences in the level of medical care and its quality control system depending on the territory.

The Gelli-Bianco Law represented a major reform in medical liability and patient safety. It mandated professional liability insurance for healthcare providers, introduced national guidelines to standardise clinical practice, and established the role of independent technical bodies (*collegi tecnici*) to assess alleged medical errors. One of the key aspects was a clear distinction between criminal and civil liability of medical professionals: criminal liability is now limited to cases of gross negligence, while most cases of alleged malpractice are resolved under civil law. The introduction of this law was prompted by the growing number of lawsuits against doctors, which created serious financial risks for medical professionals and even led to the phenomenon of "defensive medicine" (*quando i medici preferiscono non rischiare*).

Despite the existing regulatory framework, Italy still faces problems related to the overburdened judicial system and the complexity of proceedings in medical cases. The introduction of alternative dispute resolution methods, such as mediation and arbitration, could improve the protection of patients' and health professionals' rights (Karpushyna & Veresha, 2023). The Gelli-Bianco Law already promotes conciliation procedures as a mandatory step before litigation in certain cases, yet they have not been implemented evenly across regions.

The issues of medical security are widely considered in modern legal science. Yanovska et al. (2019) and Nozimakhon & Faringiz (2022) noted that the decentralised model of healthcare management leads to varying levels of quality of medical services in different regions, a conclusion we confirmed in the present study. These prior studies also observed a great degree of health workers' insurance coverage, which is in line with the findings presented in the current study. However, Borysowski et al. (2021) and Ruppel et al. (2022) pointed out that uncertainties remain in interpreting and enforcing liability rules, which may lead to ambiguous enforcement practices.

The right of Kazakh citizens to healthcare is prescribed in Article 29 of the Constitution of the Republic of Kazakhstan (1995). The most significant regulation governing the safety of medical procedures is the Code of the Republic of Kazakhstan No. 360-VI "On the Health of the People and the Health Care System" (2020). Unlike Bulgaria and Italy, Kazakhstan adheres to a centralised approach to regulating the medical sphere. The state exercises strict control over the provision of medical services, including mandatory accreditation of medical institutions, certification of specialists, and control over the implementation of standards of medical care.

One of the priorities of the Kazakhstan model is introducing digital technologies to improve the safety of medical procedures. Within the framework of the State Programme of Development of Health Care of the Republic of Kazakhstan for 2020-2025 (2019), a unified electronic database of patients is being created, which allows for minimising the risks of medical errors, automating the processes of diagnosis and treatment, and increasing the transparency of medical services. However, there is a risk of patient personal data being leaked, which requires further legal regulation.

One of the unresolved problems continues to be the absence of a full-fledged mechanism to protect medical professionals from unjustified claims (Tulina, 2024). Even though Article 270 of the Health Code outlines the concept of a "medical incident" (the innocent infliction of harm on a patient), in practice, professional liability insurance for doctors is still a formal norm. This creates risks for medical personnel, who may be held liable even in cases where harm has been caused without their fault, as confirmed by Polac (2023) and Adu-Gallant et al. (2024), who noted the increase in digitalisation and the introduction of modern technologies in the medical field. The findings of the present study confirmed this thesis but revealed the need to improve the mechanisms to legally protect patients and to regulate the liability of medical workers, which partially contradicts the conclusions of the above-mentioned researchers, who considered the existing regulatory framework of Kazakhstan sufficient.

An analysis of the legal regulation of the safety of medical procedures in Bulgaria, Italy, and Kazakhstan revealed both shared features and fundamental differences, reflecting the specifics of the socio-economic and legal systems of each country. In all three countries, the safety of medical procedures is ensured at the level of the constitutional right to healthcare. However, the mechanisms employed to fulfill the countries' constitutional mandates differ. Italy and Bulgaria employ the model of insurance medicine with active participation of private medical structures, while in Kazakhstan, the state plays a leading role in controlling and organising medical care. This factor substantially impacts assuring the safety of medical procedures and protecting the rights of patients and health workers (Millar, 2023).

The Italian model is characterised by the decentralised management of the healthcare system, which has the advantage of being able to accommodate specific regional features. Each region of Italy organises the provision of healthcare differently, such as, for example, variations in access to innovative technologies and levels of insurance coverage. This decentralised approach has disadvantages as well because it has created an imbalance in the quality and availability of health services, which in turn has sparked a debate on the need to more fairly harmonise regulatory standards to better ensure health security across all of Italy. For example, some regions have adopted more advanced digital systems and risk management protocols, while others lag behind, exacerbating healthcare inequalities.

Bulgaria is oriented towards European standards of medical safety, as evidenced by the fact it has actively implemented EU directives and regulations. However, in practice, the country faces challenges in law enforcement. One of the key challenges facing Bulgaria is protecting doctors' rights in the context of medical errors and professional liability. Although Bulgarian legislation provides for a system of professional liability insurance for medical professionals, the mechanisms used to implement the legislation have yet to be perfected, sometimes leading to litigation and a lack of reliable guarantees for doctors. These shortcomings can be remedied through not only a review of existing insurance mechanisms but also by introducing stricter legal guarantees for medical professionals, which is in line with the findings of Palm et al. (2020) on the need for a comprehensive approach to the protection of the rights of participants in the medical process.

Kazakhstan is actively introducing digital technologies into its healthcare system. In recent years, the country has seen active digitalisation of medical processes, including the creation of a unified medical database, the use of telemedicine, and the development of electronic medical records. However, gaps persist in the legal regulations that protectboth doctors and patients. For instance, despite introducing medical liability provisions, Kazakh practices lack a clear mechanism to protect medical professionals from unfair accusations, and patients do not always have sufficient tools to assert their rights.

The findings of the present study suggest that adopting digital technologies has a twofold impact: positively, they significantly improve process efficiency; negatively, they increase the risk of privacy breaches. This is in line with the observations of

Beauchamp & Childress (2019), who highlighted the significance of developing robust data protection mechanisms in the digitalisation of healthcare.

Table 2: SWOT-Analysis of Legal Regulation of Safety of Medical Procedures in Bulgaria, Italy, and Kazakhstan

Country	Strengths	Weaknesses
Bulgaria	Compliance with European standards of medical safety (EU directives). Developed insurance medicine. Protection of patients' rights within the framework of EU legislation	Underfunding of the healthcare system. Problems with the performance of insurance obligations. Lack of effective legal protection for health workers
Italy	Decentralised healthcare system tailored to regional needs. Legally codified procedures for informed consent. Implementation of national safety guidelines (e.g., Gelli-Bianco) with variable regional oversight	Regional disparities in service quality and access. Migration and demographic imbalances strain public health infrastructure. Lengthy and costly medical litigation contributes to defensive medicine
Kazakhstan	State control over medical security. Introduction of digital technologies in the sphere of healthcare. The latest legislation in the field of medical safety	Inadequate insurance coverage for health workers. Complexity of law enforcement practice. Bureaucratic barriers in the implementation of new medical standards
Country	**Opportunities**	**Threats**
Bulgaria	Further harmonisation of legislation with EU standards. Strengthening of the health insurance system. Development of programmes to protect patients' rights	Insufficient protection of doctors' rights may lead to a decrease in the quality of medical care. Outflow of qualified specialists to more developed EU countries
Italy	Potential for a national digital platform to harmonise safety monitoring. Strengthening interdisciplinary education in medicine and law. Expansion of structured alternative dispute resolution systems	Pressure on hospital capacity may hinder risk management. Regional autonomy in legislation may challenge legal consistency and equal protection of patient rights.
Kazakhstan	Creation of an effective system of professional liability insurance for doctors. Further digitalisation of medicine. Improvement of the regulatory framework based on international practices	Risk of corruption factors in the system of state regulation. Ineffective application of digital solutions without adaptation to the reality of healthcare

Source: compiled by the authors based on Code of the Republic of Kazakhstan No. 360-VI "On the Health of the People and the Health Care System" (2020), Constitution of the Republic of Kazakhstan (1995), Constitution of the Italian Republic (1947), Constitution of the Republic of Bulgaria (2003).

To compare the legal regulation of the safety of medical procedures in Bulgaria, Italy, and Kazakhstan more clearly, it is advisable to conduct a SWOT analysis. The SWOT method is useful not only because it helps to reveal the strengths and weaknesses of each system, but also because it can identify potential threats and opportunities for its further development. Considering the analysis, each country employs its unique approaches due to historical, socio-economic, and legal factors. However, despite their differences, all three countries have common ground, such as the desire to improve the quality of healthcare and protect the rights of patients and physicians. The SWOT analysis presented below helps systematize the principal aspects of legal regulation of the safety of medical procedures in the countries under study (Table 2).

Each of the states under study adopts a system of regulating the safety of medical procedures depending on its socio-economic reality. The Italian practices demonstrate the effectiveness of insurance protection for medical workers, minimising financial risks for doctors and patients. The Italian experience shows the importance of balancing regional autonomy with the need for uniform national standards, especially in areas like medical liability, data protection, and the use of clinical guidelines. Recent reforms have aimed to reduce variability and improve equity, but challenges remain in enforcement and coordination. The Bulgarian model shows the significance of adherence to European quality standards, although it requires further improvement of law enforcement practices. Kazakhstan relies on digitalisation and state control, which can increase access to medical care, but requires clarification of legal mechanisms to protect all participants in the medical process.

In the long term, each of these countries can learn useful lessons from the practices of the others. Italy could strengthen the harmonisation of medical safety standards, Bulgaria could improve the protection of medical professionals, and Kazakhstan could develop more explicit legal provisions governing professional liability and insurance in the medical field. Only a comprehensive approach and harmonising national legislation with international standards will help achieve a greater level of safety in medical procedures and the protection of the rights of all stakeholders.

3.3 Prospective Areas of Improvement of Legislation Considering the Best International Practices

The analysis of legal regulation of the safety of medical procedures in Bulgaria, Italy, and Kazakhstan, as well as the results of SWOT analysis, allows identifying promising areas for improving the legislation, considering the best international practices. The crucial task is to develop a system of medical workers' insurance protection, which has proven effective in Italy. Guaranteed insurance of doctors' professional liability helps not only to protect medical personnel from unjustified claims, but also to increase the general level of confidence in the healthcare system.

In Bulgaria and Kazakhstan, this mechanism still needs to be further developed: uniform insurance standards must be introduced, transparent procedures for dealing with medical incidents must be established, and a fair balance must be struck between the rights of patients and the responsibilities of medical institutions.

Another key area is the harmonisation of national legislation with international standards. Bulgaria, as an EU member state, has already largely adapted its legal regulations to the requirements of the EU. However, Kazakhstan should increase alignment with international documents such as the Convention on Human Rights and Biomedicine of the Council of Europe. At the same time, Italy – already bound by these instruments as an EU and Council of Europe member – should focus on ensuring they are consistently implemented across regions. This includes the uniform application of Directive of the European Parliament and of the Council No. 2011/24/EU "On the Application of Patients' Rights in Cross-Border Healthcare" (2011), the WHO recommendations, and the General Data Protection Regulation in managing digital health data. This will help to create a unified system for protecting patients' rights and ensuring uniform law enforcement.

Another vital aspect is the expansion of digitalisation and the introduction of medical information systems (Bali et al., 2019). Kazakhstan is already actively using digital technologies in the healthcare sector, but further development requires improved legal regulation in personal data protection. Italy, despite having a solid data protection framework under the General Data Protection Regulation and the Privacy Code of the Italian Republic (2003), still faces challenges in uniformly implementing digital security protocols across regions and healthcare facilities. Strengthening legal provisions in this area will not only increase citizens' trust in medical institutions but also minimise the risks of confidential data leakage, which is especially relevant in the era of digitalisation.

An equally significant area is the creation of uniform standards for the safety of medical procedures. Even though each of the countries under study already regulates medical safety at the level of national legislation, considerable differences persist in practice. Introducing mandatory international standards based on the recommendations of the WHO and the European Centre for Disease Prevention and Control will help minimise medical errors, improve the level of medical care, and unify approaches to safety in the medical sphere.

Other major steps in developing legislation should be the strengthening of state control and developing public monitoring. In Kazakhstan, the state plays the dominant role in ensuring the safety of medical procedures, while independent public institutions are not yet sufficiently involved in this process. In Italy and Bulgaria, independent expert organisations are more actively involved, and there are also social movements, which, in tandem, enable more transparent control of the quality of medical services. To improve legal regulation in this area, Kazakhstan must develop mechanisms of public control and independent expertise. At the same time, Bulgaria must strengthen state regulation to improve the efficiency of implementing existing provisions.

Finally, improving liability mechanisms for breaches of medical safety standards should be an essential area of reform. In the decentralised structure of the Servizio Sanitario Nazionale, resulting in heterogeneous application of medical liability laws and enforcement procedures across regions in Bulgaria, there are gaps in law enforcement, and Kazakhstan lacks clarity in professional liability insurance. Introducing more transparent and clear mechanisms of liability – administrative, civil, and criminal – would not only strengthen the protection of patients' rights but also create a fairer environment for health care workers, eliminating cases of unfounded accusations.

The findings of the present study demonstrate that the legal regulation of the safety of medical procedures in Bulgaria, Italy, and Kazakhstan has both common features and significant differences due to the specificity of national legal systems, economic conditions and the level of development of their healthcare systems. Comparison of the data with the results of previous studies confirms that integrating international standards into national legal systems requires continuous monitoring and adaptation of the regulatory framework, which is consistent with the findings of Ruppel et al. (2022). Introducing uniform standards and control mechanisms is the key to improving the quality of medical care and ensuring the protection of patients' rights.

4 Conclusions

The research that was conducted helped to identify the specific features and problems of legal regulation of the safety of medical procedures in Bulgaria, Italy, and Kazakhstan, as well as to assess the effects of international provisions on national healthcare systems. In each of the countries under study, the right to healthcare is set out at the constitutional level, but the mechanisms for fulfilling those constitutional mandates differ significantly. In Bulgaria, a mixed model of public and private care with insurance-based elements prevails. In Italy, the healthcare system is based on a universal, tax-funded public model, Servizio Sanitario Nazionale, where private structures also operate under accreditation by the public sector, which ensures a strong level of standards, but also creates problems related to accessibility of medical care. Kazakhstan, on the contrary, is oriented towards state regulation, which guarantees medical services for a broad audience, but requires stronger legal protection for patients and doctors.

An analysis of national legislation has identified key problems that must be addressed. One of them is that medical professionals are inadequately protected from legal risks. Bulgaria and Kazakhstan lack effective mechanisms for professional liability insurance, leaving doctors vulnerable to legal action. In Italy, although such a system is in place, its practical implementation and effectiveness still vary across regions due to differences in the interpretation of national guidelines and the availability of insurance plans. Another problem is inadequate patient protection mechanisms. In Bulgaria, despite implementing European standards, there are still challenges in law enforcement. In Kazakhstan, legal safeguards for patient protection must be improved, especially in the context of actively introducing digital technologies. Furthermore, there is no unified approach to the regulation of the latest medical technologies. In Italy, the decentralised healthcare system enables regions to independently set requirements for innovative procedures, which leads to heterogeneity in law enforcement practice. This variability adversely affects not only access to innovation but also the consistency of legal protections across regions. In Kazakhstan, the regulation of digital medicine is just emerging, which creates potential legal gaps.

To solve these problems, it is necessary to improve legislation that considers the best international practices. Critically, developing a system of professional liability insurance for medical workers, following the example of Italy, will help protect doctors from unfounded accusations and improve the quality of medical services. It is also necessary to strengthen control over observing patients' rights, including through adoption of mechanisms that can independently assess the quality of medical care. Introducing effective dispute resolution procedures is another reform that protects the interests of both patients and healthcare workers. A significant task is to harmonise national legal provisions with international standards. This is particularly crucial for Bulgaria within the framework of integration with the EU legal system. Italy, as an EU member, already complies with major international instruments, but should improve uniform application across its regions and reduce the disparity in enforcement practices. Furthermore, a unified legislative framework to regulate innovative medical technologies is required, as this will both minimise legal risks and increase the level of medical safety.

Thus, improving legislation in the field of safety of medical procedures should include enacting comprehensive measures to protect the rights of patients and medical workers, integrating international standards, and developing new legal mechanisms to regulate medical innovations. These steps will help improve the level of safety and quality of medical care in each of the countries under consideration and create a more effective and balanced system of regulation in this area.

The present study had certain limitations. Differences in law enforcement practices within each country complicate the proposal of universal recommendations. Furthermore, the analysis was based on existing regulations, but the dynamics of legislative changes require constant updating of data. This study focused primarily on the legal aspects of the safety of medical procedures, but further research could focus on a comprehensive analysis, including economic and social factors.

Prospects for further research in this area may be related to analysing the effectiveness of introducing digital technologies into the medical security system and investigating the legal aspects of the use of artificial intelligence in diagnostics and treatment. Also beneficial would be a comparative study of the national legislations of different countries to identify best practices and to develop unified international standards. Furthermore, a significant area of future research is to assess the effects of legal regulation on the quality of medical services and the degree of protection of patients' rights, which will help to create a more effective and balanced system of regulation in this area.

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Povzetek v slovenskem jeziku

Ta članek preučuje pravno ureditev varnosti medicinskih posegov in predlaga možnosti za zakonodajne izboljšave, oblikovane na podlagi mednarodnih standardov. Opravljena je bila primerjalnopravna analiza, ki je vključevala primere Bolgarije, Italije in Kazahstana. Študija je uporabila sistematično metodologijo za oceno pravne učinkovitosti ter napovedne tehnike za opredelitev možnih izboljšav. Ugotovitve razkrivajo, da vse tri države na ustavni ravni priznavajo pravico do zdravstvenega varstva, vendar se strategije izvajanja razlikujejo. Bolgarija in Italija uporabljata na zavarovanju temelječ zdravstveni sistem, ki vključuje sodelovanje zasebnega sektorja. Bolgarija se sooča z izzivi pri usklajevanju svoje zakonodaje z evropskimi standardi, medtem ko decentralizirani Servizio Sanitario Nazionale v Italiji povzroča regionalne razlike. Kazahstan ohranja državno usmerjen regulativni okvir, vendar mu primanjkuje celovitih pravnih zaščit za paciente in zdravstvene delavce, zlasti glede zavarovanja odgovornosti. Nobena izmed držav nima celovitega pravnega okvira za digitalno medicino. Ključni predlogi vključujejo izboljšanje zavarovalnih zaščit, uskladitev nacionalne zakonodaje z mednarodnimi standardi ter regulacijo novih medicinskih tehnologij.

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NASVAY AS A SMOKELESS TOBACCO PRODUCT: AN EXAMINATION OF METHODS OF USE, EFFECTS ON HEALTH, AND REGULATORY ASPECTS

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Abstract The purpose of the study is to evaluate the effect of nasvay on oral health in the Kyrgyz Republic. The study utilized a mixed-methods approach, combining a standardized questionnaire and dental examinations of 2,388 participants. It is determined that 32.9% of schoolchildren, 41.1% of students, and 35.7% of rural residents use nasvay. The prevalence rate is higher among men. The use of nasvay is associated with a high prevalence of dental diseases: leukoplakia, hyperaemia, and swelling of the mucous membrane. The index of caries, fillings, and lost teeth in users is 6.8. Among the methods of use, the most popular is in the cheek. It is discovered that the availability and low cost of nasvay contribute to its widespread use. The need for comprehensive preventive measures is emphasised, including increased regulation, educational campaigns, and reduction of economic dependence on the production of nasvay.

Keywords
mokeless tobacco, swelling of the mucous membrane,0 leukoplakia, smokeless tobacco warnings, periodontal disease, precancerous dental lesions

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1 Introduction

Smokeless tobacco, including nasvay, poses a serious public health problem, especially in Central Asian countries. Nasvay is widely used among various age and social groups in the Kyrgyz Republic, due to its accessibility and low cost. However, its use has a pronounced negative impact on oral health and the general condition of the body, which requires in-depth analysis and the development of regulatory measures. In conditions of weak legislative control and limited preventive work, the prevalence of nasvay continues to grow.

1.1 Nasvay: Composition, Patterns of Use, and Public Health Risks

A type of smokeless tobacco known as nasvay (sometimes spelt nasvar or nasvai) is traditionally used in Central Asia, especially in Kazakhstan, Uzbekistan, Kyrgyzstan, and portions of Afghanistan and Pakistan. Usually, a blend of slaked lime, ash, dried tobacco leaves, and different flavourings are used to make it. The product typically has a strong, pungent smell and is greenish in colour. Nasvay slowly releases nicotine and other chemicals into the bloodstream when users place tiny amounts of it behind their lower lip, under their tongue, or inside their cheek. This mode of ingestion produces a powerful addictive effect and quick absorption. Its popularity is linked to low cost, accessibility, and cultural acceptance, making it especially common among adolescents and rural populations. Patterns of use are shaped not only by availability but also by social norms and misperceptions. Many users, particularly students and manual labourers, view nasvay as less harmful than cigarettes and use it as a means of stress relief (Bazrafshan et al., 2024). Such beliefs, combined with limited health literacy, reinforce its persistence.

Nasvay presents serious health risks in spite of its low cost and rich cultural heritage. According to studies, it contains carcinogenic substances like heavy metals and nitrosamines, which raise the risk of gastrointestinal issues, periodontal disease, and oral cancers. Long-term use has also been connected to chronic nicotine dependence, gum recession, and dental erosion (Iqbal et al., 2025). Furthermore, using tobacco and lime together can irritate the oral mucosa, increasing the risk of lesions and precancerous conditions.

Nasvay use during pregnancy carries significant risks for the mother and foetus because nicotine and carcinogenic compounds easily pass through the placental barrier, decreasing uteroplacental blood flow and compromising the delivery of oxygen and nutrients. Evidence from a study conducted in Pakistan's Thatta District revealed that smokeless tobacco usage more than doubled the risk of negative outcomes (Mufaddal et al., 2024). In addition to raising the risk of preterm delivery and stillbirth, this exposure directly contributes to intrauterine growth restriction, low birth weight, and increased neonatal susceptibility to respiratory disorders and developmental delays. These results highlight the critical need for rigorous regulation of nasvay use among women of reproductive age and preventive education.

Nasvay regulation is still a major public health concern, especially in South Asian nations where its use is common and deeply ingrained in the culture. With little enforcement of current tobacco control laws and few public awareness campaigns highlighting the risks of nasvay, Pakistan's efforts to curb it have been patchy (Ochani et al., 2022). Since nasvay is frequently made and distributed informally, unlike cigarettes, it is challenging to control its composition, sale, and accessibility, particularly among young people and those with low incomes.

1.2 Impact of Nasvay on Oral Health

The use of smokeless tobacco, such as nasvay, has been linked to a variety of adverse oral health conditions, which pose a significant public health concern. The precancerous lesion known as leukoplakia, which appears as white patches in the oral mucosa, is one of the most prevalent conditions linked to its consumption. Usually, the chemicals in smokeless tobacco, like nicotine, and alkaline substances like lime, cause these lesions through long-term irritation. Leukoplakia is a well-documented risk factor for oral cancer, which is much more common in smokeless tobacco users than in non-users (Kravchenko & Lykhota, 2024). If treatment is not received, the prolonged irritation caused by nasvay use results in epithelial changes that raise the risk of cancer.

Smokeless tobacco users also frequently experience mucosal hyperaemia, or inflammation of the oral mucous membranes. Because of its alkaline qualities, lime in nasvay irritates the mucosa, increasing blood flow and redness. If this inflammatory reaction continues, it may lead to more serious oral health issues like tissue erosion and ulcers (Muthukrishnan & Warnakulasuriya, 2018). Oral health is further compromised by chronic mucosal inflammation, which also increases the susceptibility of oral tissues to secondary infections.

Nasvay users are also more likely to have periodontal disease, such as gingivitis and periodontitis. It has been demonstrated that smokeless tobacco weakens the gums' immune system, leaving them more vulnerable to inflammation and infection. Periodontal diseases affect the structural integrity of the teeth and surrounding tissues, and they are especially concerning because they can result in tooth loss if left untreated. According to research, using smokeless tobacco makes these conditions worse and raises gum disease rates when compared to non-users (Kolte et al., 2025; Mammadov et al., 2022). The association between tobacco products and various oral diseases was further highlighted by Alamer et al. (2024), who also pointed out that Americans who use smokeless tobacco are more likely to develop periodontitis and its complications.

Nasvay use over an extended period of time is linked to a higher risk of oral cancer. Oral tissues gradually deteriorate due to the carcinogenic qualities of tobacco and its chemical additives, including tar and heavy metals. Smokeless tobacco greatly increases the risk of developing cancerous lesions in the mouth because of its direct and extended contact with the mucosa (Chaffee et al., 2022). Public health initiatives to reduce the use of smokeless tobacco are desperately needed, as evidenced by the cumulative effect of these harmful substances, poor oral hygiene, and a lack of preventive care.

1.3 An Analysis of Nasvay in Central Asia

One of the critical problems is the high prevalence of use among young people. Oskonbaeva (2021) has shown that smokeless tobacco is becoming increasingly popular among teenagers, due to its accessibility and lack of prohibitions. The paper highlights that young people make up about 40% of all users of nasvay, with many starting to use it at the age of 12-14 years. However, the author did not address the issue of differences in the methods of consumption among different age groups and their impact on health. The problems associated with the effects of nasvay on oral health remain poorly understood. Stepanov et al. (2017) investigated the effect of smokeless tobacco on the condition of the oral mucosa and noted that regular consumption of tobacco increases the risk of developing leukoplakia (precancerous white patches in the mouth) and mucosal hyperplasia. Their data showed that the risk of dental diseases in smokeless tobacco users is twice as high as in non-smokers. However, the study did not include a detailed analysis of the effects of lime as a product with a unique composition, including lime and ash.

The methods of using nasvay also play an important role in the development of complications. Shats et al. (2018) stated that putting smokeless tobacco in the cheek leads to localised tissue damage, while using it under the lip and tongue increases the risk of generalised dental problems. However, this study was limited to adult users, without considering the characteristics of adolescents and young people. Epidemiological data show that the availability and low cost of nasvay contribute to its widespread distribution among rural residents. Bekbasarova et al. (2022) indicated that nasvay is available in more than 80% of rural regions, and its cost is 3-4 times lower compared to cigarettes. This makes it especially popular among low-income people. However, their study lacked an analysis of the social and cultural factors influencing nasvay consumption.

The lack of effective regulation exacerbates the problem. Saxena et al. (2022) underline that the weakness of legislation regulating the quality and labelling of smokeless tobacco leads to a high level of illegal production and a lack of control over the content of toxic components. However, their work was limited to analysing the markets of Southeast Asia and did not cover the countries of Central Asia, including Kyrgyzstan, where the problem is particularly relevant. The effect of nasvay on the index of caries, fillings, lost teeth (CFL) and the periodontal index (PI) also requires further study. Gupta et al. (2022) demonstrated that smokeless tobacco users have an average CFL index 30% higher than non-users. Their data confirm that regular intake of nasvay is associated with a high risk of caries and inflammatory gum diseases. However, the authors did not analyse the effect of the lime-based composition on the mineralisation of tooth enamel. The problem of educational campaigns and informing the public about the dangers of smoking remains relevant. Gangwani et al. (2024) and Gupta et al. (2021) showed that in India, where regular educational programmes are conducted, the use of smokeless tobacco decreased by 15-20% between 2017 and 2021. However, their recommendations do not account for the specifics of Kyrgyzstan, where the population is poorly aware of the risks associated with nasvay, and access to medical services is limited in rural areas.

The purpose of the study is to examine the ways of using nasvay and their impact on the oral cavity, as well as to analyse the regulatory framework for improving smokeless tobacco control. The objectives of the study include the analysis of the prevalence of tobacco use among various population groups, the analysis of dental diseases associated with its use, the assessment of risk factors, and the development of recommendations to strengthen the prevention and regulation of smokeless tobacco.

2 Materials and Methods

The study was conducted in the Kyrgyz Republic in 2024 from September 1 to December 31 and covered two regions: Osh city and the Batken region. The sample included 283 students from secondary school No. 4 named after Kirov in Osh, 394 students of Osh State University, and 1,711 residents of the village of Abdusomat, Kadamzhai district, Batken region. Among schoolchildren, 79.5% (225 people) were boys, and 20.5% (58 people) were girls. The age distribution was as follows: 15 years – 69 people, 16 years – 115 people, 17 years – 99 people. Among the students, the proportion of men was 72.8% (287 people), women – 27.2% (107 people). The age structure of the students included groups of 18-19 years old (89 people), 20-21 years old (159 people), and 22-23 years old (146 people). The inhabitants of the village of Abdusomat represented a total population of 230 families, among which men accounted for 50.1% (858 people), women – 49.9% (853 people). Children under the age of 14 accounted for 39.7% (680 people) of the population.

The study used a standardised questionnaire, which was prepared by the authors, who incorporated relevant questions based on existing literature and expert input in the field of tobacco use and oral health. It included questions aimed at collecting information about the frequency, methods, and places of nasvay use, as well as about side effects and the level of awareness of respondents. The questionnaire contained sections covering the general data of the respondents (age, gender, place of residence, level of education), their experience of using nasvay (first experience, frequency, reasons for use), methods of use, observed side effects, level of awareness about the dangers of nasvay and its legislative regulation. For example, respondents were asked if they used nasvay, at what age they started, what reasons prompted them to use it, and whether they noticed a deterioration in their health or addiction. Additionally, questions were asked about whether they were aware of the health risks and legal restrictions, as well as their opinion on measures aimed at reducing consumption. In total, the questionnaire contained a total of 20 questions.

The survey was conducted both on paper and using electronic platforms. Paper questionnaires were used for Osh secondary school students and residents of the village of Abdusomat, while electronic forms created on the Google Forms platform and in the SurveyMonkey application were used for Osh State University students. This approach allowed the survey to reach a wide range of respondents, making it accessible to different groups.

The respondents were divided into two groups to analyse the data: experimental (people who use nasvay) and control (people who do not use it). The experimental group included 1,649 participants who used nasvay for different periods, and the control group included 739 people who had never used nasvay. Among the participants of the experimental group, a further distribution took place according to the duration of nasvay use: (1) less than one year, (2) from one to five years, (3) more than five years. This separation helped assess the progressive impact of nasvay on oral health.

The dental examination was conducted at Osh Regional Dental Clinic No. 1 to identify damage to the oral mucosa associated with the use of nasvay. The examination was conducted on 1,454 participants from the experimental group, divided into groups depending on the duration of nasvay use. Dental mirrors, probes, and lighting devices manufactured by Dentsply Sirona (USA) were used for the examination. The examination included a visual inspection of the oral mucosa with special attention to the areas in contact with the substance. Dental indices, including CFL, PI, and the Green-Vermillion index, were calculated to assess the hygienic condition of the oral cavity. Signs of leukoplakia, ulcers, hyperaemia, and swelling of the mucous membrane were visually detected. The survey included 1,454 people, of whom 71.9% needed oral sanitation.

The study examined the legislative acts of the Kyrgyz Republic, including the Law of the Kyrgyz Republic No. 121 "On Protection of Health of Citizens of the Kyrgyz Republic from the Consequences of Tobacco Consumption, Nicotine and Exposure to Ambient Tobacco Smoke and Aerosols" (2021). International standards included the World Health Organisation Framework Convention on Tobacco Control (WHO

FCTC) (2025) and Partial Guidelines for the Implementation of Articles 9 and 10 of the WHO FCTC (2017). Publications on the effects of nasvay on health were analysed using PubMed, Scopus, Web of Science databases and reports from international organisations such as the World Bank (2024) and WHO FCTC (2012).

The Statistical Package for the Social Sciences (SPSS Statistics) (2025), version 27, was used for data processing. Descriptive statistical methods were used, including the calculation of averages and standard deviations.

All manipulations related to the survey of the respondents' health were performed in strict accordance with the principles of the Declaration of Helsinki (World Medical Association, 2013), the voluntary consent of the participants, and compliance with ethical standards.

3 Results

Nasvay use remains one of the most widespread forms of tobacco use in Central Asia, especially among young people and rural populations. According to the WHO FCTC (2012), about 20-30% of the region's residents have used nasvay at least once in their lives, and in some age groups this figure can reach 40%. Bekbasarova et al. (2022) confirmed that in several rural areas of Kyrgyzstan, the prevalence of nasvay consumption among men exceeds 50%, which makes it one of the key risk factors for public health. In addition, according to Oskonbaeva (2021), more than 60% of nasvay users started using it in adolescence, which is due to social accessibility and a lack of educational programmes. This high prevalence is due to several factors: the ease of access to the product, its low cost, cultural traditions, and lack of awareness among the population about the dangers of smokeless tobacco. In rural areas, nasvay is often perceived as a "traditional" product that increases vigour and productivity, especially among men. The low level of government regulation, the lack of age restrictions on purchases, and the absence of preventive programmes additionally exacerbate the problem. The spread of nasvay among adolescents and young people is associated with the mistaken perception of it as a less harmful alternative to cigarettes, which contributes to the development of addiction and the formation of long-term health risks.

The prevalence of its use shows substantial differentiation among different age and social groups, reflecting the depth of the problem (Table 1). Among the students of secondary school No. 4 named after Kirov in Osh, 32.9% of respondents use nasvay. This figure is substantially higher among boys and amounts to 38.6%, while among girls, it is only 10.3%. This difference is related to gender-specific social expectations and the lower involvement of girls in risky behaviour. However, even these indicators exhibit an increasing trend in the participation of adolescents in the use of harmful substances.

Table 1: Prevalence and methods of nasvay use among various population groups

Population group	Total amount	Heavy users (%)	Methods of use	Men (%)	Women (%)
Schoolchildren (the city of Osh)	283	32.9	In the cheek – 70%, under the lip – 20%, under the tongue – 10%	38.6	10.3
Students (Osh State University)	394	41.1	In the cheek – 50%, under the lip – 30%, under the tongue – 20%	47.7	22.4
Rural population (Batken region)	1711	35.7	Under the lip – 40%, under the tongue – 35%, in the cheek – 25%	42.1	29.3

Source: compiled by the authors.

The nasvay consumption is even more widespread among Osh State University students, amounting to 41.1%. In male students, this figure reaches 47.7%, which is substantially higher than the proportion of women, which is 22.4%. The differences between men and women in this group may be due to both cultural norms and the perception of nasvay as a "traditional" product among men. For students, nasvay is often associated with an affordable stress reliever, especially during exam sessions, which underscores the need for targeted preventive measures in educational institutions.

The rural population of the Batken region demonstrates a high prevalence of nasvay consumption – 35.7%. Here, men (42.1%) are substantially more likely to use nasvay than women (29.3%). This difference can be explained by the greater involvement of men in agricultural work, which is often used to maintain vigour during the day. In addition, limited access to information about the dangers of nasvay and poor preventive work in rural areas exacerbate the problem. Special attention should be paid to the fact that the use of nasvay among young people and rural populations is associated with its accessibility and low cost. It is perceived as a harmless alternative to tobacco products, which creates a false sense of safety among users. This situation requires strengthening prevention programmes, including awareness-raising among young people, educational events, and public awareness of the long-term effects of nasvay use.

The analysis of the data from the table displays a variety of methods of nasvay consumption among various social and age groups. Among secondary school pupils, the dominant method is to put it in the cheek (70%), which is due to the desire for secrecy and minimising social risks. This method allows students to avoid being judged by parents and teachers, as the visual and behavioural signs of use are less noticeable. There is a more mixed picture among students. Although the in-the-cheek method remains the most common (50%), the percentage of students who place it under the lip (30%) and under the tongue (20%) is noticeably increasing. This is due to greater freedom in the behaviour of students and the availability of information about various ways of consumption, obtained both from the Internet and peers.

Other trends are observed in rural areas. Here, placing nasvay under the lip (40%) and under the tongue (35%) is more common than using the in-the-cheek method (25%). This is due to traditional practices and the convenience of using it during physical work outdoors. Placing nasvay under the lip and tongue allows it to stay longer, which is important for the rural population engaged in hard work, where the distraction of frequent substance replacement is undesirable. On the contrary, putting it in the cheek is used less often since this method dissolves nasvay faster, requiring more frequent replacement. Such a difference in the methods of consumption may be due to cultural, behavioural, and age factors. For example, in rural areas, women hide consumption more often, which explains the popularity of methods that minimise the visibility of the process, such as putting it under the tongue.

Nasvay, as a form of smokeless tobacco, has a substantial negative impact on oral health. The main component of nasvay is tobacco containing nicotine in concentrations up to 30 mg/g, which is several times higher than the level of nicotine in conventional cigarettes. Alkali, as a rule, is represented by slaked lime, which is necessary for the release of free nicotine, which enhances its addictive effect. However, the same compound destroys the epithelial barrier of the mucous membrane, increases its permeability, and promotes the development of chronic inflammation (Khan et al., 2019). Lime in the composition has a corrosive effect on the mucous membrane, provoking microtrauma and irritation. Thus, regular exposure to these components leads to tissue hyperplasia, the formation of leukoplakia, and other pathological changes that can develop into oncological diseases. Additives in the composition of nasvay, such as ash, are abrasive substances that worsen damage to the mucous membrane, increasing the risk of infections (Ahmad et al., 2020).

Dental examinations of the study participants showed a substantial deterioration in the condition of the oral cavity in those who use Nasvay compared to non-users. Of the examined 1,454 participants, 71.9% needed oral rehabilitation. Leukoplakia, ulcers, hyperaemia, and swelling of the mucous membrane were the most common pathological changes. These changes are explained by the effect of the chemical composition of the substance containing lime and alkali, which aggressively affects the tissues of the oral cavity. A comparative analysis showed that the CFL and PI indices were substantially higher for those who consumed nasvay than for those who did not (Table 2).

Table 2: Comparative analysis of dental indicators between users and non-users

Indicator	Heavy users (average value)	Non-users of nasvay (average value)	Differences (% or p-value)
CFL index	6.8	4.2	p<0.01
The PI Index	65.4%	34.2%	p<0.01
Leukoplakia (%)	23.1%	4.8%	+381%
Hyperaemia (%)	48.7%	19.6%	+148%
Mucosal oedema (%)	34.5%	8.3%	+316%

Note: The difference column shows the percentage increase in the prevalence of oral health issues (leukoplakia, hyperaemia, and mucosal oedema) among nasvay users compared to non-users.
Source: compiled by the authors.

The results of the study demonstrate a high prevalence of dental diseases in nasvay users, which indicates a substantial impact of this product on oral health. Leukoplakia, which is characterised by changes in the mucous membrane, was detected in 23.1% of users. This is four times higher than in the control group of non-user drinkers, which indicates a chronic irritation of the oral cavity tissues by the components of the nasvay, in particular, lime and tobacco. The hyperaemia and swelling of the mucous membrane observed in nasvay users were also substantially more common than in the control group (48.7% and 19.6%, respectively), which confirms the aggressive effect of the substance on soft tissues. The chemicals contained in nasvay create an irritating effect, contributing to the development of inflammatory processes. These changes increase the risk of secondary infections and the transition of pathologies to a chronic form.

The CFL index, which is an indicator of the general condition of the teeth, was 6.8 for nasvay users, which is substantially higher than in the control group, where it is 4.2. These data highlight the increased caries rate and the need for dental treatment among this group. This is due to the destructive effect of nasvay on tooth enamel and increased acidity of the oral cavity, which creates favourable conditions for the development of caries. The PI index, which reflects the condition of the soft tissues of the oral cavity, was 65.4% among nasvay users, which is almost twice as high as in the control group. This indicates the prevalence of inflammatory periodontal diseases such as gingivitis. The constant exposure to toxic substances contributes to the deterioration of the periodontal condition, reducing tissue resistance and increasing the risk of damage. Thus, the use of nasvay drastically worsens the condition of the oral cavity, which requires attention from both dentists and public health specialists.

The duration of nasvay consumption had a substantial impact on the state of oral health, which manifested itself in a pronounced correlation between the duration of use and the degree of damage to the mucous membrane and teeth. In people who have been using nasvay for more than 5 years, the CFL and PI indices were 15% higher compared to users with shorter use terms. This indicates an increasing negative effect of the toxic components of nasvay on the tissues of the oral cavity with longer use time. Ulcers and erosions on the mucous membrane were more often detected in this group, which may be due to prolonged exposure to irritating substances such as lime and carcinogens contained in the substance. The incidence of leukoplakia, characterised by precancerous mucosal changes, was 12% higher in long-term users, which highlights the progressive nature of tissue damage. Statistical analysis of the data confirmed the significance of the differences between the groups ($p<0.01$), which indicates a high degree of correlation between the duration of nasvay consumption and the deterioration of the oral cavity. This highlights the need to consider the length of use when assessing the risk of dental diseases among users of nasvay.

Pathogenetic changes caused by nasvay include destruction of the epithelial barrier and inflammatory processes associated with exposure to alkaline components. These chemicals increase tissue permeability, cause chronic inflammation, and contribute to the development of precancerous conditions. Nicotine additionally increases vascular disorders and leads to tissue hypoxia, worsening the general condition of the mucous membrane.

An analysis of the legal framework of the Kyrgyz Republic revealed insufficient regulation of smokeless tobacco, including nasvay use, which significantly reduces the effectiveness of measures to protect public health (Table 3). The main legislative acts, such as the Law of the Kyrgyz Republic No. 121 "On Protection of Health of Citizens of the Kyrgyz Republic from the Consequences of Tobacco Consumption, Nicotine and Exposure to Ambient Tobacco Smoke and Aerosols" (2021), focus primarily on restrictions related to traditional tobacco products such as cigarettes. Smokeless tobacco is mentioned only superficially in this regulatory framework, which leaves substantial regulatory gaps.

Table 3: Comparative analysis of the legislation of the Kyrgyz Republic and WHO international standards

Regulation parameter	Kyrgyz Republic	WHO International Standards	Gaps in the legal framework
Prohibition on sale to minors	Implemented	Recommended	Compliance control is weak
Product labelling	Basic information	Detailed warnings about the dangers	Insufficient warnings
Restriction on advertising	Partial	Full	Advertising is indirectly allowed
Quality and composition standards	Not regulated	Implemented	Absent
Liability for violation	Moderate fines	Stringent sanctions	Insufficient penalties

Source: compiled by the author based on Law of the Kyrgyz Republic No. 121 "On Protection of Health of Citizens of the Kyrgyz Republic from the Consequences of Tobacco Consumption, Nicotine and Exposure to Ambient Tobacco Smoke and Aerosols" (2021), WHO FCTC (2012).

Law of the Kyrgyz Republic No. 121 "On Protection of Health of Citizens of the Kyrgyz Republic from the Consequences of Tobacco Consumption, Nicotine and Exposure to Ambient Tobacco Smoke and Aerosols" (2021) establishes minimum requirements for regulating the quality of smokeless tobacco products, including nasvay. The main focus is on compliance with sanitary standards at the stage of production and sale, but there are no specific standards for the control of toxic substances. Substances such as heavy metals (lead, cadmium) and calcium oxide hydrate are not subject to mandatory testing, which poses risks to consumer health. In addition, the law does not provide for mandatory certification of products, which allows manufacturers to avoid inspections and limit their responsibility for the quality of goods. A separate disadvantage is the lack of a requirement to indicate the full composition of the product on the package. This deprives consumers of the opportunity to obtain reliable information about the content of the product. The law also does not oblige to post health warnings, which contradicts the international recommendations developed by WHO FCTC (2012). Such measures are insufficient to prevent the negative effects of nasvay consumption and to raise public awareness.

The WHO, in its recommendations set out in the Partial Guidelines for the Implementation of Articles 9 and 10 of the WHO FCTC (2017), stresses the need for strict regulation of smokeless tobacco products. The main provisions include mandatory testing and certification of products to identify toxic substances such as heavy metals and alkalis. The organisation insists on introducing restrictions on the content of such substances to minimise their harmful effects on health. In addition, WHO recommends that manufacturers indicate the full composition of the product and publish the results of laboratory tests, ensuring transparency of information. One of the key measures is the mandatory placement of health warnings on product packaging, including graphic images. These warnings should cover at least 50% of its area. The WHO also stresses the importance of banning the addition of flavourings and other substances that may make nasvay more attractive, especially to young people.

Unlike international standards, the existing norms in the Kyrgyz Republic do not oblige manufacturers to test or specify the composition of the product. This creates a risk of products with a high content of toxic components appearing on the market. For example, the European Union and the United States have introduced strict rules that mandate the testing of each batch of smokeless tobacco and the control of its composition at the state level (Hatsukami et al., 2014). Such measures ensure a high level of protection of citizens' health. The lack of such an approach in Kyrgyzstan increases the risk of negative consequences for public health, especially among young users, who most often perceive nasvay as a safe alternative to tobacco products. The incorporation of WHO recommendations into national legislation, such as limiting the content of calcium oxide hydrate, mandatory product testing, and the introduction of graphic warnings, can substantially diminish the prevalence of nasvay use and reduce the associated risks. This will strengthen the legal framework and improve the effectiveness of measures to protect public health.

Gaps in legislation also complicate the monitoring and management of the production, import, and sale of nasvay, which contributes to its widespread and uncontrolled dissemination. Bekbasarova et al. (2022) show that the concentration of these substances varies depending on the region and the manufacturer, which indicates a complete lack of regulation of the technological processes of the production of nasvay. In addition, the lack of clear control over the production of nasvay makes it difficult to track its origin and its constituent components. This makes it difficult to take harm reduction measures and inform consumers.

Restrictions on advertising smokeless tobacco in the Kyrgyz Republic remain partial and do not cover the full range of marketing strategies, which allows manufacturers to use indirect approaches such as sponsorship of events, neutral branding, and the absence of warnings about the dangers of the product. This approach substantially lowers the effectiveness of tobacco control, especially among young people, who are most susceptible to advertising. The international standards proposed by WHO within the framework of the FCTC (2025) offer tougher and more comprehensive measures that have proven effective in reducing tobacco consumption.

One of the fundamental aspects is the complete ban on advertising, promotion, and sponsorship of tobacco products provided for in Article 13 of the FCTC. These measures include the prohibition of both direct advertising and indirect methods such as the use of colours, images, or logos associated with the brand. Such a ban is aimed at minimising the impact of marketing on young people and at-risk groups. Therefore, the existing legislation of Kyrgyzstan allows for the maintenance of elements of indirect marketing, which reduces the effectiveness of control over tobacco products. Another important standard is the unified packaging and labelling of tobacco products described in FCTC Article 11. International recommendations require the mandatory placement of health warnings with images that cover at least 50% of the packaging area. A unified packaging design is also used, eliminating any advertising elements. Such measures lessen the attractiveness of tobacco products and promote awareness of their harm among the population.

The control of minors' access to tobacco products is another critical part of international standards. According to Article 16 of the FCTC, states undertake to take measures to prevent the sale of tobacco products to persons under the age of 18. However, in Kyrgyzstan, despite the existence of legislative restrictions, control over the sale of nasvay remains weak. The survey data shows that teenagers can easily purchase nasvay at markets or kiosks. This indicates insufficient implementation of legislation and disregard for WHO recommendations in this area. The effectiveness of the implementation of international standards is confirmed by the examples of countries that have successfully enforced strict control measures. For example, where a complete ban on advertising and uniform packaging with graphic warnings has been introduced, a substantial decrease in the smoking rate among young people is observed (McNeill et al., 2017). In Thailand, stringent restrictions on advertising and large warnings about the dangers of the product have led to a decrease in the attractiveness of smokeless tobacco (Amul et al., 2020).

The implementation of comprehensive measures provided for by the FCTC, including a complete ban on advertising, strict control over the sale to minors, and unified packaging, is necessary to increase the effectiveness of tobacco control in the Kyrgyz Republic. These measures not only contribute to reducing consumption but also contribute to improving public health by preventing the long-term negative effects of smokeless tobacco use. Reducing the level of nasvay consumption requires the implementation of a multi-level approach, including educational initiatives, improvement of public policy, and the introduction of comprehensive preventive measures. The basis of this approach is to inform the public about the health risks associated with nasvay use. The above study showed that only 24% of respondents are aware of the possible link between the use of nasvay and oncological diseases of the oral cavity. This indicates the need for targeted information campaigns aimed at raising awareness.

Educational programmes should cover schoolchildren, students, and the adult population, including groups at high risk of nasvay use. Integrating relevant topics into school curricula, especially in health and biology lessons, will ensure early prevention. Practical exercises that include demonstrations of the medical effects of nasvay use, such as photographic materials and patient reports, can be particularly effective. In addition, universities can organise lectures and seminars for students, where medical experts and representatives of public organisations will be able to convey to young people the importance of giving up this bad habit. The use of multimedia formats such as videos, social media, and street advertising is necessary for wide coverage. Materials should be tailored to the target audience, focusing on the long-term effects of nasvay consumption, including tooth loss, lesions of the oral mucosa, and the development of cancers. It is important to emphasise the negative impact on the quality of life, which especially affects young people who tend to perceive unhealthy habits as "harmless".

The improvement of public policy should begin with the development of standards for the production of raw materials. Setting maximum permissible concentrations of toxic substances such as nicotine, nitrosamines, and heavy metals will be the first step in limiting the harmful effects of this product. An analysis of international experience shows that in countries where strict standards and production controls have been introduced, there has been a substantial decrease in smokeless tobacco consumption. For example, in India, after standards more stringent for smokeless tobacco, its use decreased by 40% within five years (WHO FCTC, 2025). Banning advertising and marketing is an important element of a comprehensive approach. In Kyrgyzstan, it is possible to apply models that have been successfully implemented in EU countries, where tobacco advertising is prohibited. This will minimise the impact on young people, who are most susceptible to aggressive marketing strategies. Monitoring of compliance with such measures should be strengthened by coordinating the efforts of health authorities, law enforcement agencies, and public organisations.

It is important to offer alternative economic programmes to support economically dependent groups of the population. The introduction of subsidies and grants for farmers to switch to other crops, such as cotton or cereals, can reduce rural residents' dependence on tobacco production. Additionally, it is necessary to organise educational programmes for farmers and entrepreneurs aimed at mastering new skills and increasing the competitiveness of their products on the market. Financing measures to combat tobacco use through international grant programmes and taxes on tobacco products are an important tool for regulating smokeless tobacco consumption and protecting public health. International organisations such as the

World Bank (2024) and the WHO FCTC (2012) provide targeted resources and recommendations to countries for the implementation of effective measures to reduce tobacco use, including nasvay.

The World Bank's initiatives are aimed at increasing excise taxes on tobacco products, which makes them less accessible to the public, especially to young people and socially vulnerable groups. The funds received from such taxes can be used to finance educational programmes, improve the health system, and monitor tobacco use. For example, a substantial portion of the proceeds can be used to develop prevention campaigns aimed at schoolchildren, students, and rural populations, as well as to support medical institutions involved in the treatment of diseases caused by tobacco use. In addition, the World Bank helps countries establish sustainable financing mechanisms to combat the tobacco epidemic by allocating resources to long-term programmes. WHO FCTC (2017) provides technical and financial support to countries. The Convention covers a full range of measures, including a complete ban on tobacco product advertising, the introduction of standardised packaging, and mandatory certification. Under this programme, countries gain access to grants that can be used to implement graphic warnings on their packages, conduct mass educational campaigns, and strengthen control over production and sales. WHO also supports the monitoring of tobacco consumption, which allows for the assessment of the effectiveness of implemented measures and the prompt adjustment of the strategy.

The initiatives of the World Bank (2024) and WHO (WHO FCTC, 2012; 2017; 2025) help to regulate the consumption of nasvay by increasing excise taxes, which would make the product less affordable, especially for young people. These funds can be used for educational activities, including awareness raising in schools, universities, and rural areas. Additionally, international grants allow for the introduction of strict laws governing the production, sale, and advertising of nasvay, which reduces its spread. In addition, financial support contributes to improving the diagnosis and treatment of nasvay-related diseases. This is achieved through the modernisation of medical institutions and the training of specialists. Another important area is the creation of alternative sources of income for farmers who grow raw materials for the production of nasvay (Ahmad et al., 2020). International grants can be used to support their transition to less harmful and more profitable crops. Communities and local leaders play a vital role in reducing nasvay use, as their influence on public opinion and behaviour often exceeds the effect of official government campaigns. Involving spiritual, cultural, and community leaders in anti-nicotine initiatives can substantially raise public awareness of the dangers of cannabis and convince people to stop using it.

Spiritual leaders, such as imams in rural and urban regions of Kyrgyzstan, can use their platform to inform about the dangers of nasvay and its impact on health (Bekbasarova et al., 2022). Including this topic in Friday sermons or other religious events can be an effective way to communicate information to a wide audience. Such messages, supported by religious or moral arguments, are often received with great trust, especially in rural communities where religion plays a substantial role in everyday life. Cultural leaders, including local poets, musicians, and artists, can also contribute to the fight against nasvay use by integrating information about the dangers of tobacco into their work. For example, organising cultural events dedicated to a healthy lifestyle or creating works of art with anti-nicotine messages can be an effective way to attract the attention of young people (Ochani et al., 2022).

Non-governmental organisations (NGOs) are instrumental in developing local programmes tailored to the needs and specificities of specific population groups (Mehta & Sharma, 2022). For example, in rural areas where information about the dangers of smoking is limited, NGOs can organise training, round tables, and educational campaigns involving health workers, teachers, and residents themselves. Non-governmental organisations can also be key partners in conducting research aimed at evaluating the level of nasvay use and developing targeted programmes to reduce it.

The involvement of local communities is of particular importance in rural areas where traditional values play an important role (Mehta & Sharma, 2022). Initiatives that involve the active participation of the population, such as the creation of youth health clubs and the organisation of sports events and competitions on the topic of a healthy lifestyle, contribute to the formation of negative attitudes towards nasvay consumption. Thus, the involvement of local leaders and communities ensures the creation of more effective, targeted, and sustainable initiatives to reduce nasvay use. Their participation helps adapt programmes to the cultural, social, and economic characteristics of the region, which increases the chances of success and long-term change in the behaviour of the population.

In conclusion, reducing the level of nasvay consumption is possible only if an integrated approach is applied, combining educational initiatives, government regulation, and economic support. This approach will enable the achievement of a sustainable reduction in smokeless tobacco consumption, enhance public health, and improve the quality of life in Kyrgyzstan in general.

4 Discussion

The results of the study demonstrate a high prevalence of nasvay use in various population groups in Kyrgyzstan, especially among schoolchildren and students. Thus, among secondary school pupils, the level of nasvay consumption is 32.9%, which coincides with the conclusions of Solhi et al. (2021) who examined a similar problem in Tajikistan. Their paper also noted the substantial involvement of adolescents in the use of cannabis due to its availability and low cost. However, unlike Brinchmann et al. (2022), who recorded a lower awareness of adolescents about the dangers of smoking, the study showed that schoolchildren are aware of the negative consequences, but underestimate them, which requires increased preventive work in educational institutions.

41.1% of students use nasvay, which is higher than among schoolchildren. Men use it much more often than women. These results are consistent with the conclusions of Singhavi et al. (2021), which link such gender differences with cultural traditions and the perception of nasvay as a "manly" product. However, the study determined that students use nasvay more often during stressful periods such as exams, which proves the data obtained by Dhage & Nagtode (2024) on the effect of nasvay on anxiety reduction. However, while Hatami et al. (2024) argued about the uniform popularity of nasvay among students of different specialities; higher rates of use among students of technical faculties were identified, which is associated with a higher level of stress in their studies.

The level of nasvay consumption among the rural population of the Batken region was 35.7%. These data are consistent with the findings of Reed et al. (2021), who noted that in rural areas of Central Asia, nasvay is often used to maintain energy during physical work. Unlike Jerez et al. (2024), who linked the use of nasvay with economic factors, this study established that the rural population perceives nasvay as part of a cultural tradition, which makes it difficult to take preventive measures.

Zia & Kashif (2022) also stressed that in rural areas, the availability of alternative products such as nicotine patches or chewing gum is extremely limited, which increases tobacco dependence.

The analysis of dental indicators confirmed a substantial deterioration in the oral cavity of the nasvay users. The CFL index was 6.8, which is substantially higher than that of non-users. This is in line with the results of Stjepanović et al. (2022), which connect nasvay with the destruction of tooth enamel. In contrast to the paper of Malhotra et al. (2021), it was recorded that users of nasvay in Kyrgyzstan are more likely to have leukoplakia and hyperaemia, which is associated with a higher content of toxic substances in the product. Alaws et al. (2023)attribute this to the lack of quality standards in the region, which requires increased control at the legislative level.

The methods of using nasvay vary between different social groups. Putting the substance in the cheek prevails among schoolchildren, which is associated with the desire to hide the fact of use. Placing it under the lip and tongue is more popular among students and rural populations, which agrees with the findings of Biyo (2023). Agrawal et al. (2023) claimed that in Uzbekistan, nasvay is more often used in a mixture with chewing tobacco. However, this study does not record the widespread use of such practices, which may be due to differences in cultural traditions.

The duration of its use has a substantial effect on the condition of the oral cavity, exacerbating the degree of tissue damage with increasing length of consumption. For users who have been using nasvay for more than five years, the CFL index is 15% higher, which indicates the progressive nature of damage to teeth and soft tissues. Leukoplakia, which is a precancerous condition, is also registered much more frequently in this group, which confirms the negative effect of prolonged use of nasvay on the tissues of the oral cavity. These results align with the conclusions of Rogers et al. (2022), underlining the cumulative nature of damage caused by chemicals contained in the mixture, including calcium, heavy metals, and other toxic compounds.

These studies also demonstrate differences in the clinical picture of lesions depending on the region. In particular, in Kyrgyzstan, damage to the oral mucosa of users often becomes chronic. This phenomenon may be due to a lack of access to quality dental care, which is typical in rural areas, as well as a low level of awareness among the population about the need to prevent dental diseases. Unlike the data of O'Brien et al. (2021), where the focus is on acute forms of lesions in more developed regions, in Kyrgyzstan, chronic conditions are aggravated by constant exposure to chemicals from nasvay and a lack of timely treatment.

Kyrgyzstan's legal framework for regulating smokeless tobacco has proved insufficient to combat its use. The legislation does not include mandatory product certification and warnings about harm on the packaging, which parallels the study by Siddiqui et al. (2024). Petruzzelli et al. (2023) claim that in countries with stricter regulations, such as Turkey, the level of smokeless tobacco use decreases by 30%. However, Kyrgyzstan has substantial legislative gaps, including weak controls on sales to minors, requiring comprehensive reforms.

The use of nasvay is associated with precancerous changes in the oral mucosa. Mehta & Sharma (2022) emphasise that the carcinogenic substances contained in nasvay are the main risk factor. The authors confirmed that long-term use increases the likelihood of developing leukoplakia by 12% compared to users with a shorter use period. This confirms the data of Parmar et al. (2023) that chronic inflammation caused by exposure to alkaline components is a key mechanism of tissue damage.

Educational programmes are an effective tool in combating nasvay use. Quadri et al. (2024) state that information campaigns in schools and universities lead to a 15% reduction in nasvay consumption. This study shows that the use of multimedia formats such as social media can be particularly effective among young people, which is consistent with the findings of Siddiqui et al. (2021). However, such programmes must be adapted to cultural and social specificities, which will increase their effectiveness.

The implementation of quality standards and strengthening control over the composition of nasvay remain critical areas. Vishwakarma & Verma (2021) underscored that setting maximum permissible concentrations of toxic substances substantially reduces the harm from smokeless tobacco. This study discovered that the absence of such standards in Kyrgyzstan contributes to the widespread use of substandard nasvay, which requires immediate intervention at the legislative level.

Thus, the fight against nasvay consumption in Kyrgyzstan requires the integration of legislative reforms, educational programmes, and product quality control to reduce its negative impact on public health.

5 Conclusions

The study emphasises how using nasvay has a major effect on oral health, especially for young people and those living in rural areas of the Kyrgyz Republic. The results show that nasvay consumption is very common and varies significantly by age, gender, and social group. Notably, using nasvay is associated with serious oral health problems like mucosal oedema, hyperaemia, and leukoplakia, demonstrating the harmful effects of this smokeless tobacco product. The findings also highlight the necessity of focused preventative actions and educational initiatives to increase public knowledge of the risks to one's health posed by nasvay.

Additionally, the analysis found that there are insufficient controls over the production, sale, and consumption of nasvay due to gaps in the current legislative framework. The extensive use of inferior nasvay is exacerbated by its detrimental effects on health due to unclear quality standards and product labelling. The study suggests tightening regulations to address these problems, such as requiring health warnings, implementing more stringent quality controls, and launching extensive public health campaigns. Additionally, reducing nasvay consumption, especially among adolescents and young adults, may be significantly aided by incorporating preventive education into curricula at schools and universities.

The limitations of the study included the lack of accurate data on the composition of nasvay, which made it challenging to assess its long-term health effects. A limited sample size in individual groups could affect the generalisability of the results. The prospects for future research include a deeper analysis of the chemical composition of nasvay, its systemic effects on the body, and the development and testing of effective preventive programmes. Studies may also focus on examining the socio-economic factors influencing the prevalence of tobacco use and evaluating the long-term effectiveness of legal and educational measures to combat smokeless tobacco use.

Legal Acts

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Povzetek v slovenskem jeziku

Namen raziskave je oceniti vpliv "nasvaja" na ustno zdravje v Kirgiški republiki. Raziskava je uporabila kombinacijo metod, ki sta vključevali standardiziran vprašalnik in zobozdravstvene preglede 2.388 udeležencev. Ugotovljeno je bilo, da "nasvaj" uporablja 32,9 % šolarjev, 41,1 % študentov in 35,7 % prebivalcev podeželja. Razširjenost je višja med moškimi. Uporaba "nasvaja" je povezana z visoko pojavnostjo zobnih bolezni: levkoplakije, hiperemije in otekline sluznice. Indeks zobne gnilobe, plomb in izgubljenih zob pri uporabnikih znaša 6,8. Med načini uporabe je najbolj razširjena uporaba v ustni votlini ob licu. Ugotovljeno je bilo, da dostopnost in nizka cena "nasvaja" prispevata k njegovi široki uporabi. Poudarjena je potreba po celovitih preventivnih ukrepih, vključno s strožjo regulacijo, izobraževalnimi kampanjami ter zmanjšanjem ekonomske odvisnosti od proizvodnje "nasvaja."

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FACTORS AFFECTING MENTAL HEALTH AMONG POLICE OFFICERS IN THE STATE OF KEDAH MALAYSIA

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Abstract Mental health among law enforcement personnel has become a growing concern, raising questions about institutional responsibility and legal protections within the workplace. This study explores the factors influencing mental health among Royal Malaysian Police (RMP) members at IPK Kedah, focusing on legal and organizational implications. The research aims to identify key stressors and examine whether age and job rank correlate with psychological well-being, using a quantitative approach involving 100 respondents who completed structured questionnaires. Findings reveal that occupational stress is the leading contributor (mean = 4.821), followed by personal/family (4.392) and social factors (3.895). Pearson correlation shows significant positive relationships between mental health issues and both age (r = 0.416) and position (r = 0.398), with $p < 0.05$. The paper argues for the urgent need to strengthen mental health policies within policing institutions and contends that legal reform and administrative intervention are essential to safeguarding officers' psychological welfare.

Keywords
mental health,
law enforcement,
workplace,
psychological,
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1 Introduction

In this era of globalization, health is seen as a serious social problem for a country. This problem can affect an individual, society, or even a country (Abd Rahman et al., 2021). According to Abdullah & Aziz (2023), health problems are often associated with older people. However, health problems impact all age groups, not just the elderly. Health problems are multifactorial and include factors such as dietary practices, stress, and emotional disorders, among many others (Abd Malek et al., 2020). The same goes for mental health issues. According to Abd Rahman et al. (2020), mental health refers to the well-being of individuals who can act rationally and wisely in making any decision that will affect the environment. Health is related to biological, mental, emotional, social, cultural, economic and spiritual issues. Health and mental illness include biological and psychological factors, a broad understanding of nature, and social dimensions (Tayebeh, 2019). Meanwhile, mental health is also related to a person's behaviour (Bahrami et al., 2019). A person's significant changes in their behaviour and actions will affect how they function.

Furthermore, people who suffer from mental health problems will experience difficulties in functioning. This is so because other issues can cause disability and even lead to death, affecting the individual's development and growth over time (Haji Talib & Abdullah, 2020). Indirectly, the problems will negatively impact the individuals' quality of life, create economic burdens, and cause social issues involving the individual themselves, family, and society. Therefore, each individual has to play a role and take responsibility to ensure that they are not faced with mental health problems throughout their lives. Although myriad situations can affect a person's mental health, the individual needs to have the knowledge and skills to help control and manage the mental health problems faced so as to at least minimize their negative effect on their well-being to the extent possible.

2 Research Background

Bahrami et al. (2019) stated that mental health problems are influenced by many factors, such as a person's age, job, and socioeconomic status. Any one of the factors, or any combination of factors, can cause stress and pressure, and can lead to depression, loss of life considerations, and taking immoral actions, including self-harm and suicide. Eraman et al. (2021) stated that members of the Royal Malaysian

Police (RMP) are involved in a stressful profession that places them at significant risk for mental health problems. Stressful factors include the significant risks that police officers take on a daily basis, their workload and other work pressures, coupled with an often negative attitude on the part of the community they are there to serve, which often questions the competency of the RMP in maintaining security and preventing crime.

RMP members at the Kedah Contingent Police Headquarters (IPK Kedah) are also faced with the same situation. Therefore, the research aims to identify factors influencing mental health among RMP members in IPK Kedah. This study focuses on three main mental health problems, as stated below.

2.1 Work Factor

Employment was the first factor we studied to determine its influence on mental health problems among RMP members in IPK Kedah. Hassan & Khairudin (2014) stated that problems at work can significantly influence a person's health problems. Employment factors include, for example, excessive workload, risks associated with the job, leadership attitudes within the organization, and its adeptness both at managing risks on the job and caring for the welfare of its workers. All of these things can contribute to an increase in mental health problems among workers. Eraman et al. (2021) also stated that employment factors are primary contributors to mental health problems among RMP members. The primary aim of this study was to examine job factors and evaluate the extent to which they bear on the mental health problems of RMP members in IPK Kedah.

2.2 Personal and Family Factors

The second factor we studied was the impact personal and family factors had on the mental health of RMP members in IPK Kedah. Abd Rahman et al. (2021) stated that personal factors such as age and health problems, especially stress and depression, are among the elements that cause a person to experience mental health problems. Likewise, social and financial problems, uncertain sources of income, and some other family factors also affect a person's mental health level. The more personal and family problems faced, the higher the risk of experiencing mental health issues.

Our study examined how these personal and family factors influence mental health problems in RMP members at IPK Kedah.

2.3 Social Factors

In this study, we also examined the social factors to see their influence on the mental health of RMP members in IPK Kedah. Rohany (2020) states that a lack of social support impedes a person's ability to cope with mental health problems. For example, low moral support from family members, friends, and society causes a person to feel isolated and further exposes them to the risk of experiencing stress in life. Indirectly, this situation exposes individuals to an increased risk of mental health problems. Our study also examined the impact of these social factors on RMP members at IPK Kedah. Abd Rahman et al. (2021) stated that many environmental factors can also increase mental health problems, especially for those who are employed. Such factors include the burden and stress factors associated with work, age, and life stress, among other factors. Our study also examined how these environmental factors influence mental health among RMP members in IPK Kedah.

3 Problem Statement

Mental health is the normal state of a person with no disease problems and who lives a peaceful and purposeful life. Thus, Abdullah & Aziz (2023) stated that good mental health will help a person live a quality and prosperous daily life. However, as indicated in Section 2, many conditions may cause a person, including, of course, RMP members, to develop mental health problems. Eraman et al. (2021) stated that workload and stress in work, occupational risks, and increasing age are among the main factors that contribute to mental health problems among RMP members. The Minister of Home Affairs, Datuk Seri Saifuddin Nasution Ismail, in a media announcement, stated that the results of a study conducted by the Royal Malaysian Police (RMP) found that stress, health status and the workplace environment are the three main factors that contribute to mental health problems among members RMP (Mohd Khalid, 2023). The Minister also stated that loneliness caused by being away from family is another factor that contributes to a decline in mental health involving police officers (Ramlan et al., 2023).

According to the National Health and Morbidity Survey (NHMS) 2019, almost half a million people in the country were found to experience symptoms of stress or depression. The survey also revealed that both the COVID-19 pandemic and the Movement Control Order (MCO) (isolation order) legislated by the government also caused emotional stress following changes in the work environment, such as working from home, losing sources of income and employment and worrying about safety. Although the situation has improved since the Recovery Movement Control Order (RMCO) was implemented, serious problems remain. This is confirmed by statistics from Befrienders Kuala Lumpur, which show there was an increase in calls received from those who were in distress and wanted to commit suicide in July, August and September as compared to April, May, and June 2020 (News Daily, 2020).

According to Haji Talib & Abdullah (2020), factors that may contribute to increasing mental health problems include financial troubles, academic issues, family difficulties such as separation and divorce, along with environmental factors. Aspects of mental health are also often linked to emotional intelligence, choice of behavioural strategies, and psychological well-being. Abd Malek et al. (2020) in their study found that financial problems, pressure in the family, and also a failure to control oneself, negatively impact a person's mental health problems that drive the individual to take immoral actions such as suicide.

Clearly, many people, including RMP members and RMP members who are on duty at IPK Kedah, who have to deal with work stressors, struggle with mental health problems. In addition to the risks they face while at work, RMP members in IPK Kedah might also struggle with family issues, strain stemming from ageing, coupled with other factors that have a significant influence on increased mental health problems.

Therefore, RMP members must be aware of the need to improve their knowledge of how to manage good mental health. Lacking these skills limits the ability of RMP members to control and handle various life and work situations, which in turn can increase their mental health problems, and if left unchecked, can lead to dangerous proclivities such as suicide and criminal acts. Sinarharian.com.my reported on 5 July 2021 that the decline of mental health among the community in Malaysia needs to be given serious attention, considering the increasing number of suicide cases linked to stress due to the COVID-19. Aware of this acute situation, various studies on mental health issues have been carried out either at the government or NGO level. Thus, the mental health problems that exist in the environment of Malaysian society today have motivated us to carry out this study, which focused on the mental health problems among RMP members in IPK Kedah.

4 Research Objectives

The primary objectives of our study were as follows:

1. Identify the main factors that affect mental health among RMP members in IPK Kedah.
2. Identify the relationship between age factors and mental health among RMP members in IPK Kedah.
3. Identify the relationship between position factors in RMP and mental health among RMP members in IPK Kedah.

5 Research Questions

The primary research questions raised by our study were as follows:

1. What are the main factors that affect mental health among RMP members in IPK Kedah?
2. Is there a relationship between the age factor and mental health among RMP members in IPK Kedah?
3. Is there a relationship between the position factor in RMP and mental health among RMP members in IPK Kedah?

6 Research Methodology

Chua Yan (2017) and Abdul Razak (2018) both discuss the main elements of research methodology, which are the methods used by the researcher in collecting research data. These authors are in general agreement about the proper elements. They include the following. The aspects of study design include the method of selecting the study samples, the methods used to analyze study data, the study data collection procedure, and the procedures employed to implement the study procedure.

6.1 Research Design

This study employed a quantitative research design in order to achieve its objective of statistically analyzing the factors that affect mental health among Royal Malaysian Police (RMP) members in IPK Kedah. Quantitative methods are particularly well-suited to research that seeks to measure variables, test hypotheses, and establish relationships among factors (Chua Yan, 2017). By gathering numerical data through structured instruments, the approach facilitates an objective evaluation of the research hypotheses.

A structured questionnaire was selected as the primary data collection instrument. The questionnaire was divided into sections addressing work factors, personal and family factors, and social factors, and utilized a five-point Likert scale (Ahmad & Mahali, 2020) to quantify respondents' opinions. This scale, ranging from "Strongly Disagree" (1) to "Strongly Agree" (5), has been widely used in quantitative studies to assess the reliability of attitudes and perceptions.

We applied both descriptive and inferential statistical methods to analyze the data. We also employed frequency analysis and mean calculations to summarize the overall trends, while the T-Test and Pearson Correlation analysis allowed us to examine relationships, particularly the links between mental health and demographic variables such as age and position. This multifaceted analytic approach is in line with best practices recommended in the literature for handling large-scale datasets and extracting meaningful insights from raw data (Chua Yan, 2017; Rohaya, 2020).

6.2 Population and Sample

The study's target population comprised all RMP personnel stationed at the Kedah Contingent Police Headquarters (IPK Kedah), who shared similar professional and demographic characteristics. This homogeneity in context, such as shared job responsibilities, similar organizational culture, and comparable academic backgrounds, supports the focus on mental health within a specific and relevant professional group (Chua Yan, 2017).

A sample of 100 respondents was drawn from this population using a simple random sampling technique. Simple random sampling was chosen because it ensures that each member of the target population has an equal probability of being selected, thereby minimizing sampling bias and increasing the representativeness of the sample (Chua Yan, 2017; Rohaya, 2020). This method is particularly advantageous when the research intent is to generalize findings to the broader workforce of RMP members at IPK Kedah.

The diverse background of the respondents, spanning a range of ages, ranks, and service experiences, provided an adequate basis for analysing the variations in mental health outcomes. The literature suggests that a heterogeneous sample in terms of both demographic and professional attributes can enhance the robustness of the findings, especially when exploring factors such as work-related stress and organizational pressure (Ahmad & Mahali, 2020; Rohaya, 2020).

6.3 Research Instrument

The study was carried out using a questionnaire that collected data from the study sample. The questionnaire contained several sections on factors affecting mental health among RMP members at IPK Kedah, as follows:

Part A: Respondent Demographics

The first part of the questionnaire collected relavant data and personal information of the study respondents, such as gender, position in RMP, length of service in RMP, length of service in Kedah IPK, and some other background aspects.

Part B: Work Factors

The second part of the questionnaire contained survey items related to job factors that may directly influence mental health among RMP members in IPK Kedah. Examples included workload, job pressure, job risks, and leadership practices that put pressure on members, and so on. This information was designed to reveal the influence of work factors on mental health among RMP members.

Part C: Personal and Family Factors

The questionnaire also had questions that focused on personal and family matters. These included, for example, respondents' attitudes and perceptions towards their jobs, age factors, personal problems faced, family problems, etc.

Part D: Social Factors

We also studied social factors to evaluate their influence on mental health among the survey members. For example, the respondent's social relationships with family, colleagues, neighbours, and the community are directly related to their mental health or vice versa. We evaluated each survey item found in Part B, Part C, and Part D using five Likert scales as shown in the Table below:

Table 1: Likert Scale

No	Likert Scale	Scale Value
1	Strongly Disagree	1
2	Disagree	2
3	Moderate	3
4	Agree	4
5	Strongly Agree	5

7 Research Findings

The following is a discussion of our research findings:

7.1 Respondents Background

The information displayed in Table 2 shows that nearly 80% of the respondents were male and slightly more than 20% were female. Nearly half of the respondents were between 30-39 years old with the next larger group, at 35 %, between 20-29 years of age. A much smaller group, 15 %, were between 40-49 years old, with only 2% older than 50 years of age.

The following are the background findings of the study respondents:

Table 2: Findings of the Respondents' Background

No	Item	Percent (%)
1	Sex Male Female	 78% 22%
2	Age 20-29 Years 30-39 Years 40-49 Years More Than 50 Years	 35% 48% 15% 2%
3	Position DSP / ASP Inspector Sergeant Corporal / Lance Corporal Constable	3% 22% 28% 25% 22%
4	Ever Experienced Mental Health Problems YesNo Experiencing	29% 64% 7%

Concerning the positions held by respondents, study findings revealed that 3% held the position of DSP/ASP in IPK Kedah; 22% held the position of Inspector; 28% held the position of Sergeant; 25% held the position of Corporal / Lance Corporal; and, a total of 22% were Constables.

Section 4 of the Table contains findings regarding whether respondents had ever experienced mental health problems. A total of 29% of respondents, nearly a third, had experienced mental health problems; a total of 64% of respondents had never experienced mental health problems; and 7% of respondents were currently experiencing mental health problems, especially depression.

7.2 Main Factors Affecting Mental Health

The second research finding sought to identify the main factors affecting mental health among RMP members in IPK Kedah. Therefore, the following is an analysis of the research findings that we obtained and analyzed using a T-Test to identify the mean for each mental health factor studied:

Table 3: T-Test Results

Mean			N	Std. Deviation	Std. Error Mean
Pair 1	Work Factors	4.821	100	5.369	.980
	Personal and Family Factors	4.392	100	5.594	1.021
	Social Factors	3.895	100	4.902	1.190

Note: Paired Samples Statistics

Based on the results of the T-Test displayed in Table 3 above, we can see that three mental health factors were studied to assess their influence on RMP scores in IPK Kedah. Based on the T-Test results in Table 3 above, we can see that the mean for job factors is 4.821, the mean for personal and family factors is 4.392, and the mean for social factors is 3.895. This means that the main factors affecting mental health among the study respondents were job factors such as stress and workload, less effective leadership culture, risks in the job, less conducive organizational environment, organizational policies, and several other factors. Mud Shukri et al. (2023) stated that occupational factors highly influence mental health problems faced by RMP members and officers. The burden and risk of high tasks, stress in work, as well as less satisfactory policies and organizational environment are seen as factors that contribute to mental health problems among RMP members in IPK Kedah.

7.3 Relationship between Age and Mental Health

The third aspect of the study's findings was to identify the relationship between age factors and mental health problems, whether they have a positive relationship or vice versa. We examined the relationship between these two variables using Pearson's Correlation analysis. The following Table summarizes the results of this analysis:

Table 4: Results of the Analysis of the Relationship Between the Age Factor and the Respondent's Mental Health

Age			Mental Health
Age	Pearson Correlation	1	.416(*)
	Sig. (2-tailed)	.	.015
	N	100	100
Mental Health	Pearson Correlation	.416(*)	1
	Sig. (2-tailed)	.015	
	N	100	100

**Correlation is significant at the 0.01 level (2-tailed).

Based on the findings of the Pearson Correlation analysis displayed in Table 4 above, we can observe that the respondent's age bears a significant relationship to their mental health. This is confirmed by the positive correlation value of r = 0.416 ($p < 0.05$), which shows that age influences mental health problems. The older the respondent, the higher the risk of experiencing mental health problems. Abd Rahman et al. (2021) stated that there is a positive correlation between an increase in age and mental health problems that are influenced not only by a work environment that has high work pressure but also by non-work environment factors, including, but not limited to, financial problems, declining physical intelligence, etc. Indirectly, this makes it easier for a person to experience mental health problems if they are unable to control and manage environmental factors.

7.4 Relationship between Position and Mental Health

Our study also analysed the impact of the relationship between the respondent's position and the mental health of all respondents. Eraman et al. (2021) stated that the higher a person's position in an organization, the more responsibility and workload they have to bear. Correlatively, this results in increased pressure on such workers and further exposes them to an increase in mental health problems. The following are the results of a Pearson Correlation analysis conducted on the study respondents to identify the relationship between their positions in the organization and their mental health problems:

Table 5: Results of the Analysis of the Relationship Between Position Factors and Respondents' Mental Health

Position			Mental Health
Position	Pearson Correlation	1	.398(*)
	Sig. (2-tailed)	.	.015
	N	100	100
Mental Health	Pearson Correlation	.398(*)	1
	Sig. (2-tailed)	.015	.
	N	100	100

**Correlation is significant at the 0.01 level (2-tailed).

Based on the findings of the Pearson Correlation analysis displayed in Table 5 above, we may conclude that the respondent's position factor indeed has a significant relationship with their mental health. This finding is evidenced by the positive correlation value of r = 0.398 ($p < 0.05$), which shows that the position factor also influences mental health problems in RMP. The higher the position in RMP, such as DSP / ASP and Inspector, the greater the responsibility that needs to be borne, which in turn increases their risk of experiencing mental health problems. Masilamani et al. (2013) state that mental health problems are not only affected by age factors but also influenced by the job rank of the respective officers. Police inspectors are more likely to experience a higher level of stress as compared to junior officers.

The level of a person's employment responsibilities affects their mental health. However, when we speak of one's responsibilities, these can not be limited solely to one's formal work place. To the contrary, they also extend to one's family responsibilities, to the larger society, and so on. Generally speaking, persons holding higher positions of authority have greater work responsibilities. These increased responsibilities place added pressure on the individual, which can ultimately have a negative influence on their level of mental health. Based on the study's findings, which have been explained above, the main factor affecting mental health among RMP members in IPK Kedah is work, followed by personal and family factors, and then social factors. Meanwhile, the factor of age and position in RMP also affects the quality of mental health among RMP members in IPK Kedah.

8 Recommendation and Conclusion

Mental health is a growing concern that affects individuals across various life circumstances, including marital status, employment, and social conditions. Daily stressors, ranging from workplace burdens to personal and familial pressures, are significant contributors to mental health problems. This was evident in the findings of this study involving 100 Royal Malaysian Police (RMP) officers at IPK Kedah, where work-related factors emerged as the primary cause of mental health issues, followed by personal/family and social influences. According to Yahya et al. (2021), police officers, particularly those approaching retirement, face increasing mental health risks due to declining physical and cognitive abilities compounded by job stress. Rasdi (2018) further highlighted that higher-ranking officers face greater psychological strain due to heightened responsibilities. These realities demand proactive measures, including structured mental health programs that educate RMP members about risk factors and equip them with tools to manage their emotional well-being. Abd Malek et al. (2020) emphasized that mental health literacy plays a crucial role in shaping behavior and supporting both emotional and physical resilience.

Despite increased awareness, national data reflects a troubling trend: 2.3% of Malaysians aged 16 and above suffer from mental health problems, with suicidal behavior among adolescents rising from 7.9% in 2012 to 10% in 2017 (Metro Daily, 2020). This indicates an urgent need for holistic and sustained mental health support, especially for high-risk groups like law enforcement personnel. Organizational leadership, particularly within the RMP, must take a central role in creating a conducive, low-stress working environment that prioritizes psychological well-being. Strategies should include fostering positive workplace relationships, reducing undue pressure, and cultivating a sustainable organizational culture. Abdullh & Aziz (2023) stressed that effective leadership and a supportive work environment are essential for enhancing employee satisfaction and reducing mental health risks. In the context of IPK Kedah, these efforts are critical not only for individual well-being but also for maintaining operational effectiveness and ensuring that officers are equipped mentally and emotionally to uphold national peace and public security.

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Povzetek v slovenskem jeziku

Duševno zdravje pripadnikov organov pregona postaja vse večja skrb, kar odpira vprašanja o institucionalni odgovornosti in pravni zaščiti na delovnem mestu. Ta študija raziskuje dejavnike, ki vplivajo na duševno zdravje članov Kraljevske malezijske policije (RMP) na IPK Kedah, s poudarkom na pravnih in organizacijskih implikacijah. Raziskava si prizadeva prepoznati ključne stresorje ter preveriti, ali sta starost in delovno mesto povezana s psihološkim blagostanjem, pri čemer uporablja kvantitativni pristop s 100 anketiranimi udeleženci, ki so izpolnili strukturirane vprašalnike. Ugotovitve razkrivajo, da je glavni dejavnik poklicni stres (povprečje = 4,821), sledijo osebni/družinski dejavniki (4,392) ter socialni dejavniki (3,895). Pearsonova korelacija je pokazala pomembne pozitivne povezave med težavami v duševnem zdravju ter starostjo ($r = 0{,}416$) in položajem ($r = 0{,}398$), pri čemer je $p < 0{,}05$. Članek poudarja nujno potrebo po krepitvi politik duševnega zdravja znotraj policijskih institucij ter zatrjuje, da sta pravna reforma in administrativni posegi bistvena za zaščito psihološkega blagostanja policistov.

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EXPLORING RESEARCH TRENDS IN HEALTHCARE ASSET MANAGEMENT SYSTEMS: KEY AREAS, STRATEGIC PRIORITIES, AND ACTIONABLE RECOMMENDATIONS

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Abstract Asset Management Systems (AMS) are increasingly recognized for their potential to enhance operational efficiency, cost-effectiveness, and sustainability across asset-intensive sectors. In healthcare, however, the implementation of AMS remains fragmented, despite mounting pressures to improve medical equipment usage, infrastructure reliability, and service delivery. This study presents a literature review supported by a bibliometric analysis of 248 documents on AMS research in healthcare, published up to 2024 and indexed in the Scopus database, examining the evolution of AMS research with a specific focus on healthcare applications. Using Python and VOSviewer, the bibliometric analysis focuses on scientific production, geographical coverage, and major research clusters. The findings highlight a growing global interest in AMS and indicate a broader shift toward digitalization and strategic integration within healthcare systems. We synthesize these insights into a set of key areas and priorities, offering evidence-based recommendations to support more effective AMS adoption in healthcare.

Keywords
asset management system,
healthcare,
medical equipment,
research trends,
bibliometric analysis

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1 Introduction

The term *asset* is interpreted in various ways across disciplines; however, it is generally understood as any item, entity, or resource that holds value for an individual, company, or organization. Assets are typically classified into five principal categories: financial, human, informational, intangible, and physical (Van der Lei et al., 2012). Over the past three decades, the absence of well-established methods and practices for effective asset management has compelled organizations to explore more systematic approaches to improve asset performance. In the early stages, many organizations adopted trial-and-error strategies to enhance asset utilization, which led to the development of guidelines grounded in experiential knowledge (Al Marzooqi et al., 2019). Over time, these guidelines have been formalized, standardized, and globally disseminated, positioning asset management as a critical component of organizational performance and a driver of long-term growth (da Silva & de Souza, 2022). At the core of asset management lies the objective of maximizing the value derived from assets through a comprehensive and integrated management approach. Widely recognized definitions emphasize that asset management involves the coordinated activities of an organization aimed at realizing value from its assets. More specifically, it encompasses systematic and structured processes for managing assets, asset systems, performance, risks, and associated costs in a sustainable and optimized manner across their life cycles, all in alignment with the organization's strategic objectives (International Organization for Standardization, 2014).

Since its origins in the 1970s, the concept of asset management has undergone substantial evolution. Initially, it was predominantly concerned with the optimized maintenance of physical assets, emphasizing a balance between financial and operational objectives to ensure cost-effectiveness over the asset lifecycle – a practice commonly referred to as economic asset management (Ugarelli & Saegrov, 2022). With the progression of information and communication technologies (ICTs), asset management practices have become increasingly structured and data-driven, facilitating broader adoption across sectors (Gavrikova et al., 2020). The integration of advanced software systems and emerging technologies, such as Radio Frequency Identification (RFID), the Internet of Things (IoT), and Artificial Intelligence (AI), has further promoted the field by enhancing asset tracking, enabling predictive maintenance, and improving overall operational efficiency

(Chang et al., 2023; Chen & Chen, 2022). Asset Management Systems (AMSs) play a critical role in ensuring the effective operation, control, maintenance, cost savings, risk mitigation, better decision-making, and sustainability of both tangible and intangible assets within organizations (Diop et al., 2021; Lima et al., 2021). However, despite their potential, AMSs remain underutilized in many sectors, often resulting in fragmented activities, inefficiencies, and missed opportunities for optimization. The healthcare sector, in particular, has been identified as one of the most affected domains, characterized by poor coordination, unclear business processes, and limited control over asset-related activities.

Healthcare systems worldwide are under increasing pressure to deliver high-quality, efficient, and resilient services in the face of rising costs, staff shortages, and rapidly evolving technologies. Medical institutions are increasingly leveraging advanced technologies to improve diagnostics, treatment, and rehabilitation outcomes, relying on complex, high-value equipment, complicated infrastructure, and digital platforms that require coordinated and proactive management (Haleem et al., 2022). However, persistent challenges, such as inadequate tracking of medical equipment utilization, downtime, suboptimal maintenance planning, deficient resource allocation, and regulatory non-compliance, continue to hinder operational effectiveness. These shortcomings can lead to extended patient waiting times, financial inefficiencies, and diminished credibility. Medical equipment, often highly sophisticated and capital-intensive, demands specialized management and maintenance strategies. Consequently, effective asset management is imperative, as equipment underutilization or failure not only strains institutional budgets but also compromises the quality of patient care (Salem & Elwakil, 2023). AMSs, which provide a structured, lifecycle-oriented framework for asset management, could therefore offer significant benefits and development opportunities in the healthcare sector as well. These include improved medical equipment usage, better planning and procurement, predictive maintenance, transparent budgetary operations, and efficient business processes (Abd Rahman et al., 2023). Yet, in healthcare, where asset performance directly impacts patient care, treatment coordination, and overall financial effectiveness, the adoption of AMS has been inconsistent and often narrowly applied (Call, 2024). While emerging technologies like the IoT and AI are beginning to transform asset management capabilities (Tjebane & Musonda, 2024), their uptake in healthcare settings remains limited, often constrained by institutional inertia, organizational and process hurdles, and insufficient strategic considerations.

The main objective of this study is to map the key areas and thematic priorities that have been the focal point of AMS research in healthcare in recent years and to derive practical recommendations for implementing AMS in healthcare institutions. The study employs a literature review supported by a bibliometric analysis of 248 documents on AMS research in healthcare, published up to November 2024 and indexed in the Scopus database. The literature review is therefore enhanced by both established and innovative bibliometric methods, utilizing Python and VOSviewer software. Through a comprehensive bibliometric analysis, we chart the evolution of AMS research, uncover dominant topics, and examine the extent to which healthcare-specific issues are addressed. Special attention is given to technological enablers, stakeholder engagement, and the operationalization of AMS in real-world healthcare environments. The study is conducted in two phases. The first phase provides a comprehensive overview of AMS research in healthcare, focusing particularly on identifying both declining and emerging research trends. This phase highlights key areas and emerging priorities addressed in recent AMS research. The second phase centers on identifying the prerequisites for effectively adopting AMS in the healthcare sector and outlines actionable recommendations for implementing it. This phase highlights the importance of a well-structured AMS framework to ensure seamless integration and sustained use within healthcare settings.

Beyond simply documenting research output, this study seeks to inform implementation strategies by highlighting underexplored areas and offering targeted recommendations. These include improving alignment between clinical operations and asset planning, investing in smart infrastructure, fostering interdisciplinary collaboration, and developing policy frameworks that support AMS integration at the organizational and system levels.

Following the introduction, the second section offers a targeted review of existing literature, highlighting current applications of asset management within the healthcare sector. The third section presents the methodological framework, outlining the structure of the literature review and detailing the bibliometric analysis approach, including the functionalities of the Python VOSviewer software employed. The fourth section presents research findings, mapping the specific landscape and key characteristics of AMS research in healthcare. The fifth section provides a critical discussion, examining the potential benefits and challenges associated with AMS integration, and offers actionable recommendations for effectively implementing it in healthcare systems. Finally, the sixth section concludes with a synthesis of the main findings and reflections on the strategic opportunities that asset management presents for the future development of healthcare services.

2 Literature Review

The concept of asset management has evolved considerably since its early beginnings, when it was primarily seen as a technical or maintenance concern. Over time, it has matured into a multidisciplinary framework for optimizing the performance, lifecycle, and value of assets across industries (British Standards Institution, 2008). AMSs provide organizations with the tools and methodologies to systematically manage assets while balancing performance, costs, and risks. While much of this evolution has been shaped by advances in engineering, information systems, and operational research, the healthcare sector has only recently begun to engage with the broader potential of AMS.

Bibliometric studies have shown a steady increase in AMS-related publications, particularly since the 2000s. The growth of AMS research over the past 20 years was further accelerated by the global diffusion and application of the ISO 55000 standard. Studies by Tajudin et al. (2021) and da Silva and de Souza (2021) confirm a concentration of research around the following research areas: engineering, business, management and finance, infrastructure, maintenance, risk, and computer science, with limited attention to healthcare. The findings reveal that most contributions to asset management research have been disseminated through journal articles and conference proceedings. The linguistic distribution of these studies is markedly imbalanced, with English comprising the predominant language of publication. Furthermore, these studies also highlight geographic disparities, with North America, Europe, and Asia dominating the field, while healthcare-specific AMS research remains fragmented and underrepresented. Although the studies focus on different subject areas, they predominantly emphasize the role of specialized digital applications in establishing asset management, along with the associated benefits and challenges (Garramone et al., 2020; Rampini & Cecconi, 2022). ICTs play an interesting dual role in this context: they are both assets that AMSs must monitor and manage, and tools that enable the functioning and application of AMSs.

In healthcare, although AMS studies span diverse thematic domains, they tend to concentrate on more specific aspects of asset management, such as predictive maintenance for medical equipment or digital systems for hospital facilities and infrastructure, rather than on comprehensive, strategic integration across healthcare operations. For instance, Leiblein et al. (2016) explored facility management, water system risks in hospitals, and associated infections. Several studies corroborate the growing adoption of asset management practices in the healthcare sector, highlighting its substantial potential for integrating digital technologies with asset management principles (Rousek et al., 2014). A recurring focus within this body of research is the strategic management of medical equipment, healthcare facilities, and digital assets aimed at improving operational efficiency (Aboelmaged & Hashem, 2018). Moreover, digital transformation, particularly through implementing AMSs incorporating technologies such as the IoT and AI, has recently emerged as a prominent trend in healthcare asset management research (Sen et al., 2018). Despite these advancements, notable gaps persist within the current literature. Although prior studies emphasize aspects such as medical facility maintenance, lifecycle optimization, and the integration of digital technologies, there remains a lack of comprehensive investigations examining the broader impact of enhanced asset management on patient care, healthcare service delivery, and treatment outcomes.

On the other hand, it is important to note that analyses of AMS-related research (including bibliometric studies) often employ methodologies such as co-word analysis, thematic clustering, and topic modeling to identify key themes. These methodological approaches predominantly rely on keywords, terminology, and constructs derived from the corporate domain, which are frequently absent in the healthcare context. As a result, numerous studies that substantively address asset management and its implications in healthcare tend to be overlooked, and their impact and visibility within both professional and academic communities remain relatively limited.

In comparison to studies within the broader asset management domain, research on healthcare asset management remains underdeveloped, particularly with respect to systematic frameworks and patient-centered perspectives (Yuen et al., 2022). An essential critique of the existing literature in this field is its predominant focus on narrow, technology-driven aspects of asset management, often at the expense of human and material resources, development, organizational, and other dimensions.

These include stakeholder engagement, employee participation, regulatory and decision-making frameworks, and broader business processes. Moreover, interdisciplinary perspectives are noticeably underrepresented, despite the clear relevance of fields such as public health, operations management, finance, and organization in the healthcare asset management concept (Chen et al., 2021). One of the underlying reasons for the relatively limited volume of research in this area may be attributed to the structural and operational characteristics of healthcare systems themselves. These systems are typically rigid, heavily regulated, and resistant to rapid transformation, posing significant challenges for integrating novel management concepts and emerging technologies. In this context, effectively adopting AMS necessitates a paradigm shift, entailing comprehensive reforms across managerial practices, organizational structures, operational processes, regulatory frameworks, and information systems.

3 Materials and Methods

Comprehensive bibliometric data on AMS research in the healthcare domain were systematically retrieved in May 2025 from Scopus, one of the most comprehensive and widely recognized bibliographic databases for peer-reviewed literature. Scopus was selected as the primary source for this bibliometric study due to several well-established advantages that position it as a more suitable choice over alternative databases such as Web of Science.

Firstly, Scopus offers broader disciplinary coverage, encompassing a wider spectrum of scientific publications compared to Web of Science (Gerasimov et al., 2024). This inclusivity is particularly critical in an interdisciplinary field such as AMS in healthcare, which spans medical technology, engineering, hospital operations, and public health policy. Secondly, Scopus provides more extensive indexing of Social Sciences and Humanities research, an area underrepresented in Web of Science (Singh et al., 2021). Since implementing AMS often involves organizational, managerial, and behavioral dimensions within healthcare institutions, access to this broader coverage enriches the analytical scope. Thirdly, Scopus includes a greater volume of non-English publications while still providing English-translated titles, abstracts, and keywords – ensuring that global perspectives are captured without sacrificing consistency in language processing for bibliometric analysis (Vera-Baceta et al., 2019).

Furthermore, from a methodological standpoint, the decision to use Scopus is underpinned by a fundamental statistical principle: larger sample sizes and more diverse datasets typically lead to more robust, precise, and generalizable analytical results (Rogers et al., 2020). In light of this, Scopus appears to be the more relevant bibliographic database, as it aligns with the specifics of AMS research. Its extensive coverage increases the likelihood of capturing all relevant publications related to AMS in healthcare, thereby enhancing the comprehensiveness and validity of the findings.

To extract relevant documents, we employed an advanced search strategy using Scopus' sophisticated query engine to conduct a comprehensive title, abstract, and keyword search. The search focused on retrieving specific documents that included the phrase "asset management" in conjunction with at least one of the following healthcare-related terms: "healthcare," "hospital," "medical equipment," or "medical devices." This targeted strategy ensured that we captured only publications directly relevant to the intersection of AMS and healthcare. Accordingly, the full search query was structured as follows: (TITLE-ABS-KEY ({asset management}) AND TITLE-ABS-KEY ({healthcare} OR {hospital} OR {medical equipment} OR {medical devices})).

No language restrictions were applied to the search, allowing us to include documents in any language. However, since Scopus indexes all titles, abstracts, and keywords in English, the language of the full text does not affect the consistency or interpretability of bibliometric results. To avoid skewed temporal distributions and ensure comparability across publication years, the dataset was restricted to documents published up to and including the year 2024. This cut-off ensures a stable reference time frame and eliminates distortion from disproportionate representation of data for 2025. Based on this search strategy and the presented search query, we identified a total of 248 documents on AMS research in healthcare as eligible for inclusion in the following bibliometric analysis.

To extract insights from the retrieved literature, we conducted a multi-step bibliometric analysis using a combination of data analysis and visualization tools. We executed the core bibliometric analysis using the Python data analysis libraries Pandas and Numpy (McKinney, 2012), and visualized using the Python visualization library Matplotlib (Hunter, 2007). We performed the network analysis, i.e., keyword co-occurrence with VOSviewer, a widely used software tool for constructing and visualizing bibliometric networks (Van Eck & Waltman, 2010). This enabled us to identify dominant themes, emerging topics, and interconnections among conceptual clusters within the literature.

In addition to the quantitative mapping, we were able to draw qualitative content clusters (research hotspots), including representative keywords, from the abstracts of selected publications to provide contextual insights into how AMS is conceptualized, implemented, and evaluated in healthcare settings. These content-based reflections complemented the bibliometric indicators and provided a more nuanced understanding of the field's current landscape, including research gaps, key areas, and strategic priorities.

4 Results

AMS research in healthcare comprises 248 documents published between 1979 and 2024. The majority of these are journal articles (50.4%) and conference papers (31.9%), followed by book chapters (8.1%), conference reviews (3.2%), and review articles (2.8%). The least represented document types are books (1.6%), short surveys (1.2%), and notes (0.8%). Figure 1 illustrates how the scientific production in AMS research evolved within the healthcare domain from 2000 to 2024. Prior to 2000 (not shown in Figure 1), AMS research in healthcare was already present but limited, with a total of 28 documents published between 1979 and 1999. From 2000 to the mid-2000s, publication activity remained relatively steady with low annual output. A noticeable increase began after the mid-2000s, with consistent growth in the number of publications and rising academic interest. From 2010 onward, both publication output and citation impact began to accelerate, reflecting a broader interest in AMS topics within healthcare research. This upward trend continued into the 2020s, culminating in a peak of scientific activity in the most recent years, highlighting the field's growing scholarly significance and maturity over time.

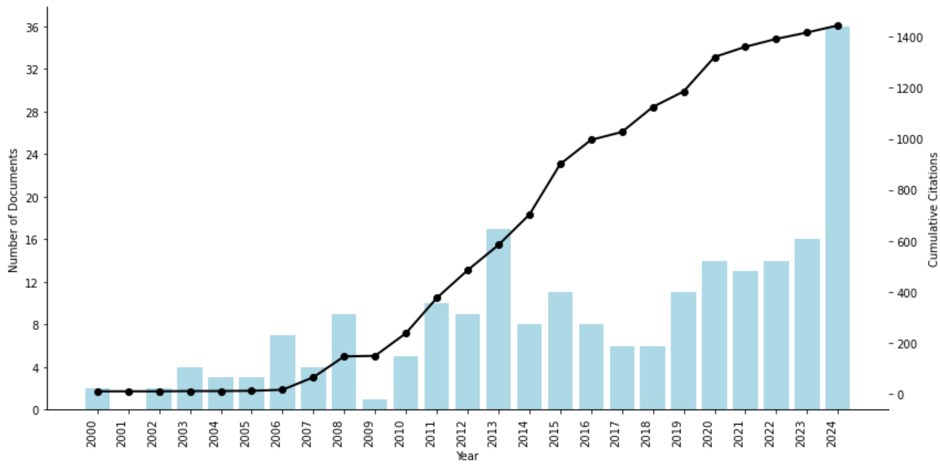

Figure 1: Scientific production in AMS research in healthcare

Source: Own elaboration based on the Scopus database.

Figure 2 presents a comparative overview of the most relevant countries contributing to AMS research in healthcare, based on the number of published documents and total citations received, both shown on logarithmic scales. The size of each bubble reflects the H-index, indicating the combined measure of productivity and citation impact. At the same time, the color gradient represents the average year of publication, with lighter tones indicating more recent research activity. The figure shows that the United States and the United Kingdom lead in both research output and impact, suggesting strong and sustained engagement in AMS research. Countries such as Canada, Australia, and South Korea exhibit notable influence with relatively high citation counts despite smaller publication volumes. Meanwhile, India, Malaysia, and China represent more recent contributors to the field, with growing scholarly output and emerging citation impact. Overall, the figure highlights both established and emerging contributors to AMS research in healthcare on a global scale.

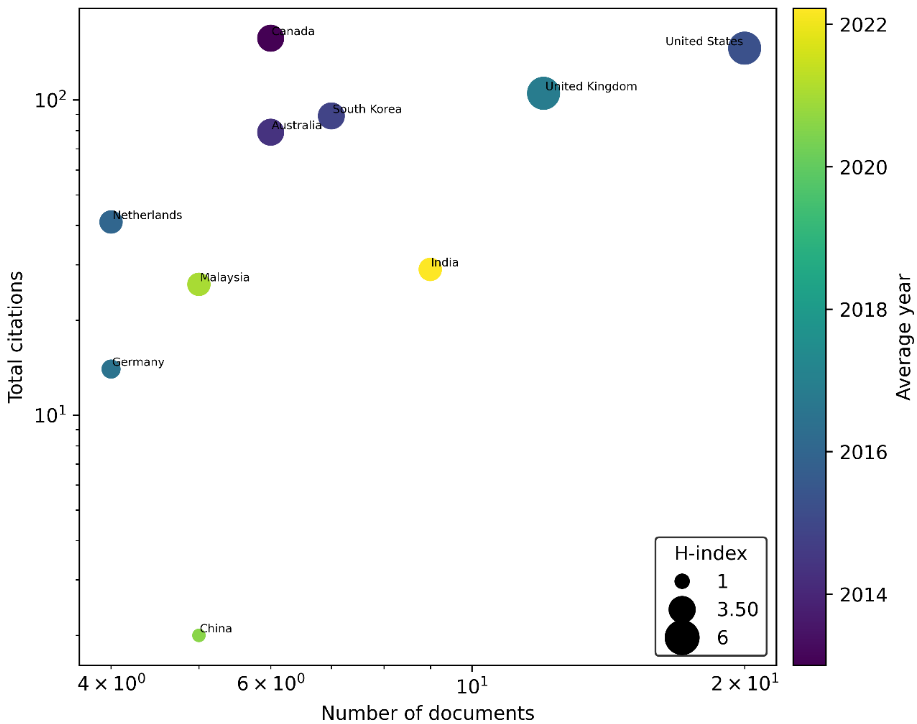

Figure 2: The most relevant countries in AMS research in healthcare
Source: Own elaboration based on the Scopus database.

Figure 3 presents a network analysis, i.e., keyword co-occurrence, performed on the 50 most frequent authors' keywords. Note that the nodes indicate keywords and the links the co-occurrence relations between them. The node size is proportional to the number of keyword occurrences, showing research intensity (node degree), while the link width is proportional to the co-occurrences between keywords (edge weight). Additionally, the node color indicates the cluster to which a particular keyword belongs (Wang et al., 2020). The analysis identifies five key hotspots in AMS research focused on deterring unethical practices, each addressing a critical area of AMS: 1) emerging technologies in maintenance and infrastructure (red cluster), 2) core infrastructure and reliability management (green cluster), 3) risk and resilience in infrastructure (blue cluster), 4) infrastructure condition assessment and rehabilitation (yellow cluster), and 5) smart grid and asset monitoring (purple cluster).

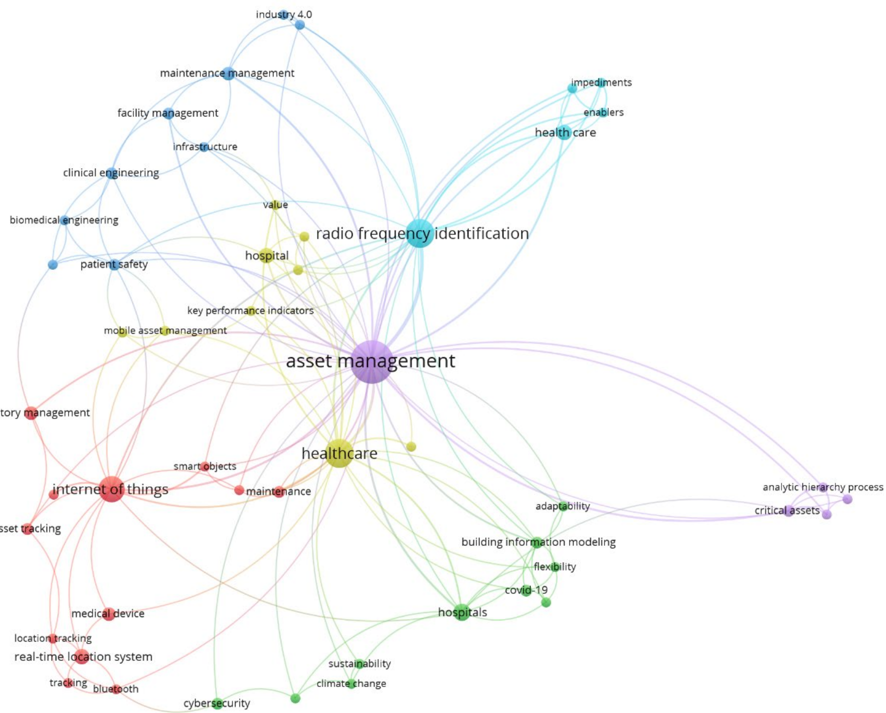

Figure 3: Keyword co-occurrence network of AMS research in healthcare

Source: Own elaboration based on the Scopus database.

Table 1 provides a detailed synopsis of the main research hotspots identified in AMS research in healthcare, derived from a keyword co-occurrence network analysis. The first cluster focuses on smart technologies and asset tracking, emphasizing the integration of advanced digital tools, automation, and interconnected systems that enable real-time monitoring, location tracking, and effective asset utilization. This research direction underscores the importance of leveraging technologies such as IoT and wireless communication to improve operational transparency, reduce asset loss, and support data-driven decision-making. The second cluster addresses risk and sustainability, reflecting a growing interest in the capacity of AMS to contribute to resilient and sustainable healthcare systems. It highlights how asset management can support preparedness for external shocks such as pandemics and climate change, and promote environmentally responsible practices within healthcare infrastructure. The third cluster centers on engineering and operational systems, focusing on the foundational role of clinical and biomedical engineering, as well as digital transformation strategies that support efficient facility management, system integration, and continuous operational improvement. This cluster also encompasses the evolution of AMS alongside developments in industry 4.0 and 5.0, indicating a shift toward intelligent, interconnected, and adaptive healthcare environments.

Table 1: Research hotspots based on keyword co-occurrence network of AMS research in healthcare

Research Hotspots	Representative keywords
Smart technologies and asset tracking (red cluster)	5g, asset tracking, Bluetooth, internet of things, inventory management, location tracking, logistics, maintenance, medical device, real-time location system, smart objects, tracking
Risk and sustainability (green cluster)	adaptability, building information modeling, climate change, COVID-19, cybersecurity, flexibility, hospitals, pandemic, risk management, sustainability
Engineering and operational systems (dark blue cluster)	biomedical engineering, clinical engineering, enterprise resource planning, facility management, industry 4.0, industry 5.0, infrastructure, maintenance management, patient safety
Performance value management in healthcare logistics (yellow cluster)	critical infrastructure, healthcare, hospital, key performance indicators, mobile asset management, performance, real-time location system, supply chain management, value
Strategic asset capital planning (purple cluster)	analytic hierarchy process, asset management, capital renewals, critical assets, healthcare facilities
Patient centric enablers and barriers (light blue cluster)	enablers, health care, impediments, patient management, radio frequency identification

Source: Own elaboration based on the Scopus database.

The fourth cluster is concerned with performance value management in healthcare logistics, emphasizing the need to measure and enhance the value generated by AMS through key performance indicators, real-time data, and supply chain optimization. Research in this area seeks to improve the efficiency, reliability, and responsiveness of logistics operations, ultimately supporting better patient outcomes and institutional performance. The fifth cluster addresses strategic asset capital planning, drawing attention to the importance of long-term investment strategies, lifecycle analysis, and prioritization frameworks in managing healthcare infrastructure. It highlights the role of AMS in supporting evidence-based decision-making around capital renewals, critical assets, and infrastructure upgrades, especially in the context of limited financial resources and growing demand. Finally, the sixth cluster focuses on patient-centric enablers and barriers, exploring the human, organizational, and technological factors that influence the adoption and success of AMS initiatives. This research area stresses the importance of aligning asset management practices with patient care objectives, addressing user needs, overcoming implementation challenges, and ensuring that technology serves to enhance, rather than hinder, patient experience. In this regard, patient well-being, including mental health support, should be considered as a critical enabling factor for AMS adoption. Coaching-based approaches aimed at enhancing children's mental health and well-being, for example, can provide valuable psychosocial support that increases user acceptance and reduces resistance to change (Cajnko, Cajnko, & Gomboc, 2025).

5 Discussion

The results of conducted literature review and bibliometric analysis underscore a rapidly expanding body of research on AMSs, with a clear shift toward digitalization, predictive analytics, and smart infrastructure (Truong et al., 2023). However, this growth is not uniformly distributed across sectors. While AMS is now firmly embedded in fields like engineering, management and finance, construction, infrastructure, manufacturing, energy, and transport (Frankó et al., 2020; Pericault et al., 2023), its integration in healthcare remains both limited and uneven. AMS research in healthcare has grown steadily since the mid-2000s, with a sharp rise in publications and citations after 2010, reflecting increasing academic interest and the field's maturation. This growth is driven by global contributions, with the United States and United Kingdom leading in both output and impact, while countries like Canada, Australia, and South Korea show strong influence despite smaller publication volumes, and newer contributors such as India and China are gaining momentum. The thematic landscape of the field, revealed through keyword co-occurrence analysis, is organized into six dominant clusters that span topics from smart technologies and asset tracking to patient-centered planning and system-level strategy. Together, these trends highlight the expanding role of AMS as both a technical and strategic enabler of healthcare innovation, operational efficiency, and digital transformation.

Nevertheless, several gaps remain. First, the existing research predominantly emphasizes managerial and technological potentials rather than healthcare-specific AMS implementations, applications, and improvement opportunities (Abd Wahab, et al., 2024). Studies focus on how AMSs can reduce equipment downtime, optimize infrastructure reliability or energy use (Pascale & Achour, 2024), but give far less attention to how it can improve clinical workflows, reduce patient wait times, or support care coordination. The potential of AMS to inform broader strategic decisions, such as public health policymaking, developing and implementing healthcare programs, or budgetary planning, is hardly addressed. Second, while technological enablers like IoT and AI are increasingly discussed (Saritha et al., 2024; Godager et al., 2024), there is little research on the human, organizational, and process factors that condition the successfully implementing AMS in healthcare. For example, adopting digital asset tracking tools may require significant changes to hospital governance, data-sharing protocols, and interdepartmental collaboration – areas rarely explored in AMS literature. Third, despite healthcare being one of the most asset-intensive and risk-sensitive sectors, very few studies investigate the return on investment of AMS from a healthcare system's perspective. There is a lack of rigorous evaluation frameworks that measure how AMS contributes to health outcomes, cost-efficiency, or operational performance over time.

Beyond the primary findings, this study has uncovered several critical insights that require careful consideration in guiding future research and practice. A crucial area of focus should be the strategic alignment of AMSs with both clinical and organizational objectives. For AMS to deliver meaningful value, it must be more effectively integrated into healthcare planning, service delivery approaches, and budgeting processes. This requires a clearer understanding of how AMS can support institutional objectives such as enhancing patient safety, improving care quality, and optimizing the use of resources. Another critical area is digital readiness and interoperability. Successfully implementing AMS depends on robust digital infrastructure that enables real-time asset tracking, predictive maintenance, and data-driven decision-making. Future studies should investigate the technological and organizational challenges of achieving interoperability, with a focus on developing standardized frameworks that connect AMS platforms with existing health information systems. Stakeholder engagement and organizational change management also emerged as key considerations. Adopting AMS is not solely a technical process but involves significant behavioral and cultural shifts (Morecroft, 2017). Research should therefore explore how leadership commitment, effective staff training, and targeted communication strategies influence the uptake, use, and long-term sustainability of AMS in healthcare institutions. Strong leadership and a culture of knowledge sharing are equally important for fostering innovation and building organizational capacity. Knowledge leadership that actively promotes the exchange of expertise among stakeholders can significantly improve the success rate and sustainability of AMS implementation (Rahman et al., 2025). Equally important are policy and governance frameworks that can support systematically integrating AMS into healthcare environments. There is a pressing need for comprehensive guidelines addressing utilization rates, data governance, regulatory compliance, risk mitigation, and long-term asset lifecycle planning (Yong & Kundakchian, 2020). These frameworks should be adaptable to different healthcare contexts while ensuring accountability and transparency. The importance of evaluation and evidence-based implementation should not be overlooked. There is a notable gap in empirical studies that assess the real-world impact of AMSs on clinical outcomes, operational efficiency, financial performance, and patient satisfaction. Future research should include cost-benefit analyses, longitudinal case studies, and robust evaluation models to provide actionable insights for decision-makers. Ultimately, while AMSs hold considerable promises for transforming healthcare operations, realizing their full potential requires a purposeful reorientation of both research and practice. Interdisciplinary collaboration, stakeholder engagement, robust digital infrastructure, patient-centered design, and well-considered implementation strategies will be essential in advancing the effective use of AMSs within healthcare systems.

Based on the research findings, particularly the identified key areas and strategic priorities, we propose the following general recommendations to guide effectively implementing AMS in healthcare settings:

1. Establish policy and strategic foundations
   - Develop policy and regulatory frameworks:
     - Collaborate with national and regional policymakers to create AMS-specific healthcare guidelines.
     - Ensure regulations address data governance, privacy, procurement rules, and healthcare-specific compliance.
   - Integrate AMS into institutional strategy:
     - Embed asset management into strategic plans, operational frameworks, and budgeting cycles.
     - Establish governance structures and leadership endorsement to support AMS sustainability and accountability.

- Set clear objectives and operative/outcome performance metrics and indicators:
  - Define clear strategic objectives for AMS (e.g., optimize asset utilization, reduce equipment downtime, extend asset lifespan, etc.).
  - Identify key performance indicators (KPIs) such as service quality, patient safety, utilization rate, asset lifecycle cost, maintenance response time, and asset availability.
  - Align goals and KPIs with patient care quality benchmarks and healthcare regulatory standards.

2. Conduct initial assessments and planning

- Comprehensive asset inventory and assessment:
  - Perform an exhaustive inventory of all physical assets (medical equipment, IT infrastructure, and facilities).
  - Classify assets by type, function, usage, criticality, risk, condition, and maintenance costs.
  - Establish standard data collection procedures, capturing relevant information like serial numbers, location, purchase dates, service history and records, and warranty details.
- Establish asset lifecycle management framework:
  - Define each stage of the asset lifecycle, from acquisition and installation to utilization, maintenance, upgrades, and decommissioning.
  - Use lifecycle data to plan budgets for replacing assets approaching the end of their effective life, reducing emergency expenditures.
  - Develop clear policies and protocols for decommissioning and disposal of assets, ensuring they meet environmental and safety regulations.

3. Invest in AMS and infrastructure

- Select and procure a suitable AMS platform:

    - Choose software capable of real-time asset tracking, condition monitoring, maintenance management, compliance reporting, and predictive analytics.
    - Prioritize systems with integration capabilities for electronic health records, hospital information systems and other devices, and IoT for real-time monitoring.
    - Ensure scalability and customization of the software to fit the organization's size, number of assets, and specific healthcare needs.
- Develop a centralized asset database:
    - Implement a secure and centralized database to store all asset-related information, accessible to authorized personnel across departments.
    - Ensure data is accurate, regularly updated, and protected to prevent unauthorized access and comply with data privacy regulations.
    - Allow access to the database for relevant departments such as management, finance, maintenance, and procurement to facilitate cross-functional cooperation and coordinated asset management.
- Enhance digital infrastructure and interoperability:
    - Invest in digital platforms and connectivity solutions linking AMS with enterprise resource planning, clinical, and admin systems.
    - Adopt standard protocols and application programing interfaces to support data flow between AMS, external tools, and health IT systems.
    - Enable smart asset tracking using IoT sensors and condition-monitoring technologies (computerized maintenance management system).

4. Build organizational capacity and engagement
- Training and organizational readiness:
    - Develop workforce training programs to build technical, analytical, and operational AMS competencies.
    - Conduct comprehensive training sessions for various staff levels covering AMS use, reporting, control, and maintenance.

- Include AMS education in onboarding and ongoing professional development programs.
- Involve end-users and frontline personnel in system design and feedback loops to foster adoption and reduce resistance to change.

- Promote a culture of asset responsibility:
  - Encourage departments to take ownership of equipment care and accurate asset data reporting.
  - Establish clear roles, responsibilities, and promote accountability for asset management across the organization, where each staff member understands the importance of maintaining and properly using equipment.
  - Provide ongoing communication and establish regular feedback channels to support users, improve the system and address barriers to adoption.

5. Operationalize AMS and enhance maintenance strategy
   - Implement preventive and predictive maintenance measures:
     - Schedule regular preventive maintenance based on asset importance, age, usage, and manufacturer guidelines.
     - Leverage predictive analytical tools and performance data to foresee failures and schedule repairs proactively, reducing unexpected asset outages.
     - Establish emergency response protocols to address sudden equipment malfunctions swiftly and minimize the impact on patient care.
   - Ensure regulatory compliance:
     - Familiarize with local and international healthcare asset management standards and regulations, such as those from the International Organization for Standardization (ISO 55000) and medical device safety codes.
     - Keep comprehensive documentation, reports, and records of maintenance activities, inspections, and incidents to meet compliance requirements and facilitate auditing.

    - Regularly review compliance status and conduct periodic audits to ensure adherence to all legal and safety standards, reducing risks of equipment-related incidents and penalties.

6. Monitor, improve, and ensure the AMS's resilience and adaptability
  - Monitor and review system performance:
    - Conduct periodic audits and AMS performance reviews against the defined KPIs and compliance benchmarks.
    - Use findings to refine maintenance schedules, asset replacement timelines, and update policies for continual improvement.
    - Introduce beneficial system/process updates based on emerging technologies, innovative concepts, and organizational feedback.
  - Promote interdisciplinary research and innovation:
    - Encourage collaborative research among healthcare, IT, engineering, management, and operations experts.
    - Launch pilot projects and living labs to experiment with AMS innovations in real-world settings.
    - Use insights from these initiatives to drive continuous improvement and evidence-based scaling.
  - Plan for strategic development and long-term sustainability:
    - Plan for the future by ensuring AMS scalability to accommodate growing asset base, new business processes, and technology advancements.
    - Use data-driven insights from the AMS (asset performance, usage trends, and maintenance costs) for decision-making, long-term planning, procurement strategies, and risk management.
    - Keep informed about industry advancements in asset management and healthcare technology to continually improve and update the system.

Implementing AMS in healthcare is a dynamic, multi-phase process requiring alignment between policy, infrastructure, people, and technology. This integrated framework of recommendations guides institutions through a logical and actionable roadmap, from foundation-setting to ongoing performance optimization. When regularly reviewed and adapted, asset management could empower healthcare organizations to optimize asset utilization, enhance the quality of patient care, and improve financial efficiency and productivity.

The implications of our findings are manifold. First, they highlight the need for sustained investment in AMS research to address asset management challenges in healthcare, where asset reliability and operational efficiency are critical. The identification of emerging technologies, such as AI and IoT within AMS research underscores the growing demand for intelligent, automated asset management solutions. However, the much-needed shift toward rigorous studies that examine the tangible effects of AMSs on inherently clinical aspects, such as care quality, patient outcomes, public health status, and healthcare expenditure, remains regrettably limited. Policymakers, healthcare managers, industry leaders, and researchers can leverage these insights to drive innovation and promote a more proactive approach to integrating AMSs into healthcare institutions. Accordingly, future research projects and analyses should focus on how AMSs support public health priorities, such as care quality, patient safety, and resource optimization. In this context, it would be beneficial to reorient the overall research approach to AMS in healthcare more explicitly toward patient-centered value and impact. Our findings emphasize the need to move beyond theoretical exploration and isolated managerial and technological case studies, toward more practical, interdisciplinary, and outcome-oriented research. To unlock the full potential of AMS in healthcare, future efforts must align technological innovation with policy development, institutional strategies, and public health goals.

Despite its comprehensive scope, this study has certain limitations. The analysis is based on bibliometric data from the Scopus database, which, while extensive, may not capture all relevant research published in other databases such as Web of Science or IEEE Xplore. Additionally, the reliance on keyword co-occurrence analysis means that emerging but less frequently used terms might not be fully represented in the research. While our study provides a global overview of AMS research in healthcare, it does not consider the specific methodologies employed in individual studies, thereby limiting our ability to assess the methodological rigor within the field. Moreover, the general recommendations proposed for the effective implementation of AMS in healthcare settings are largely theoretical, grounded in prior research and conceptual frameworks, and have not yet undergone empirical validation in real-world healthcare environments. As a result, both the chosen methodological approach and the derived inferences may be open to debate, and the proposed recommendations should be interpreted with caution. Nonetheless, this study provides valuable insight into AMS research in healthcare, highlights the potential for utilizing AMS within healthcare institutions, and outlines the associated dynamics and complex challenges involved in integrating AMSs into healthcare systems.

6 Conclusion

This study provides a comprehensive overview of global research trends regarding the role and application of AMSs in the healthcare sector. Through a bibliometric analysis of 248 Scopus-indexed documents, we identified key thematic clusters, technological enablers, and gaps in the literature regarding adopting AMS in healthcare environments. The results reveal a clear evolution of AMS from traditional maintenance-focused practices toward more intelligent, data-driven systems powered by IoT and AI. While sectors like engineering, management and finance, manufacturing, energy, and transport have largely embraced these advancements, healthcare continues to lag behind, with most studies concentrating on isolated technological applications rather than systemic implementation. Despite this underutilization, the healthcare sector stands to benefit significantly from AMSs. Medical equipment, digital health assets, and physical infrastructure represent high-value and mission-critical components of healthcare delivery. Better management of these assets could improve efficiency, reduce costs, and enhance patient care. Yet, while existing research acknowledges the role of AMSs in healthcare, it pays only limited attention to how asset management can influence broader healthcare outcomes, such as quality of health services, productivity of health care providers, and patient wait times. To fully unlock this potential, it is essential to ensure the strategic alignment of AMSs with both clinical and institutional objectives. This requires a deeper integration of AMSs into healthcare planning, budgeting, and service delivery strategies. By embedding asset management into the core of healthcare activities and decision-making processes, organizations can not only optimize resource utilization but also drive meaningful improvements in patient care and operational efficiency. Future research should further explore these integrative strategies to provide actionable insights for healthcare leaders and policymakers.

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Povzetek v slovenskem jeziku

Sistemi za upravljanje sredstev (AMS) so vse bolj prepoznani kot orodje z velikim potencialom za povečanje operativne učinkovitosti, stroškovne učinkovitosti in trajnosti v sektorjih, ki temeljijo na intenzivni uporabi sredstev. V zdravstvu pa je izvajanje AMS še vedno razdrobljeno, kljub naraščajočim pritiskom za izboljšanje uporabe medicinske opreme, zanesljivosti infrastrukture in kakovosti storitev. Ta študija predstavlja pregled literature, podprt z bibliometrično analizo 248 dokumentov o raziskavah AMS v zdravstvu, objavljenih do leta 2024 in indeksiranih v podatkovni bazi Scopus, pri čemer analizira razvoj raziskav na področju AMS s posebnim poudarkom na zdravstvenih aplikacijah. Z uporabo orodij Python in VOSviewer bibliometrična analiza zajema znanstveno produkcijo, geografsko pokritost in glavne raziskovalne grozde. Ugotovitve poudarjajo naraščajoče globalno zanimanje za AMS ter kažejo na širši premik k digitalizaciji in strateški integraciji znotraj zdravstvenih sistemov. Na podlagi teh spoznanj so oblikovana ključna področja in prioritetne usmeritve ter ponujena na dokazih temelječa priporočila za učinkovitejše uvajanje AMS v zdravstvu.

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Abstract This article provides an analysis of the Slovenian Voluntary Assisted Dying Bill, in both its previous and amended versions, which is founded upon the paradigm "My life, my right". The original bill, which was regarded as highly liberal, contained numerous exceptions that effectively allowed euthanasia for all individuals with chronic illnesses or disabilities. This analysis critically examines the most controversial legal provisions of the bill and anticipates consequences should it be implemented, particularly from the perspective of vulnerable healthcare users. The analysis demonstrates that the original formulation of the right to medically assisted dying conflicts with the foundational principles of the healthcare system and is inconsistent with the Patient Rights Act. The amended Voluntary Assisted Dying Bill provides physicians with the options to both reject medically assisted dying applications and to employ safeguards to protect patients in transitional distress from premature death.

Keywords
euthanasia,
medical aid in dying,
legal regulation,
patient rights,
disabled persons

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1 Introduction

In recent years, Slovenia has been engaged in a public debate concerning the legalization of euthanasia and assisted suicide. In 2024, a civil initiative, supported by a sufficient number of voter signatures, introduced the Voluntary Assisted Dying Bill (VADB)[1] (Predlog zakona o pomoči pri prostovoljnem končanju življenja, 2023) to the National Assembly. After deliberation, VADB was rejected as unsuitable for further consideration, although a consultative referendum was subsequently held. With a voter turnout of 41.43%, 54.89% of participants supported enacting a law regulating assistance in the voluntary ending of life (Republic of Slovenia State Election Commission, 2024).[2] Despite this, the law faced significant opposition from various entities, including medical organizations, the Commission for Medical Ethics of the Republic of Slovenia, the Catholic Church, and the Islamic Community in Slovenia. The Chamber of Nursing and Midwifery did not take an explicit stance but saw many of its members support the proposal (Ažman, 2023). By early 2025, the governing coalition, in collaboration with the civil initiative, amended the bill and submitted it to the National Assembly. In July 2025, the National Assembly adopted the VADB. Opponents of the VADB submitted a request for a legislative referendum.

The debate surrounding the legal regulation of voluntary end-of-life assistance has been predominantly undertaken in very general terms, with insufficient emphasis on the specifics of the bill that served as the foundation for the proposed law. Following the results of the referendum, the governing coalition introduced amendments to the bill, modifying the most controversial provisions, notably converting the patient's right to assisted dying from an absolute right to a relative one. This change was intended to enable the adoption of sub-legislative measures aimed at protecting vulnerable individuals in distressing transitional periods.

This article systematically examines the key legal provisions of the VADB, focusing on those that pose the greatest risks of misconduct and/or abuse. It also evaluates the amendments to these provisions and their implications for patient rights. Additionally, the article presents a comparative analysis of certain provisions of the

[1] Voluntary Assisted Dying Bill – VADB (Slovene Predlog zakona o pomoči pri prostovoljnem končanju življenja – ZPPKŽ (2023, 2025)).
[2] Republic of Slovenia State Election Commission, 2024 (Slovene Državna volilna komisija Republike Slovenije).

Slovenian VADB and the Dutch Termination of Life on Request and Assisted Suicide (Review Procedures) Act.[3] We have chosen to use the Dutch law for comparison, as the proponents of the VADB frequently cite it and, in certain instances, also misinterpret it (VADB, 2025, pp. 18, 19–23). It critically addresses the problematic nature of the "My life, my right" principle, which, while ostensibly promoting autonomy, may open the door to non-autonomous decisions made by individuals in transitional crises. This scenario is problematic from the perspectives of medical ethics and the Patient Rights Act (PRA).[4] The article concludes by presenting an alternative vision for regulating assistance in end-of-life decisions.

2 The Principle "My Life, My Right" as the Basis for Exercising Rights under Health Insurance

Upon a closer examination of the arguments proposed by opponents of euthanasia and the legal regulation of end-of-life assistance, it becomes evident that their opposition does not stem from a denial of an individual's right to a peaceful death, but from concerns regarding the broader societal implications (Ošlaj, 2018, p. 38). In the case of the previous bill, these concerns were substantiated. Proponents of the VADB, invoking the slogan "My life, my right", emphasize the patient's right to autonomy and self-determination as a fundamental principle that allows the patient to request assistance in ending their life. However, the European Court of Human Rights held in the case of *Pretty v. the United Kingdom*[5] that Article 2 of the European Convention on Human Rights[6], which protects the right to life, cannot be interpreted as conferring a diametrically opposed right, namely, a right to die.

Proponents of the VADB primarily reference Article 34 of the PRA, which they argue supports this right (VADB, 2025, p. 4). However, a closer examination of Article 34, in conjunction with Article 12 of the PRA, suggests a different understanding of the patient's right to make decisions. The right to existence and

[3] Termination of Life on Request and Assisted Suicide (Review Procedures) Act, The Dutch legal framework, which has allowed the performance of euthanasia and assisted suicide since 2002.
[4] Patient's Rights Act - PRA (Slovene Zakon o pacientovih pravicah – ZPacP): Uradni list RS, št. 15/08, 55/17, 177/20, 100/22 – ZNUZSZS.
[5] European Court of Human Rights. (2002, April 29). *Pretty v. the United Kingdom* (Application no. 2346/02).
[6] European Convention on Human Rights, retrieved from: https://www.echr.coe.int/documents/d/echr/convention_ENG (July 20, 2025).

self-determination cannot simultaneously serve as a right to demand that the healthcare system assist in ending one's life.

Article 34 of the PRA specifically safeguards the patient's right to decide which medical treatments they refuse. Although Article 34 ensures that a patient's autonomy is respected by allowing them to refuse treatment, it does not extend to granting the patient the authority to dictate medical procedures.

Proponents of the VADB, however, have extrapolated from this right a patient's correlative right to demand particular treatments, regardless of their medical validity or alignment with medical doctrine (VADB, 2025, p. 4). Notably, Article 6 of the previous version of the VADB stipulated that a patient could request assistance in ending their life if they were "experiencing unbearable suffering for which no acceptable option of relief exists." This provision could be interpreted to mean that the patient's subjective experience of suffering alone determines eligibility for assisted dying, without considering whether the relief options align with established medical practices.

This interpretation contrasts with the safeguards provided by Dutch law and conflicts with Article 12 of the PRA, which articulates that: "*A patient is entitled to treatments funded by public resources if they are deemed necessary by medical standards and are reasonably expected to benefit the patient*." The entitlement to such treatments is contingent upon medical necessity, not solely on the patient's subjective interpretation of their suffering. In other words, a patient is entitled to treatment funded by public resources if it is necessary and justified according to medical standards, and not solely based on the subjective feelings of a patient with a chronic illness or disability. Thus, it is not the patient who determines what they are entitled to, based on their interpretation of their suffering and the interventions they wish. Demanding euthanasia solely based on the patient's experience and their acceptance of only personally acceptable options for relief is akin to a patient with occasional tachycardia having the right to demand a chest CT[7] scan with contrast from a physician, without medical indication, because an ECG[8] is not an acceptable option for the patient. Such a need expressed by patients may be the result of unsuccessful

[7] Computed Tomography.
[8] Electrocardiogram.

treatment or inadequate symptom management. To prevent such situations in palliative care, physicians should, once all options for effective symptom relief in the terminal phase of an incurable illness have been exhausted, communicate this openly to the patient and allow them to propose the possibility of assisted dying.

Furthermore, the subjective nature of suffering in the VADB contrasts sharply with the more stringent criteria in the Dutch Termination of Life on Request and Assisted Suicide (Review Procedures) Act, which require that unbearable suffering must be tangible and verifiable by a physician, and that the patient hold the conviction that no reasonable alternative exists. The Dutch system also includes a comprehensive "Euthanasia Code"[9], which governs the procedures and safeguards for euthanasia and assisted suicide, ensuring that these services are delivered within a framework of strict medical and ethical guidelines, according to which a patient may choose to reject a reasonable alternative; such rejection does not automatically authorize euthanasia.

In contrast, the Slovenian proposal, by allowing euthanasia based solely on the patient's subjective experience, lacks such a regulatory framework. Additionally, this approach raises questions about the potential for misuse, as it would allow services that are not medically indicated, but rather requested purely by the patient, to be funded by public health insurance. The amended VADB addresses this issue by removing the phrase "they are experiencing" from Article 6 of the VADB, which allows suffering to be assessed objectively.

Another significant concern with the 'My life, my right' principle is that it places the right to end life above the right to receive comprehensive support for terminally ill individuals. By prioritizing access to assistance in ending life over other forms of care, such as quality palliative care, psychological support, and specialized treatments, the VADB risks depriving patients of adequate healthcare. If the legislature provides deadlines for implementing assisted dying that are more favorable than the possibility of exercising alternatives (such as a psychiatrist or palliative care), then it prioritizes assisted dying over the alternative. If patients are denied proper care, they may resort to euthanasia as a perceived solution, even when

[9] Euthanasia Code, Professional guidelines for performing euthanasia and assisted suicide, periodically reviewed by the Regional euthanasia review committees.

other viable options are available. By making such a choice a priority, we would undermine the right of patients to receive appropriate, high-quality, and safe healthcare, in accordance with established medical standards.

3 Access to End-of-Life Assistance

Proponents of the VADB advocate for the law as a solution to unbearable suffering during the final stages of an incurable illness (VADB, 2025, p. 3). However, the provisions of the previous bill were structured in such a way as to permit numerous exceptions, with almost no restrictions. Paragraph 1 of Article 6 in the previous VADB stipulated that a patient could claim the right to medically assisted dying (MAID)[10] if the following conditions were met: "*They are experiencing unbearable suffering, for which no acceptable relief option exists for the patient, and which is the result of a terminal illness, a severe permanent illness with persistent or recurring symptoms, or another health impairment, the treatment of which does not give a reasonable expectation of cure or improvement of the condition*."

It is the portion of Article 6 of the previous bill, with the phrase "or another health impairment", which is, in my view, problematic. This broad categorization encompasses individuals with conditions such as hemiplegia, paraplegia, amputations, loss of vision, chronic obstructive pulmonary disease (COPD), heart failure, kidney failure, neurogenic or rheumatoid diseases, chronic intestinal diseases, and others. Essentially, the law would have allowed MAID for individuals suffering from chronic, incurable health conditions that might cause frequent or occasional exacerbations of their condition. Moreover, many elderly individuals who have at least one chronic health condition could be included in this category. The amended VADB continues to permit MAID in cases of "other serious permanent impairment of health", which affects disabled individuals. However, even the amended VADB is deficient because it fails to define what severe health impairments mean. If we consider that severe health impairments only mean 100% disability, then in addition to the impairments mentioned above, we can also include patients who have received transplants of the heart, liver, lungs, after amputation of fingers, or both tibias. However, if we include patients with 90% or 80% disability among the severe health impairments, this list is much more exhaustive. The amendment places limitations

[10] Medical aid in dying- MAID (pomoč pri končanju življenja - PPKŽ).

on the absolute right of the patient by requiring a physician to assess the patient's suffering and the extent to which all potential treatment options for serious illnesses have been exhausted. Additionally, point 9 of Article 2 in the amended VADB further defines "intolerable suffering" as: *"A condition with no possibility of improvement when the patient endures severe and intense physical pain, extreme psychological distress, or both."*

This definition allows for psychological distress, not necessarily only physical suffering, to be considered as a basis for requesting MAID. All patients falling under this definition can request MAID if they suffer from extremely severe psychological distress due to a medical condition. However, the physician may refuse the request if they determine that the psychological distress is reversible or expected to improve. The first judicial decision will likely determine the adequacy of this safeguard.

The previous VADB, by providing such broad exceptions, effectively extended the right to MAID to a significant portion of the population. In combination with Article 28, or Article 26 of the amended VADB, which states that "the death insurance contract also covers death that occurs as a result of the MAID procedure, regardless of how much time has elapsed between the conclusion of the contract and the implementation of the MAID procedure", the law not only provided a medical justification for MAID but also implicitly included a social rationale (Bračič, 2023). Thus, there is a risk that the possibility of a financial windfall from life insurance will give some chronic patients an additional incentive to request MAID. So, a patient who does not see a prospect for himself, who is unable to support his family or his children in school, who has a severe chronic illness or is disabled, can help his loved ones by asserting the right to MAID, even though he could live with his illness or condition for years. Proponents of the VADB argue that insurance companies would adjust their actuarial calculations accordingly (Mišič et al., 2023), although this could result in chronic patients and disabled individuals being excluded from obtaining life insurance, given the VADB's provision that these individuals are entitled to MAID under certain conditions.

Furthermore, Paragraph 3 of Article 26 in the previous VADB states: *"The death of a patient, which occurred as a result of the MAID, shall not be considered as a direct cause of death. The direct cause of death shall be considered as a serious incurable disease or other serious permanent impairment of health ..."* This provision raised further concerns (Zwitter, 2025), as it allowed a disability that was not a direct cause of death but could lead to death over time to be classified as the "cause of death". This provision conflicted with Paragraph 2 of Article 21, which defined the cause of death for the purposes of medical certification as "assisted suicide".

4 Limitation of the Right to Medical Aid in Dying

The drafters of the VADB assumed that MAID would not be widely applied (VADB, 2025, p. 18). Rather, their entitlement would be subject to fulfilling specific legal conditions, which would be assessed and determined by the attending physician, an independent physician, and the competent Commission for Assistance in Voluntary Termination of Life in Slovenia ("Commission"). Under the previous VADB, physicians were merely required to confirm the patient's experience rather than assess it substantively. However, the amended VADB introduced the opportunity for physicians to more thoroughly assess the patient's condition. Whether physicians will actually be able to protect patients in transitional distress remains to be seen with the legal precedent.

Proponents of the VADB believe that any potential issues related to the standardization of the law would be addressed through by-laws developed by the medical profession (Mišič et al., 2023). However, if a law explicitly defines rights, those rights cannot be reinterpreted or altered by an executive actor's arbitrary interpretations of legal provisions. There is also a decision of the Constitutional Court[11] which, among other things, in paragraph 8 stipulates: *"... that the rules are adopted for the purpose of enforcing the law, which presupposes that they are substantively bound to the law. The rulebook must not stipulate anything in the substantive sense without a legal basis and outside the substantive frameworks that must be explicitly set out in the law or at least ascertainable from it by interpretation ..."*

The previous VADB would have allowed a young individual with paraplegia to request MAID during the mourning phase, when the individual had not yet come to terms with their condition. Under the previous bill, such a patient would have been entitled to MAID, even without a reasonable expectation of recovery. The amended

[11] Decision annulling the Rules on the Methodology for Setting Rents in Non-Profit Apartments, issued by the Constitutional Court of the Republic of Slovenia, adopted 17. 12. 1998 (Slovene Odločba o razveljavitvi pravilnika o metodologiji za oblikovanje najemnin v neprofitnih stanovanjih; Uradni list RS, št. 4/99).

VADB, however, gives physicians the ability to challenge requests for MAID in such cases.

5 Limitations of the Right to Medical Aid in Dying Due to the Patient's Inability to Make Independent Decisions

Both proponents and opponents of euthanasia place a strong emphasis on human autonomy. In contrast, opponents highlight the complexities and potential external pressures that could diminish autonomy, particularly if euthanasia were legalized.

Some authors (Velleman, 1999; Wright, 2017) contend that the ability to make autonomous decisions in the face of severe pain or mental illness is often compromised, as the capacity for rational decision-making can be severely limited by suffering.

The previous VADB did not limit the exercise of the right to MAID solely to individuals who have an acute mental disorder. Instead, it allowed patients who experienced mental distress due to chronic conditions to assert their right to MAID. As we have already written, according to the provisions of the previous VADB, the right to MAID could also be exercised by a young injured person with paraplegia, during the mourning phase, when he or she has not yet accepted their health condition. According to the provisions of the previous VADB, it would not have been possible to prevent MAID for such a patient. Namely, paragraph 2 of Article 6 in the previous VADB stated that *»the right to MAID could not be exercised solely on the basis of suffering caused by an acute mental disorder.«* This meant that MAID could not be accessed *solely on the basis* that the patient had an acute mental disorder; in order to exercise this right, an additional condition was required. In other words, in addition to the mental disorder, the patient would also need to have a chronic illness or disability. Paragraph 2 did not impose any limitations beyond those already specified in Paragraph 1 of Article 6 of the VADB. This lack of restriction raised questions about whether individuals undergoing significant mental distress following a serious illness or injury would be able to make autonomous decisions, especially during the mourning phase or periods of denial.

Paragraph 12 of Article 4 of VADB states: *"The psychiatrist shall state in his opinion whether the patient is capable of making decisions about himself."* There are also chronic depressions and anxiety disorders with suicidal tendencies, which, due to the inaccessibility and stigmatization of psychiatric treatment in Slovenia, are not treated, diagnosed, or treated at all in many patients (Rifel et al., 2008; Jerala & Selič-Zupančič, 2021; Ropret et al., 2023). A psychiatrist might judge that a patient is incapable of making decisions about himself only based on acute mental distress. Yet, many patients, after a serious injury or after being diagnosed with an incurable disease, are incapable of making completely rational decisions, even if these distresses are transient. In times of hardship, in the process of grief and coping with new life circumstances, a person's ability to make rational judgments is significantly limited (Velleman, 1999; Wright, 2017). However, the distress of patients due to a serious medical condition cannot be considered a mental condition that could deprive them of the right to MAID. A patient who is diagnosed with disseminated lung cancer and is in a phase of denial or anger is no more capable of making decisions (McFarland et al., 2020; Ungvari et al., 2025) about himself than a patient who has been involved in a car accident with consequent spinal cord injury and is in a phase of denial or anger (Mayou et al., 1993; Usta Sağlam et al., 2023). This is the case because if the patient's mental distress is considered a reason for denying the right to MAID, then no one who actually suffers would be entitled to MAID. This result is contrary to the fundamental purpose of passing such a law. If, on the other hand, seriously ill people in distress are able to make decisions about themselves and thus also about MAID, then young injured people in distress (paraplegia, amputations), but who temporarily do not see prospects for recovery during their mourning phase, are capable of making decisions about themselves, and yet would be entitled to MAID (paragraph 1 of Article 6).

6 Possibility of Patient Complaint

Proponents of the VADB assert that Slovenian physicians, in accordance with the VADB, can be as critical of the conditions necessary to implement MAID as their Dutch counterparts, and therefore, they will be able to issue a negative opinion that will be considered (Pleterski, 2024). While the amended VADB allows this, the original version explicitly stipulated that physicians and the Commission should only provide an opinion on whether the patient met the conditions of Article 6 of the VADB. If a physician offers an opinion contrary to this provision, it would be considered a violation and grounds for judicial protection. Article 13 of the VADB states that an appeal against the Commission's decision is not allowed; however, judicial protection before a court is permitted within thirty days of the notification of the decision. In the event of a rejected application for MAID, in accordance with Article 14 of the VADB, the patient may seek judicial protection at the social court and challenge the decision of the Commission. Additionally, the patient may refer to Article 27 of the Administrative Dispute Act[12] if the law was either not applied or incorrectly applied during the procedure that led to the issuance of the administrative act, and if procedural rules were not adhered to, affecting the legality or correctness of the decision.

It is conceivable that patients suffering from renal failure on hemodialysis, visual impairments, deafness, paraplegia, or amputation, for whom most physicians would reject a MAID application, might still seek judicial protection if they meet the conditions outlined in Article 6 of the VADB. These patients may argue that they endure unbearable suffering, that no suitable relief options are available (such as being ineligible for kidney transplantation), and that their health impairment does not offer a reasonable expectation of recovery. In these instances, the amended VADB makes it more challenging to implement MAID for chronic patients, as it requires a physician's assessment under Article 6 of the VADB, which was absent in the previous version. Without this amendment, a judge would only be able to adhere to the explicitly stated conditions of the original VADB.

7 The Right to Euthanasia and the Expected Frequency of Its Exercise

Proponents of the VADB have removed the provision for euthanasia from the previous Bill. Paragraph 2 of Article 5 of the previous VADB stated: *"Euthanasia is performed if the patient is unable to administer the lethal substance themselves, due to religious, moral, or other justified reasons, or if other justified reasons exist."* The previous VADB therefore, allowed euthanasia instead of assisted suicide based on the patient's religious or moral objections, which are subjective and unchallengeable. That is to say, because moral and religious reasons are entirely subjective, they cannot be objectified, the patient only has to refer to them. Furthermore, the previous VADB

[12] Administrative Disputes Act (Slovene Zakon o upravnem sporu – ZUS-1: Uradni list RS, št. 105/06, 107/09 – odl. US, 62/10, 98/11 – odl. US, 109/12, 10/17 – ZPP-E in 49/23.

included undefined "justified reasons" for euthanasia to apply, essentially equating the right to euthanasia with the right to physician-assisted suicide. This distinction is significant when considering the anticipated scope of such services, which proponents of the VADB have miscalculated. In the Netherlands, where euthanasia and assisted suicide are treated similarly, the majority of patients choose euthanasia. In 2022, the Netherlands saw 8,501 euthanasia procedures and only 166 assisted suicides, with 33 assisted suicides eventually leading to euthanasia due to complications (Annual report, 2022).[13] Were one to wish to estimate the number of MAID requests in Slovenia on the basis of Dutch data, the calculation would need to include both requests for euthanasia and requests for assisted suicide, rather than only requests for assisted suicide, which are rare in the Netherlands but represent the sole option under the proposed amended VADB. It follows that the number of MAID requests would likely be significantly higher than anticipated by the proponents of the draft law. If we used Dutch data, where 5.1% of all deaths occur pursuant to the Termination of Life on Request and Assisted Suicide, we could extrapolate approximately 1,147 MAID procedures annually in Slovenia, which accounts 5.1% of 22,492 deaths in Slovenia in 2022 (source: SURS).[14] This refers only to approved requests, but we must also take into account that two-thirds of applications in the Netherlands are rejected (Expertisecentrum Euthanasie, 2024).[15] The Dutch experience suggests that theoretically, Slovenia could expect as many as 3,450 applications annually. These figures indicate that MAID would likely be requested more frequently in Slovenia - more than 33, as projected by the proponents of VADB. The removal of the option of euthanasia from the VADB is also likely to significantly reduce the number of applications for MAID. However, a direct comparison with the Netherlands is also problematic due to differences in social standards, healthcare accessibility, and cultural attitudes toward life termination.

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[13] Annual report is a report on the procedures performed for Termination of Life on Request and Assisted Suicide, issued each year by the Regional Euthanasia Review Committees.

[14] SURS - Statistični urad Republike Slovenije (Statistical Office of the Republic of Slovenia, 2022).

[15] The Expertisecentrum Euthanasie, a regional center specialized in assisted dying, received 4,508 requests for euthanasia in 2023, of which 1,269 were granted. This means that approximately 72% of the requests were rejected.

8 A Proposal for the Integration of Additional Safeguards into the Existing VADB or Beyond

Given the concerns and examples discussed above, I believe that amendments or additional safeguards are needed within the VADB, especially regarding the definitions in Article 2, Article 6, and Article 28. To ensure the appropriateness of MAID, the patient's suffering should be deemed irreversible in the terminal phase of progressive disease. Palliative care methods exist to reliably determine the irreversibility of certain symptoms or conditions when they fail to respond to treatment. The intensity of these symptoms can also be measured. A significant concern turns on the difficult question of at what point we can definitively say that no reasonable alternatives remain, and the patient is entitled to MAID. Patients have the right to refuse medical care, including palliative treatments, especially if the side effects outweigh the benefits. However, a refusal of reasonable alternatives cannot justify claiming that the patient's suffering is irreducible if, from the healthcare provider's perspective, these alternatives offer no real relief. Therefore, a balanced approach is necessary, one that considers both the patient's experience and the judgment of healthcare professionals, using objective measures to assess the intensity and frequency of physical suffering (pain, nausea, difficulty breathing) and also the intensity of these symptoms.

This shift in paradigm could not be accomplished by the VADB alone but may require a comprehensive palliative care law in Slovenia or amendments to the Healthcare Services Act and PRA. Under such a framework, medical interventions already performed in healthcare could be more clearly defined, including certain cases where treatment should be withdrawn. For example, in intensive care, physicians, without the consent of an unconscious patient, but with the consent of relatives, decide to withdraw hemodynamic and ventilatory support for patients, which sustains them and with which they could live for an indefinite period. This decision to withdraw is also MAID in cases of medical conditions that are not the result of a chronic terminal illness. Upon withdrawal, to prevent suffering, patients are prescribed doses of opiates that would cause respiratory arrest and death. It is hard to avoid the presumption that, by the current definition, this constitutes euthanasia, though the word is avoided in healthcare, due to its negative connotations. In summary, patients in the final stages of terminal progressive diseases like cancer, motor neuron disease, cardiovascular diseases, or obstructive lung diseases should be eligible for MAID.

9 Conclusion

The previous VADB contained unacceptable proposals.. The amended VADB still carries unnecessary risks for disabled and chronically ill patients in transitional distress, who may have many years of relatively high-quality life despite their conditions. However, the amended VADB provides physicians with the option of rejecting MAID applications in such cases and the possibility of introducing safeguards to protect patients from premature death. Whether the amended VADB poses a real risk to patients in transitional distress is an imponderable. This question likely will not be resolved until the first lawsuit is filed for refusing to perform MAID on a disabled person, and the court decides the matter. This risk, however, could be avoided if the previously discussed provisions of the law were amended.

While euthanasia and physician-assisted suicide are often considered ethically unacceptable from a medical ethics perspective, the paradigm where MAID is based on the patient's demonstrated need and is objectified by healthcare professionals appears ethically acceptable. This would apply primarily to patients in the final stage of terminal illness with no possibility of improvement through palliative care. This paradigm, along with other medical interventions already used in healthcare, could be defined in the law on palliative care. From a comparative law standpoint, it appears that many countries (most recently the United Kingdom's Assisted Dying for Terminally Ill Adults Bill) will adopt laws directly regulating MAID.

In conclusion, patients who are not objectively suffering, or who are not yet in the final stage of a terminal illness, should not be eligible for MAID within the framework of public healthcare. If society permits MAID for patients who are not suffering unbearably from terminal illness, it would be preferable to offer this service outside of public healthcare to avoid violations of medical ethics, palliative care principles, and patient rights under the existing law.

Note

This article is the outcome of private and partially public discourse between the author and the proponents of the proposed Slovenian Voluntary Assisted Dying Bill.

Legal Acts

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Povzetek v slovenskem jeziku

Ta članek ponuja analizo slovenskega predloga zakona o prostovoljnem končanju življenja, in sicer v njegovi prvotni ter spremenjeni različici, ki temelji na paradigmi »Moje življenje, moja pravica«. Prvotni predlog zakona, ki je veljal za zelo liberalnega, je vseboval številne izjeme, ki so dejansko omogočale evtanazijo za vse osebe s kroničnimi boleznimi ali invalidnostjo. Analiza kritično obravnava najbolj sporne pravne določbe predloga zakona ter predvideva posledice njegove morebitne uveljavitve, zlasti z vidika ranljivih uporabnikov zdravstvenih storitev. Pokaže se, da prvotna formulacija pravice do medicinske pomoči pri končanju življenja nasprotuje temeljnim načelom zdravstvenega sistema in je v neskladju z Zakonom o pacientovih pravicah. Spremenjeni predlog zakona o prostovoljnem končanju življenja zdravnikom omogoča tako zavrnitev vlog za medicinsko pomoč pri končanju življenja kot tudi uporabo zaščitnih ukrepov za varovanje pacientov v prehodni stiski pred prezgodnjo smrtjo.

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EDUCATION AGAINST AGEISM, STEREOTYPES AND GERONTOPHOBIA ABOUT THE SEXUALITY OF OLDER ADULTS (DEVELOPMENT OF A MODEL FOR INTEGRATED PROMOTION OF SEXUAL LIFE OF OLDER ADULTS)

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Abstract This study aims to develop an educational model and guidelines for promoting sexual health in older adults (55+), addressing ageism, stereotypes, and gerontophobia. Despite its significance for successful aging, sexual health in older adults is often neglected. The study involved 651 participants (aged 55-75) and used a quantitative approach, examining factors like health status, sexual activity, and education through an online survey. Key findings include a positive correlation between health and sexual satisfaction ($r = 0.2$ to 0.4, $p < 0.001$) and the importance of sexual knowledge in life satisfaction ($F = 90.027$; $p < 0.001$). Results underline the need for tailored educational programs and open discussions on sexuality. The proposed model aims to improve sexual well-being and overall quality of life, promoting a holistic approach to sexual health care to older adults. These findings are relevant for shaping policies and interventions in Slovenia and globally.

Keywords
older adults, sexuality, stereotypes, activity, withdrawal, satisfaction

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1 Introducton

The proportion of older adults is increasing worldwide, outpacing all other age groups. Trends predict that by 2050, the number of people aged 60 and older is expected to increase to 2 billion. In Slovenia, the proportion of the population aged 65 and over is projected to increase from the current 21.1% to 32.1%. This raises important questions about how to support older adults so as to maintain their independence and activity levels, while also balancing health promotion policies to enhance their quality of life. Although sexual health is not always directly included in quality of life assessment tools, it is evident that sexual well-being significantly contributes to overall life satisfaction in many older adults (WHO, 2002). Promoting sexual health plays a vital role in improving their quality of life, positively influencing emotional and psychosocial well-being, and fostering intimacy and social connections. Sexuality is a normal and healthy part of life, and within this framework lies the issue of sexual health, which encompasses a wide range of interconnected mental, physical, and emotional factors (Breuner & Mattson, 2016). These factors reflect how well-being, illness, or specific challenges can affect an individual's sexuality, their family, relationships, work, hopes, and fears (Andrews, 2001; Breuner & Mattson, 2016).

Despite societal progress, we still struggle with prejudices, as sexuality remains a taboo topic, particularly pertaining to older adults. The belief that sexual activity is inappropriate or unseemly after a certain age is widespread. While we have come to understand that healthy eating, exercise, and caring for physical and mental health contribute to the overall well-being of older adults, it is equally essential to include the importance of healthy and safe sexuality. As a society, we must accept that sexuality is not bound by age, and that the upper age limit for sexual activities is determined by each individual based on their desires and abilities.

Sexual health, defined as a state of physical, emotional, mental, and social well-being related to sexuality, does not merely mean the absence of disease or disorders (WHO, 2006); it also encompasses sexual satisfaction, a complex and significant process (Miguel et al., 2024). Sexuality is an important and evolving aspect of health throughout one's lifespan. It is crucial that individuals do not shy away from their sexual desires, as this includes the right of all people to knowledge and the ability to lead a safe and pleasurable sexual life (Starc et al., 2023), regardless of age. A satisfying sexual life provides individuals with a sense of vitality, as noted by Kastnebaum (1979) and Starc et al. (2023). Therefore, we should focus on helping older adults find the safest forms of sexual expression suited to their needs and circumstances (Aizenberg et al., 2003). Yan et al. (2011) view the maintenance of sexual life as a symbol of vitality and longevity, a perspective supported by Menard et al. (2015) and Starc et al. (2023), who further emphasize that sexual satisfaction should be regarded as a crucial aspect of sexual health, particularly for older adults. In this context, sexual satisfaction may become more significant than the frequency of sexual activity. Satisfaction with sexuality often involves emotional intimacy, affection, and mutual respect, elements that can be preserved or even strengthened despite age-related changes (Štulhofer et al., 2019). Therefore, focusing on sexual satisfaction is essential, as it allows for greater attention to the psychosocial and emotional dimensions of sexual health, which are just as vital as physical health in maintaining overall well-being. It is critical to shift the focus from merely physical sexual activity or function to a more holistic approach that incorporates sexual satisfaction as a key element of sexual health care (WHO, 2002). Menard et al. (2015) emphasize that sexuality is an integral part of healthy and positive aging (Starc et al., 2023).

The concept of satisfying sexuality is deeply connected to overall health, as it influences a person's well-being by promoting feelings of happiness, fulfillment, peace, and life satisfaction. It enhances the perception of the quality of one’s sexual life and relationships (Pascoal et al., 2014). Conversely, the absence of satisfying sexuality can negatively impact well-being.

Uwagbai & Tyrrell (2018); Even-Zohar & Werner (2018); and Gewirtz Meydan et al. (2019) find that a lack of knowledge about health-related sexual issues hinders the ability to lead a satisfying sexual life, cope with changes in sexual function and identity, and manage expectations regarding the frequency of sexual activity.

As a critical element of sexual health, sexual satisfaction deserves attention in public health research as a key factor in successful aging and a potential correlate of various health indicators. This area should be systematically studied every few years.

While the number of studies addressing the sexuality of older adults is increasing, this study is the first in Slovenia to document the impact of knowledge and sexuality on successful aging among adults aged 55 and over. Although sexuality is a deeply personal subject, Gewirtz Meydan et al. (2019) argue that exploring sexuality is both normal and healthy. Supporting the sexual health of older adults presents numerous challenges, as noted by Chilton (2021). Maintaining the misconception that older adults are not sexually active leads to the neglect of their sexual health and contributes to discrimination against those aged 55 and older.

In recent years, various strategies and policies have been adopted to promote the health of older adults. However, gaps remain, particularly in the treatment of sexual health among this population. We find that the framework for sexual health education for older adults is inadequate, inconsistent, and ineffective in promoting their sexual well-being. Additionally, there is a lack of comprehensive information on sexual health, social issues, sexual behavior, intimate relationships, and life skills within the studied population.

The data from our research highlight the need to reduce age-related inequalities in sexual health and to implement measures to prevent discrimination against older adults (55+) regarding sexuality. Although the World Health Organization typically defines older adults as individuals aged 65 and over, we have included individuals aged 55 and over in our model. In Slovenia, reproductive health care programs are available for children, adolescents, and adults up to the age of 55. However, individuals over the age of 55 are not included in these programs, resulting in their sexual health needs being inadequately addressed. Furthermore, this article addresses the critical gap in sexual health care for older adults (55+), emphasizing the lack of research, education, and support systems that adequately meet the needs of this often-overlooked population. The results of our research, which explored the connection between sexuality and the quality of life in older adults, highlighted the influence of various factors, such as health status, frequency of sexual activity, upbringing, and education, on the significance of sexuality and sexual life satisfaction. Additionally, we analyzed differences based on gender, self-assessed health, attitudes towards sexuality in later life, and the educational content about sexuality that older adults expressed interest in receiving. This content would be tailored to their specific needs and preferences within the context of sexuality education. We believe that proper education can dismantle stereotypes about older adults, revive forgotten values, and contribute to better self-acceptance, including the acceptance of age-related changes, particularly those related to sexuality.

2 Needs in Old Age

Aging can manifest implicitly or explicitly and be expressed at the micro, meso, or macro level. This definition is particularly relevant to the practice of sexuality, as it highlights well-established aspects in the literature, such as classical socio-psychological components—cognitive (stereotypes), affective (prejudices), and behavioral (discrimination)—as well as both conscious and unconscious dimensions. This underscores the individual, social, and institutional significance of the phenomenon. Consequently, the definition includes the following key dimensions:

- Three classical components (cognitive, affective, and behavioral),
- Positive/negative aspects (positive and negative aging),
- Conscious/unconscious aspects (implicit and explicit ageism), and
- Typological division (ageism at the micro, meso, and macro levels) (Iversen et al., 2009).

Ramovš (2003, p. 90) argues that human needs are the driving force that helps individuals maintain a quality life. These needs trigger specific behaviors that help achieve bodily balance and are linked to the motivations that encourage activity. Physiological needs regulate bodily functions (e.g., the need for food, rest, excretion, sexuality, etc.), while psychosocial needs express desires for safety, love, belonging, respect, health, and learning. Both physiological and psychosocial needs are interconnected and evolve over time throughout the aging process, in accordance with norms, values, and attitudes, as noted by Maslow (1943), Ramovš (2004), and Roljić and Kobentar (2017). Goriup & Lahe (2018) also observe that aging is a dynamic, evolutionary developmental process in which individuals continuously develop, adapt, and change. Avis & Green (2011) add that, as the human sexual response cycle changes with age, sexuality may not be the same as it was at twenty (Hyde, 2010), but it can still be fulfilling (Karraker et al., 2011).

Youngkin (2004) and Steinke (2005) note that intimacy is often understood in the context of sexual performance, though it encompasses far more than just "bare" sexuality. Intimacy includes key components of a relationship such as:

- Commitment,
- Emotional intimacy,
- Cognitive intimacy,
- Physical intimacy, and
- Interdependence.

All these aspects of intimate life are closely tied to the context of aging, along with other influences that contribute to a meaningful life, as Youngkin (2004) points out.

While the need for intimacy and sexuality evolves over time, Yilkan et al. (2024) found that these needs remain crucial to healthy aging and should not be overlooked, as emphasized by Bagheri et al. (2024). However, even the best fulfillment of certain needs, when other important needs are neglected, can disrupt life satisfaction, undermining the fulfillment derived from already-met needs. Understanding and addressing all human needs is, as Ramovš (2003) emphasizes, essential for meaningful work with and for people. Bagheri et al. (2024) further stress that the denial of needs and neglect of health dimensions in sexuality are also driven by a lack of knowledge, making the development of effective educational programs in this area vital.

3 Ageism and the Sexuality of Older Adults

There are numerous and varied definitions of ageism, but they all share a common theme: discrimination against specific age groups. Various sources indicate that while some experts describe ageism as discrimination against older individuals, others highlight that it can also affect all age groups, particularly the young. Ageism consists of three main components:

- Prejudice against age, aging, and older people;
- Discrimination against older adults, especially in the workplace and social environments;

– Institutional policies and procedures that perpetuate stereotypical beliefs about older adults, limiting opportunities for fulfilling lives and diminishing their personal dignity (Butler, 1980).

Ageism, in relation to aging, is so widely accepted and embedded in our perceptions of aging that it has become socially "taken for granted," as noted by Sanchez Izquierdo et al. (2022). We often forget that aging is a process that affects every one of us (Goriup & Lahe, 2018). Holstein & Minkler (2003) further argue that ageism impacts all individuals, shaping society's attitudes toward older adults and our understanding of the aging process, while reinforcing structural inequalities. In its most extreme form, ageism involves intentional neglect, harassment, and abuse of older individuals (Butler, 2008).

Table 1: Taxonomy of Ageism

	DISCRIMINATION	PREJUDICE
CHRONOLOGICAL AGE	age barrier (e.g., insurance is only available to adults up to the age of 65)	statistical weighting (e.g., by including age in calculating priorities)
OLDER BODY	formal rejection of (e.g., older adults as advertising models)	withdrawal (e.g., avoiding contact with older adults at social events)

Source: Bytheway (2005).

Thornton (2002) notes that age-related prejudices most often refer to progressive physical and mental decline, social isolation, and asexual behavior. Biggs (2005) agrees, further highlighting that ageism, when linked to the connection between age and wisdom, works in favor of age, whereas the opposite is true regarding sexuality. Older adults are often subjected to the stereotype that they are no longer capable of sexual pleasure due to their age and that sexuality is, by default, assumed to be reserved solely for the young (Kastenbaum, 1979; Thompson et al., 2014). Emphasizing reproduction as the primary purpose of sexuality in the biomedical model reinforces the belief that when fertility declines, sexual desire and pleasure also disappear. This limited view overlooks broader aspects of sexuality, such as intimacy, affection, and emotional connection, which remain significant throughout the lifespan (Thompson et al., 2014). The notion that sexuality is important solely in terms of reproduction contributes to the marginalization of sexuality in older adults, reinforcing stereotypes and potentially hindering access to the care and support they need to maintain sexual health in later life.

As a result of frequent exposure to these prejudices, older individuals often deny their own sexual needs, as noted by Olatayo et al. (2015). The loss of certain physical abilities, coupled with the development of negative attitudes toward older adults and the focus on their limitations or negative characteristics associated with aging, often leads older adults to withdraw from society (Cumming & Henry, 1961). Bagheri et al. (2024) further point out that this can result in mutual social isolation.

McAuliffe et al. (2007), Kirkman et al. (2015), and Haesler et al. (2016) emphasize that stereotypes stemming from ageism and irrational fears are primarily due to a lack of knowledge, denial of the importance of sexual well-being, and infringement on older adults' rights to sexual expression. Preventing and combating discrimination against older adults is challenging because ageism is ingrained in people's ways of thinking, behavior, and culture (Hošnjak & Goriup, 2023). Discriminatory attitudes and beliefs about the sexual activity of older adults due to their age often manifest in behavior, resulting in discrimination and social exclusion, which in turn negatively affects their well-being and quality of life (Corrigan, 2004). This is linked to increased anxiety, depression, and suicidal thoughts, all of which diminish the quality of life for those affected (Ha & Kim, 2021).

The negative perception of aging, particularly regarding sexuality in the third and fourth stages of life, is intensifying, especially in Western postmodern societies where media and entertainment frequently depict youthful images, while older adults are portrayed as physically, cognitively, and sexually inadequate (Zebrowitz & Montepare, 2000). Although aging is often associated with loss, particularly in the domain of sexuality, Wada et. al (2015) argue the opposite, highlighting that the development of PDE5 inhibitors, such as Viagra, and aesthetic procedures aimed at "aging gracefully" reflect an idealization of aging that is rooted in ageist norms and beliefs. These trends suggest that older adults are expected to maintain a youthful appearance and sexual vitality, which can increase societal pressure to ignore aging rather than accept it. In this regard, both extreme approaches-depicting older individuals as sexually inactive and pressuring them to preserve a youthful look-reflect ageist stereotypes, but in different ways.

Therefore, recognizing ageism in relation to the sexuality of older adults is crucial to ensuring they have equal opportunities to express their sexuality, just like younger adults. Additionally, there is a need to provide proper educational support, access to health information, and healthcare services to enable older individuals to lead healthy and fulfilling sexual lives in their later years.

4 The Influence of Knowledge on Older Adults' Sexual Satisfaction

A widespread stereotype is that "being old means being sick." While there is some legitimacy to the assumption that chronological age is associated with health decline and reduced functioning, the causal relationship between this decline and the sexual activity of older adults may be overestimated. Research has shown that knowledge and attitudes about sexuality are closely linked, and that the level of knowledge about sexuality among older adults is generally lower in those with a high degree of prejudice (Allan & Johnson, 2008; Funderburk et al., 2006). DeLamater (2012) also notes that the sexuality of older adults is a neglected topic, which fosters a one-sided perspective (Pavliha, 2009) and stereotypical thinking that older adults are not entitled to sexuality (Anderson, 2013).

The experience of discrimination can be interpreted by the body as a social stressor, directly impacting health by activating the hypothalamic-pituitary-adrenal axis, leading to increased cortisol release and heightened systemic inflammation. Discrimination can also promote unhealthy sexual behavior, both intentionally and unintentionally, acting as a barrier to a healthy lifestyle (Jackson, Hackett, & Steptoe, 2019). If society taboos aging and we turn a blind eye to the natural aging process, older adults are marginalized on the social periphery (Anderson, 2013). Thus, aging is not only a biological phenomenon but also a social one. As Goriup and Lahe (2018) suggest, future perspectives on aging depend on current perceptions. Bagheri et al. (2024) and Rao et al. (2024) point out that all age groups in our society often misunderstand the aging process, frequently due to inadequate information.

Sexual health cannot be defined, understood, or applied without knowledge about sexuality, which is fundamental to behaviors and outcomes related to sexual health (WHO, 2006). Nappi & Lachowsky (2009) concur, noting that aging itself affects sexual functioning. However, they emphasize that sexual behavior in older adults is strongly influenced by factors such as general physical and mental well-being, relationship quality, and life circumstances (Forbes et al., 2016). Although sexual function tends to decline with age, functionality is only one dimension of sexuality, which also includes emotional intimacy, sexual satisfaction, and overall sexual health, all of which are shaped by physical, psychological, and relational factors (Štulhofer et al. 2019). Braithwaite (2002) finds that an approach providing education and guidelines to improve quality of life at every stage of aging reduces the fear of aging, a view supported by Hamil-Luker & Uhlenberg (2002). Fear of aging affects individuals' attitudes and behaviors towards aging as well as their adaptation to their own aging process (Kinsella & Phillips, 2005), and this also extends to sexuality.

While acknowleding that the population is aging, society has not moved beyond merely recognizing this fact (Goriup & Lahe, 2018). Paunonen & Haggman Laitila (1990) highlight that the lack of information not only leads to misconceptions about older adults' sexuality but also impacts the later sexual lives of all generations. Over time, perceptions of age can change with sufficient information, leading to a better understanding of sexuality's dimensions and more effective interventions for sexual health (Bagheri et al., 2024; Yilkan et al., 2024). Instead of perceiving older adults as sexually incapable, we should offer them opportunities to learn and acquire new knowledge and skills, allowing aging to become a time of growth, fulfillment, and new opportunities—including in the realm of sexuality.

5 Methods

5.1 Study Design and Participants

The study utilized a quantitative, cross-sectional research design within a positivist framework to examine the relationship between sexuality and the quality of life in older adults. It also analyzed how various factors, such as health status, frequency of sexual activity, upbringing, and education, are associated with the perceived importance of and satisfaction with sexual life. The study sample included individuals aged 55 and older; however, for the purposes of the study, the age group was limited to between 55 and 75 years, using a purposive and opportunistic sampling approach. Data were collected through an online survey questionnaire, initially reaching a sample size of 1,050 older adults. However, questionnaires with missing responses and those completed by participants aged over 75 were excluded, as individuals over the age of 75 are generally presumed to be less sexually active. Additionally, questionnaires with incomplete data were removed. The final sample thus included 651 participants.

In our study, we designed a questionnaire to collect relevant data on the needs and attitudes of older adults regarding sexuality in later life, focusing on knowledge, attitudes, and preferences for educational content. The research aimed to gather data on key areas essential for improving sexual health within this population. The survey questionnaire consists of five sections, through which we identified the relationships between attitudes towards aging and one's own sexuality, successful aging in relation to sexuality, and the need for educational content about sexuality.

To measure knowledge, respondents were asked to respond to statements about sexuality in older age using a three-point scale (yes, no, don't know), where lower scores indicated greater knowledge. The second section assessed attitudes toward sexuality in older adults, where participants expressed their level of agreement with statements on a five-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree). Additionally, we included a section to assess the sense of well-being or successful aging, specifically in relation to sexual health. This section also used a five-point Likert scale, where participants indicated their level of agreement with various statements about aging and sexual health. Finally, we gathered information on the types of educational content that participants would like to receive in sexual health programs for older adults. Participants expressed their opinions using a three-point scale (agree, unsure, disagree) and a five-point Likert scale, allowing them to rate their level of agreement with each statement. This questionnaire was designed to collect relevant data on the needs and attitudes of older adults regarding sexual health education, which will help to develop more effective educational programs aimed at improving sexual health in this demographic group.

5.2 Ethics

All participants were provided with access to the survey, which they completed online. The sample was purposive, selected to focus on individuals aged 55 and older, which was in line with the study's objectives. The survey was conducted anonymously to ensure the confidentiality of respondents' identities. Participants were informed that their involvement was entirely voluntary and that they could withdraw from the survey at any time without providing a reason. If they completed the survey, they were considered to have given their informed consent to participate. We applied the principles of the Declaration of Helsinki to conduct the research. The ethics committee of the Health Centre Velenje approved the implementation of the research (Ref. No. 1749/2023).

5.3 Statistics

The collected data were first organized using Microsoft Office Excel 2018 and then statistically analyzed using the IBM SPSS Statistics for Windows, Version 29.0 (IBM Corp., New York) software. In the study, we employed explanatory factor analysis to extract dependent variables. We assessed the suitability of our data for performing factor analysis using the Kaiser-Meyer-Olkin (KMO) measure and Bartlett's test of sphericity.

An exploratory factor analysis (EFA) was conducted using the maximum likelihood extraction method (Promax rotation). The first analysis showed data suitability (KMO = 0.844; Bartlett's test, $p = 0.000$), identifying 34 variables with communalities below 0.4, which were excluded. A second analysis confirmed better suitability (KMO = 0.849; Bartlett’s test, $p < 0.001$), with all communalities above 0.4. The final EFA identified seven factors, explaining 54.59% of the variance. The first factor explained 23.09%, the second 8.35%, and the third 10.97%, with the remaining factors contributing progressively less. Factor loadings were rotated using Promax, and Cronbach’s alpha was calculated for each factor.

The factors were named as follows:

Factor 1 - "Coping with Age" (13 variables, Cronbach’s alpha = 0.942)

Factor 2 - "Stereotypes about Older Adults' Sexuality" (7 variables, Cronbach’s alpha = 0.871)

Factor 3 - "Attitudes towards Sexuality" (11 variables, Cronbach’s alpha = 0.710)

Factor 4 - "Satisfaction with Sexual Life" (4 variables, Cronbach's alpha = 0.802)

Factor 5 - "Permissive Attitude towards Sexuality" (3 variables, Cronbach's alpha = 0.727)

Factor 6 - "Knowledge about Sexuality" (4 variables, Cronbach's alpha = 0.728)

Factor 7 - "Perception of One's Own Body" (2 variables, Cronbach's alpha = 0.680).

Using the Kolmogorov-Smirnov test, we determined that the individual factors/new variables were not normally distributed. Therefore, we employed non-parametric tests.

The Mann-Whitney U test was used to calculate differences in extracted factors and some other key variables by gender. The chi-square test was used to calculate the importance of sexuality by education. A linear regression was used to calculate associations about the importance of sexuality and sexual well-being. A P-value of less than 0.05 was considered to be significant.

6 Results

The final sample thus comprised 651 older adults (55+), representing 61.90% of valid questionnaires, comprising 237 (36.4%) men and 414 (63.6%) women. The mean age of the respondents was 64, with the majority coming from the Savinja region, followed by respondents from Carinthia, and the fewest from the Littoral–Inner Carniola and Lower Sava regions. This likely reflects greater promotion of the study in the Savinja region.

Most respondents were married or living in a cohabiting relationship (49.2%), 20% were widows, and 31.3% lived alone or with a partner (30.0%), while the least lived with others (0.5%). About 39.6% of the respondents experienced authoritarian upbringing or lived in a non-violent family, followed by authoritarian (violent) families (27.2%) and democratic (empathetic) families (26.9%). The results indicated that sexuality was more important to respondents who experienced a non-violent and democratic upbringing (26.4%) and least important to those who had violent upbringing (4.5%). The majority of respondents had a secondary education (27.5%).

Regarding religious beliefs, 62.5% identified as Roman Catholic, followed by respondents who described themselves as atheists (9.8%), Orthodox (8.0%), and Muslims (6.8%); 4.0% of respondents chose not to specify their religious affiliation. Respondents raised in non-violent or democratic environments perceive sexuality as more important (26.4%). Individuals from violent or authoritarian families perceive sexuality as less important (4.5%).

The majority of respondents (46.9%) assessed their current state of health as moderately good, followed by respondents who assessed their state of health as very good (30.8%) and excellent (14.1%). The fewest respondents described their state of health as very bad (0.8%).

The majority of respondents (45.8%) have sexual intercourse 1 to 3 times per month, while the fewest (18.1%) reported never having intercourse in a month. According to gender, women are more often sexually active 1-3 times a month (48.1%) compared to men (41.8%), while men more often (40.5%) have sexual intercourse more than 3 times per month compared to women (33.6%). We found that the importance of sexuality differed statistically significantly based on the respondents' education level (chi-square = 97.325; $p < 0.001$). The importance increases with higher education, as (51.9%) respondents with a university degree, (57.9%) with a master's degree, and (88.9%) with a doctoral degree rated sexuality as important.

The majority of respondents ($N = 237$; 36.5%) indicated that sexuality was unimportant to them, while the fewest ($N = 28$; 4.3%) stated that sexuality was very important. Respondents who were sexually active rated the importance of sexuality with an average score of 2.67 ± 1.02, while female respondents rated it with an average score of 2.45 ± 1.14. The result of the Mann-Whitney U test ($U = 29{,}130.000$; $p = 0.020$) showed that there are statistically significant differences between genders in the perception of the importance of sexuality—sexuality is, on average, more important to male respondents than to female.

The results of the analysis indicated that religious affiliation influences how individuals assess the importance of various aspects of sexuality in intimate relationships. All observed differences were statistically significant, meaning they were not due to chance. For example, the importance of caressing, pleasure, tenderness, touching, and fidelity varied significantly across different religious groups. This suggests that religious affiliation has a tangible impact on how individuals perceive these aspects of sexuality.

Table 2 shows the importance of individual factors in interpersonal partner relationships related to sexuality. Respect is considered the most important factor by the respondents (M = 4.36; SD = 0.87), while sexual intercourse is rated as the least important (M = 3.02; SD = 1.38). The results of the Mann-Whitney U test revealed statistically significant differences between genders in seven out of eight factors related to sexuality, namely in penetrative activities (sex), trust, respect, caressing, pleasure, expression of tenderness, and fidelity.

Table 2: Descriptive Statistics on Key Aspects of Intimate Relationships and Their Importance in Sexuality-Related Partner Interactions Among Older Adults (N=651)

	M	SD
Sexual intercourse	3.2	1.3
Trust	4.21	0.99
Respect	4.36	0.87
Caressing	4.14	1.03
Pleasure	3.02	1.38
Showing tenderness	4.07	1.03
Touching	4.05	1.07
Loyalty	4.29	1.02

Legend: N = number of responses, Min = minimum, Max = maximum, M = mean, SD = standard deviation, (1 - "strongly disagree" to 5 - "strongly agree").
Source: Own.

Table 3 shows that respondents most strongly agree with the statements that satisfying sexuality contributes to a healthy life at any age (M = 3.83; SD = 0.95), that knowledge enhances the safety of sexual life (M = 3.77; SD = 0.88), and that older adults need information about sexuality in later life stages (M = 3.77; SD = 0.89). On the other hand, they agree the least with the idea that understanding sexuality in older adults helps them express the moral and ethical aspects of interpersonal relationships (M = 3.43; SD = 0.94).

Table 3: Descriptive statistics on the perceived impact of sexuality education and knowledge on the well-being of older adults (N=651)

	M	SD
Learning to express moral and ethical dimensions of interpersonal relationships.	3.4	0.9
Through knowledge, positive moral and ethical concepts are developed.	3.6	0.9
Older adults need information about sexuality in later life.	3.75	0.89
Satisfying sexuality at any age contributes to a healthy life.	3.83	0.95
Acceptance and understanding of the aging process.	3.73	0.87
Understanding sexuality alleviates and reduces loneliness among older adults.	3.66	0.89
Intimate relationships improve.	3.72	0.87
Cooperation between older adults and healthcare professionals strengthens.	3.51	0.88
Sexual safety improves.	3.77	0.80

Legend: N = number of responses, Min = minimum, Max = maximum, M = mean, SD = standard deviation (1 - "strongly disagree" to 5 - "strongly agree").
Source: Own.

Tabel 4: Gender Differences in Health Status, Sexuality-related Factors, and Sexual Life Satisfaction among Older Adults

	Gender	N	PV	SO	U	p
Current health status (self-assessment)	Men	237	3.5	0.8	48830.000	0.915
	Women	414	3.4	0.8		
F1: Coping with aging.	Men	237	3.9	0.6	47913.500	0.619
	Women	414	3.89	0.71		
F2: Stereotypes about sexuality in older adults.	Men	237	2.94	0.94	46876.500	0.344
	Women	414	2.98	0.98		
F3: Attitudes towards sexuality.	Men	237	3.19	0.35	42168.500	**0.003**
	Women	414	3.05	0.34		
F4: Sexual life satisfaction.	Men	237	3.82	0.87	43766.000	**0.021**
	Women	414	3.64	0.89		
F5: Permissive attitude towards sexuality (obligation and guilt associated with feelings related to sexuality).	Men	237	3.69	0.99	43604.500	**0.018**
	Women	414	3.49	1.04		
F6: Knowledge about sexuality.	Men	237	3.30	0.92	47634.500	0.535
	Women	414	3.40	0.80		
F7: Perception of one's body.	Men	237	4.13	0.77	47005.000	0.361
	Women	414	4.09	0.73		
Importance of sexuality.	Men	237	2.54	1.05	45712.000	0.132
	Women	414	2.42	1.12		

Legend: N = number of responses, M = mean value, SD = standard deviation; U = Mann-Whitney test; $p < 0.05$, ** $p<0.01$ (1 - "strongly disagree" to 5 - "strongly agree").
Source: Own.

Table 4 presents the results of a comparison of various aspects of sexual life and sexual satisfaction between men and women. The comparison involves the mean scores (M), standard deviations (SD), and the results of the Mann-Whitney U tests (U) with associated p-values (p). The items in the table focus on different factors such as health status, attitudes toward aging, stereotypes, sexual life satisfaction, permissive attitudes, knowledge, body perception, and the importance of sexuality. The p-value is much higher than 0.05, meaning there is no statistically significant difference between men and women regarding self-assessed health status. There is a statistically significant difference between men and women, with men having a slightly more positive attitude towards sexuality. Men report not only a slightly higher sexual life satisfaction, and the difference is statistically significant ($p < 0.05$), but also a more permissive attitude towards sexuality, and this difference is also statistically significant. The main findings of this table suggest that there are statistically significant gender differences in attitudes towards sexuality, sexual life satisfaction, and permissive attitudes towards sexuality, with men reporting more positive outcomes in these areas. However, there are no significant gender differences in the other factors measured, including current health status, coping with aging, stereotypes about sexuality, knowledge about sexuality, body perception, and the importance of sexuality. These results suggest that while men and women may have different experiences and views related to sexuality in certain aspects, in many areas, there are no significant gender-based differences.

Table 5: Associations about the importance of sexuality in older adults

	(B)	SE	t	P
Perception of one's body.	-0.426	0.058	-7.4	< 0.001
Satisfaction with sexual life.	0.110	0.051	2.1	0.031
Frequency of sexual intercourse /activities.	0.275	0.064	4.2	< 0.001

Legend: B = coefficient of correlation, SE = standard error, p = statistical significance, $R^2 = 0.098$
Source: Own.

Table 5 shows associations between body perception, sexual satisfaction, and frequency of sexual activities with the importance of sexuality in older adults. The results indicate that: Body perception has a significant negative impact ($B = -0.426$) on the importance of sexuality. Satisfaction with sexual life ($B = 0.110$) and frequency of sexual activities ($B = 0.275$) have a positive impact on the importance of sexuality. All three factors significantly influence the importance of sexuality, with p-values less than 0.05, indicating statistical significance.

Table 6: Associations about the sexual well-being

	(B)	SE	t	p
Knowledge of Sexuality	0.363	0.038	9.488	<0.001
Satisfaction with sexual life.	0.110	0.051	2.166	0.031

Legend: B = coefficient of correlation, SE = standard error, p = statistical significance, $R^2 = 0.122$
Source: Own.

Knowledge of sexuality is significantly positively associated with the dependent variable ($B = 0.363$, $p < 0.001$), indicating that as knowledge increases, the sexual well-being also increases. The association is reflected by a small standard error ($SE = 0.038$). Satisfaction with sexual life also has a positive relationship with the dependent variable ($B = 0.110$, $p = 0.031$), but this effect is weaker. The model in Table 5 explains 12.2% of the variance in the dependent variable ($R^2 = 0.122$), suggesting moderate explanatory power. Knowledge of sexuality statistically significantly and positively impacts sexual satisfaction, with higher knowledge of sexuality associated with increased sexual satisfaction. Consistent with these findings, Figure 1 emphasizes the importance of knowledge in addressing the challenges of aging and sexual well-being, further highlighting the significance of education in improving sexual health. In addition, 31.7% of respondents reported not confiding in anyone about their sexual concerns, indicating a reluctance to openly address these issues.

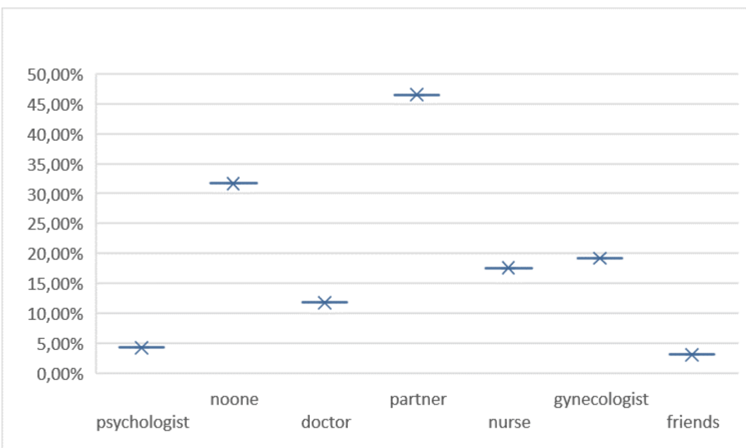

Figure 1: Distribution of who do respondents confide in about their sexual problems
Source: Own.

Since multiple responses were allowed, 31.7% of respondents indicated that they do not confide their sexual concerns to anyone, reflecting a reluctance to discuss the topic openly. However, 46.5% of participants reported that they would most likely trust their partner with such issues. Additionally, 19.2% expressed confidence in a gynecologist, and 17.6% in a nurse.

The majority of respondents (60.3%) also indicated that it would be beneficial to include topics on menopause and andropause in sexual education for older adults. In comparison, fewer (27.9%) felt it necessary to cover topics on sexually transmitted infections (STDs).

The results emphasize the need to create supportive environments and trusted relationships with healthcare professionals to promote sexual health and well-being in this often-overlooked population. They also provide a solid foundation for developing targeted interventions and educational strategies aimed at improving sexual health and quality of life among older adults, which are in alignment with the primary objectives of the study.

7 Discussion

7.1 Interpretation of Findings

The findings suggest that the significance of sexuality varies widely among older adults, influenced by factors such as upbringing, education, and religious affiliation. Those raised in non-violent or democratic environments tended to place more importance on sexuality, aligning with previous research by Bagheri et al. (2024) and DeLamater (2012), who found that social and familial contexts greatly influence sexual attitudes in later life.

Regarding education, we observed a significant correlation between higher education levels and the perceived importance of sexuality. This aligns with previous studies that show educated individuals tend to have more open and positive attitudes toward sexuality (Forbes et al., 2016). Gender differences were also evident, with men rating the importance of sexuality higher than women, reflecting findings by Kastenbaum (1979), who noted that older men generally report higher sexual satisfaction.

Religious affiliation played a substantial role in shaping sexual attitudes. Respondents identifying as Roman Catholic viewed aspects of sexuality, such as pleasure, tenderness, and caressing as more important, similar to findings from Goriup and Lahe (2018), who highlighted the influence of religious beliefs on sexual norms in later life.

Furthermore, the respondents indicated that sexuality education could improve their well-being, supporting prior research by Haesler et al. (2016), who stressed the need for sexual health education tailored to older adults. This is evident in respondents' high agreement with statements on the importance of sexuality education for older adults, particularly regarding menopause and andropause topics.

Statistical analyses revealed significant associations between body perception, sexual satisfaction, and frequency of sexual activity with the perceived importance of sexuality. As shown in Table 4, higher satisfaction with sexual life and more frequent sexual activity positively correlated with the importance placed on sexuality, echoing findings by Hyde et al. (2010) and Menard et al. (2015), who noted the centrality of sexual satisfaction for overall well-being in later life.

7.2 Implementing the Sexual Health Promotion Education Model for Older Adults (55+) in Practice

In conclusion, this study highlights key implications for healthcare professionals, therapists, and educational institutions in addressing the sexual health needs of older adults. A focus on holistic programs that cover both the physical and emotional aspects of sexuality in later life is necessary. Improving communication between older adults and healthcare providers is crucial, as only a small percentage of respondents discussed sexual concerns with healthcare professionals, indicating a reluctance to address the topic. This presents an opportunity for healthcare professionals to enhance their knowledge and actively promote sexual health among older adults.

Based on this, we have laid the groundwork for understanding the broader scope of sexual behavior in older adults, allowing us to develop an integral model of quality sexual health for older adults (55+). This model facilitates access to information about the sexuality of older individuals, understanding the physical and hormonal changes brought about by aging, and the stereotypes related to the sexuality of older adults (55+). An environment that promotes a positive approach to older adults' sexual health allows them to live fully again, preventing them from being deprived of a satisfying sexual life.

The developed model is based on real needs and age-appropriate expectations that are essential for sexual satisfaction and the acceptance of aging limitations. This allows individuals to seek solutions and nurture intimacy into old age. The model encourages the development of a positive attitude toward sexuality, shaping perspectives, habits, and practices for satisfying sexual experiences while taking responsibility for one's sexual health and its impact on successful aging. It takes a broad view of sexuality, regardless of age, and facilitates access to services and education.

It includes complex factors divided into five thematic areas, with the possibility of expanding the content for a younger population:

- The functioning of the body and the emotional aspects of sexual health,
- Risk factors affecting sexual satisfaction,
- Mental and cognitive impacts on sexual health and satisfaction,
- The influence of hormones, STIs, and oncology on sexual health and satisfaction,
- Approaches to addressing current and potential sexual health issues.

These factors influence the overall awareness of all stakeholders in society, enabling a holistic approach to the sexual health of adults (55+) and shaping its conceptualization in society.

The vision of the model emphasizes principles and activities to support the sexual health and quality of life of older adults. It is also aimed at ensuring more humane practices in the planning of social policy and long-term care, including complex, holistic solutions that we aim to make available in primary healthcare, directly and without referrals, to the entire older population.

Recognizing that older adults respond differently to health education advice regarding sexual health—some with interest, others with discomfort—we can tactfully offer free choice of topics through the developed integral model of quality sexual health care for older adults (55+). By networking with other providers focused on preserving and promoting health and acquiring healthy lifestyle habits, we can facilitate easier access to other existing workshops in primary healthcare. Effective health education advice can significantly reduce risk factors affecting sexuality, thereby improving sexual activity and quality of life.

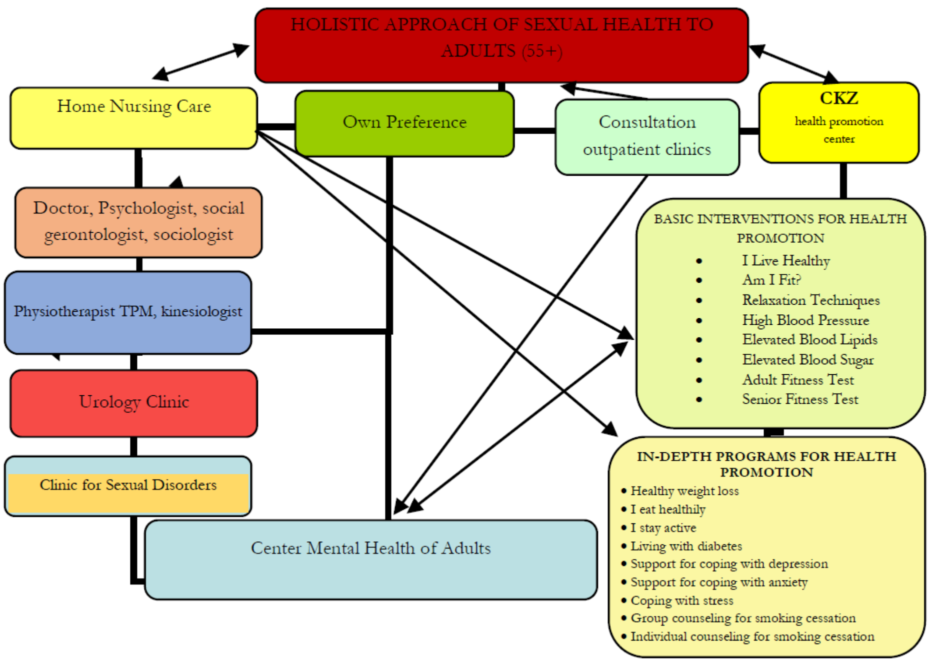

Figure 2: Organizational Chart of Multidisciplinary Collaboration within Healthcare
Source: Own.

The model enables the expansion of guidelines within primary care settings, including Reference Clinics, Health Promotion Centers, Adult Mental Health Centers, family medicine clinics, physiotherapy, home care, urology clinics, and sexual health clinics. By extending the model across the primary care network and later collaborating with an interdisciplinary team (including doctors, registered nurses, social gerontologists, physiotherapists, kinesiologists, dietitians, psychologists, sociologists, and others), we can facilitate both individual and group interventions. These efforts help individuals gain insight into potential issues, encourage developing a positive outlook on sexuality, and guide them towards healthy lifestyle choices, thereby improving sexual health and well-being in the broader population.

The role and connections between stakeholders in the model facilitate the flow of information and productive collaboration for the benefit of older adults' sexual health. The stakeholders are interconnected in such a way that older adults can access various types of care – from physical and mental support to specialized clinics – without referrals and with greater accessibility within primary health care. Older adults are empowered to choose the topics or types of care they prefer (e.g., workshops at the Health Promotion Center, counseling at a reference clinic, or home care services) based on their desires and needs. Community support is also provided through mutual connections, guiding older adults to health-promoting workshops where they not only receive information about healthy lifestyles but also learn about sexuality and its connection to healthy and quality aging. The connections also enable specialized care. If the basic care identifies specific issues, older adults can be referred (or self-refer) to a urology clinic, sexual dysfunction clinic, or adult mental health center for further professional assistance.

Home Care Services operate in the field, where registered nurses provide direct support to older adults, helping to identify issues, offering counseling, and referring them to Health Promotion Center workshops or other specialists.

Reference Clinic - provides individualized counseling and health care, helps recognize risks, promotes healthy sexuality, and refers to Health Promotion Center workshops or other specialists.

Health Promotion Center (HPC) - a key partner in organizing health promotion workshops that can meaningfully include additional topics such as healthy aging, sexual health, the impact of healthy nutrition, and physical activity on sexual health. *Physiotherapy and Kinesiology (team-based health care)* - assist in addressing physical limitations affecting sexual health and activity, including sexual function.

Urology Clinic- provides specialized care for issues related to the entire sexual health, not just reproductive health, of older adults.

Sexual Dysfunction Clinics - offer specialized help for sexual function issues and counseling.

Adult Mental Health Center - addresses psychological issues related to intimacy, stigma, and self-esteem in older adults.

Personal Choice - the model emphasizes voluntary involvement of older adults based on their desires and needs, recognizing that older adults accept health advice differently – some with interest, others with discomfort.

This content can also serve as recommendations for changes in primary health care and the education of health professionals. Furthermore, it may provide a foundation for enhancing collaboration among public health institutions, educators, and policymakers in addressing the sexual health of older adults. It could also serve as a basis for developing an Action Plan to support the sexual health of older adults, promoting greater and faster progress toward achieving equality in the treatment of sexual health for the entire adult population.

7.3 Future Research

Future research can deepen the understanding of older adults' sexual needs and desires, contributing to the development of tailored support and services. Educational programs for older adults should focus on sexual health, with content adapted to various educational levels. Increased access to sexual health resources, such as workshops and counseling services is essential. Targeted interventions should be developed to foster positive attitudes towards sexuality, particularly among less educated groups.

Healthcare policies should be adjusted to offer more comprehensive sexual health education and support, especially for older adults. Lastly, additional analysis of regional and demographic trends in sexual health perception can guide interventions that address specific needs within different populations.

8 Limitations

Our study has both strengths and limitations. We focused on older adults aged 55 to 75 as the upper age limit, based on the assumption that adults beyond this age are less sexually active. Consequently, it is more challenging to describe the experiences of individuals in later life stages. Additionally, due to the sampling method, we did not include those residing in nursing homes or requiring daily medical care. This limitation not only affects assumptions about sexual activity but also about self-assessed health status, as older individuals are likely to experience more significant health issues. Thus, our findings may not be generalizable to individuals with severe health problems. Also, gender disparity in the sample may impact the generalizability of the results.

One of the open questions in the field of sexual health among older adults is the connection between mental, emotional, and cognitive health, the connection between aspects of sexual health, and how these relationships differ by gender. It is also possible that reduced sexual function may worsen an individual's mental health or vice versa, highlighting an area worth further exploration and future research. A limitation also includes the possibility that respondents may not answer truthfully or may fail to understand the questions.

The added value of the research lies in the fact that its results can serve as a starting point for improving collaboration between public health institutions, educators, and policy makers in efforts to address the sexual health of older adults. The content of this model may also serve as recommendations for changes in primary healthcare and the education of all healthcare professionals.

9 Conclusion

By promoting an inclusive understanding of sexuality in later life and addressing societal taboos, healthcare systems can improve sexual healthcare for older adults. Ensuring open communication, increasing access to resources, and addressing misconceptions will empower older individuals to lead fulfilling sexual lives, thereby enhancing their quality of life and successful aging. Further research, particularly longitudinal studies, could help clarify whether and how sexuality directly impacts overall health and aging, providing stronger evidence for causal relationships. Intervention efforts should focus on reducing barriers to discussing sexual health and integrating it into broader health promotion strategies for aging populations.

Once implemented, this model will contribute to the development of age-appropriate educational resources and training for healthcare professionals, thus improving the quality of sexual health care for older adults. It is crucial to communicate to older adults that the desire for sexuality is normal and that maintaining this aspect of life is essential for their well-being, as long as there is a desire. A healthy perspective on sexuality goes beyond the taboos surrounding older adults' sexuality and facilitates open dialogue and understanding in this area. Finally, the model should also serve as a foundation for policy changes and collaboration between public health institutions, educators, and policymakers, which will enable the development of an action plan aimed at promoting the sexual health of older adults. By ensuring continuous access to information, professional assistance, and support, we can enable older adults to lead healthy and fulfilling sexual lives, thereby contributing to their overall well-being and successful aging.

Ethical Considerations and Conflict of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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Note

Talking about sexuality is neither wrong nor immoral; this research demonstrates that sexuality can be a positive and wonderful part of life, if we allow ourselves to embrace it. It is especially important to clearly communicate to older adults that sexual desire is normal and that maintaining this aspect of life is essential for their well-being, as long as the desire persists.

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Povzetek v slovenskem jeziku

Ta študija si prizadeva razviti izobraževalni model in smernice za spodbujanje spolnega zdravja starejših odraslih (55+), pri čemer se osredotoča na vprašanja starizma, stereotipov in gerontofobije. Kljub njegovemu pomenu za uspešno staranje je spolno zdravje starejših pogosto zanemarjeno. V raziskavi je sodelovalo 651 udeležencev (starih od 55 do 75 let), uporabljena pa je bila kvantitativna metoda, ki je s spletno anketo proučevala dejavnike, kot so zdravstveno stanje, spolna aktivnost in izobrazba. Ključne ugotovitve vključujejo pozitivno korelacijo med zdravjem in spolnim zadovoljstvom ($r = 0,2$ do $0,4$; $p < 0,001$) ter pomen spolnega znanja za življenjsko zadovoljstvo ($F = 90,027$; $p < 0,001$). Rezultati poudarjajo potrebo po prilagojenih izobraževalnih programih in odprtih razpravah o spolnosti. Predlagani model je usmerjen v izboljšanje spolnega blagostanja in splošne kakovosti življenja ter spodbuja celostni pristop k spolnemu zdravju starejših. Ugotovitve so pomembne za oblikovanje politik in intervencij v Sloveniji in po svetu.

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'HANDLE WITH CARE'? PERSON-CENTRED LIVE-IN CARE PROVIDED BY POSTED WORKERS AND OTHER CARE-RELATED PHENOMENA IN THE EU

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Abstract This article examines the growing phenomenon of live-in care in the European Union, with particular focus on services provided by posted workers, including third-country nationals. It situates live-in care within the broader EU socio-legal framework, tracing the evolution of recent policy developments such as the European Pillar of Social Rights, the European Care Strategy, and documents arising therefrom. The article analyses the latest phenomena in cross-border live-in care, including deinstitutionalisation of care, highlighting how person-centred and community-based models are reshaping the field. Special attention is devoted to gender dimensions, including the disproportionate burden on women and the 'daughterhood penalty' and 'motherhood penalty'. By linking legal, economic, and social aspects, the article assesses whether EU policies effectively address current challenges in that regard and their future impact concerning more sustainable care provision.

Keywords
person-centred live-in care,
carers,
posted workers,
deinstitutionalization of care,
'daughterhood penalty',
European Care Strategy

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1 Introducton

'Caring for someone you love is the most precious time of all' (von der Leyen, 2021). Indeed, care is central to human, social, economic and environmental well-being, and sustainable development. Care work, paid and unpaid, is essential to all other work (International Labour Organization Statistical Brief, 2024, p. 2). Inevitably, at some stage of life - whether through the effects of ageing or the onset of illness (Caracciolo di Torella & Masselot, 2020, p. 1)- every individual will require care. Likewise, at some juncture, most people will assume the role of carer (caregiver)[1], whether in the capacity of a parent or in support of dependent adults. Therefore, care and caregiving constitute universal and pressing concerns, touching individuals from all walks of life on a practically daily basis (Tronto, 2020). Indeed, at some point, during the course of our lives, we all need care to thrive, and in some cases, to survive (Caracciolo di Torella, 2023, p. 56).

The concept of care is multifaceted and the relationship of care permeates and interacts with multiple dimensions of legal systems (Herring, 2007, p. 8 *et seq.*), and it concerns different manifestations thereof. In this article I shall focus on care provided at homes of people, who, as a result of mental and/or physical frailty, disease and/or disability over an extended period of time, depend on support for daily living activities and/or are in need of some permanent nursing care (Council Recommendation of 8 December 2022, 2022, para 3(a), p. 6 – there is no doubt that this category covers also chronically ill people, even though they were not listed in detail in the Recommendation) - provided by live-in care workers – domestic long-term care workers who live with the care recipient and provide long-term care (Council Recommendation of 8 December 2022, 2022, para. 3(i), p. 6). They have also been defined as "*paid professionals, with or without formal care training, whose work primarily involves LTC (long-term care[2]) provision while living in a private residence with the care receiver*" (Andriescu et al., 2024, p. 199).

[1] I opted for the notion of 'carer' (in line with e.g. in para. 7 *et seq.* of the Council Recommendation of 8 December 2022).

[2] The Council Recommendation of 8 December 2022 does not define 'live-in care' (but only the notion of 'live-in care worker' – para. 3(i)). Hence those two terms are often used interchangeably in academic discourse on the matter, although live-in carers are often persons who had been employed e.g. on the basis of a civil law contract. For more concerning the concept of supporting elderly, ailing and helpless persons – see e.g. Hoens & Smetcoren, 2023, p. 497 *et seq.*; Safuta et al., 2022, p. 303 *et seq.*; Matuszczyk, 2021, p. 1 *et seq.*; Fernández-Reino & Vargas-Silva, 2020; Shutes & Chiatti, 2012, p. 392 *et seq.*

The demand for live-in care has been steadily increasing, driven primarily by population ageing - a widespread phenomenon in highly developed countries, closely linked to declining birth rates and rising life expectancy. Globally, the proportion of older persons has expanded at a remarkable pace, also in comparison to the working-age population that constitutes the primary potential source of care provision (OECD, 2020). In Europe, the population aged over 65 is projected to increase by 14% between 2022 and 2030, and by 38% over the next three decades, reaching 129.8 million. By 2030, the number of individuals requiring long-term care is estimated at 33.7 million, with this figure expected to rise further to 38.1 million by 2050 (Council Conclusions of 27 November 2023, para. 3, p. 4).

In this (a rather challenging) picture, an ever-growing phenomenon is care arrangements in which migrating people (in various capacities) care for elderly people on a live-in basis (Böcker et al., 2021, p. 4) - in particular, live-in care provided by posted carers, who have been posted within the framework of intra-EU posting of workers (Kiełbasa, 2023, p. 402 *et seq.*), including the so-called 'third-country nationals[3]' ('TCNs').

In the present article, I shall tackle the issue of 'person-centred' live-in care, provided by such persons as well as other most important phenomena in care, including the disproportionate impact of care responsibilities on women (Communication from the Commission, 2022, p. 2).

2 Live-in Care and the EU Policies - Between Mutual Necessity and Enduring Friction?

Despite the key importance of care to sustain our lives, the European Union lacks express competencies in this area. Accordingly, the EU legislator has traditionally been unable to address care effectively, either as a concept or in terms of its structure. Thus, in the very area, the EU has, at best, had traditionally provided a forum where Member States could exchange good practices (Caracciolo di Torella, 2023, p. 58).

[3] Under Article 2(6) of the Regulation (EU) 2016/399 of the European Parliament and of the Council of 9 March 2016 on a Union Code on the rules governing the movement of persons across borders (Schengen Borders Code) - a third-country national is any person who is not a Union citizen within the meaning of Article 20(1) TFEU and who is not covered by point 5 of this Article [*members of the family of a Union citizen exercising the right to free movement to whom Directive 2004/38/EC (…)*].

Despite the claim in one of the latest reports commissioned by the European Commission – that most LTC workers are covered by general EU labour law (Bakirtzi, 2024, p. 17) - the Union's approach to supporting carers has largely been uneven. On the one hand, the position of specific categories of carers, most notably mothers, has received growing attention – reflected in a series of legislative measures designed to enhance their protection[4]. However, the EU's engagement with carers of elderly or disabled individuals, particularly in the context of live-in care, has been limited. This is notwithstanding the fact that various policy documents addressing their situation have been issued. Notwithstanding this rhetorical recognition, the legislative framework in this area remains underdeveloped. As indicated in literature, measures aimed at carers were organised around a two-tier structure that differentiated between the care of children (childcare) and the care of elderly and/or disabled children and dependent adults (LTC) and, as such, it lacked conceptual cohesion (Caracciolo di Torella, 2023, p. 59; Daly, 2021, pp. 108-118).

Concerning the former, economic considerations cannot be 'decoupled' from normative arguments that recognise and value carers for the substantive contributions they make to society. Such an approach emphasises the intrinsic worth of carers' activities. Because the EU is no longer merely an economic structure but embraces and promotes human and social rights, the need to address the economic and moral elements of the caring relationship becomes more pressing than ever (Caracciolo di Torella, 2023, p. 60; James & Spruce, 2015, pp. 463-464).

Regarding the latter dimension, care provision constitutes a fundamental prerequisite for attaining key economic objectives within the EU. It plays an essential role in sustaining the operation of the EU's internal market and serves as a critical component of general employment policy and robust gender equality measures. From an economic standpoint, a direct and substantive relationship can therefore

[4] E.g., the Council Directive 92/85/EEC of 19 October 1992, on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (Official Journal of the European Communities L348 28.11.1992, p. 1, as amended); or the Council Directive 97/81/EC of 15 December 1997, concerning the Framework Agreement on part-time work concluded by UNICE, CEEP and the ETUC - Annex: Framework agreement on part-time work, Official Journal of the European Union L14, 20.1.1998, pp. 9–14 or Directive (EU) 2019/1158 of the European Parliament and of the Council of 20 June 2019, on work-life balance for parents and carers and repealing Council Directive 2010/18/EU, Official Journal of the European Union L188, pp. 79–93. Those legislative acts were further reinforced through the jurisprudence of a proactive Court of Justice of the European Union (CJEU) –see e.g., judgments in *Z v A Government Department*, 2012 or *Jessy Saint Prix v Secretary of State for Work and Pensions*, 2012 – see also Caracciolo di Torella, 2023, p. 58.

be identified between the provision of care and fulfilling the internal market's objectives (Caracciolo di Torella & Masselot, 2020, p. 22).

Moreover, it is also becoming increasingly apparent that care cannot be addressed solely within national borders. As a service, it can be provided freely across the Union's internal market. Thus, the demand for and the offer of care directly affect the free movement provisions within the EU (including especially free movement of services). As a regulator of the internal market and a global actor (care, including especially live-in care, is rapidly changing into services accessible on the global market, too), the EU is well placed to address care and should lead the Member States' reaction in this very area.

Events over the past decade have underscored a growing recognition that care constitutes a fundamental prerequisite for individual lives, social cohesion, and economic stability, and that the legal framework has a crucial role to play in fostering them. At the EU level, this awareness has catalysed the emergence of a new policy orientation, one more closely aligned with the needs and realities of individuals. The articulation of this shift may be seen in the proclamation of the European Pillar of Social Rights (Interinstitutional Proclamation on the European Pillar of Social Rights, 2017) in 2017 as well as the adoption of the Work-Life Balance Directive (Directive 2019/1158 of the EP and of the Council, 2019).

Then, along came the Covid-19 pandemic, triggering further EU actions, signalling a commitment to embedding care-related considerations more firmly within the EU's socio-legal agenda and culminating in the adoption of the European Care Strategy, and further documents, characterised in more detail below.

3 Live-in Care Carried Out by Posted Workers

Given both the considerations above and the drastic ageing of most of the EU Member States' populations, the growing need for live-in care became the order of the day. As demographic changes with shifts in the population pyramid lead to an increasing demand for long-term care, formal care provisions do not seem able to keep up (Steiner et al., 2020, pp. 69-70). The lack of adequate, affordable and easily accessible long-term care services in many Member States therefore results in unmet (domestically) care needs (Andriescu et al., 2024, p. 199) – hence also the growing need for posted workers in the very sector and the ever-more widespread presence of posted carers.

Posting of workers, constitutes one of the most important forms of temporary labour mobility in the EU (Jorens, 2022, p. 1-2; De Wispelaere & Rocca, 2023, p. 5). It is also described as a hybrid type of intra-EU labour mobility based on free movement of services, which has experienced a substantial upward evolution during the last two decades. This is to be differentiated from other important forms of labour mobility, especially migration to another EU Member State under the free movement of workers / persons (Article 45 *et seq*. TFEU[5]), as posted workers are persons who are sent by their employer to carry out a service in another EU Member State on a temporary basis. Posted workers, including also third-country nationals, are sent (or 'post themselves') as part of a cross-border service provided by their employer (or by themselves) pursuant to Article 56 *et seq*. TFEU (Davies & Kramer, 2024, p. 24). They are sent abroad by a posting entrepreneur, to provide a service (Lasek-Markey, 2024, p. 741). Also, the TCNs, holding a valid work and residence permit in one Member State, may be posted within the EU (Kiełbasa, 2025, p. 647 *et seq*.).

In general, posted workers retain a connection with their country of origin, which is typically the sending Member State, through the employment relationship (established *via* a contract of employment or a civil-type contract). Principally, they remain affiliated with the social security system of their home Member State (Jorens, 2022, p. 145 noted the differences between the concept of posting in the Posting of Workers Directives and social security coordination regulations), subject to the distinction between workers posted under Article 12 of Regulation 883/2004 (Regulation of the European Parliament and of the Council (EC) 883/2004, 2004) and those active in two or more Member States pursuant to Article 13 thereof (De Smedt et al, 2023, p. 27, footnote 26). Simultaneously, such workers become subject to certain terms and conditions of employment in the host Member State (Lens, Mussche & Marx, 2021, pp. 28-29; Kiełbasa, 2022).

[5] Treaty on the Functioning of the European Union – consolidated versions – Official Journal of the European Union C202, pp. 1–388.

Yet, the phenomenon of posting extends beyond its intricate legal framework. It has significant implications for broader spheres of social and economic life, as well as for politics and public policy. Scholars analysing the care sector actually emphasise that posting of workers is the only mechanism through which legal live-in care services may be provided in Germany, the largest recipient of such services (and services on the whole) in the EU (Matuszczyk, Salamońska & Brzozowska, 2022, p. 9).

The example of Germany (the largest recipient of posted workers altogether in the EU, including also live-in care posted workers) in this regard is also very telling when it comes to assessing, whether the EU migration policy (or more generally – the policy of labour mobility within the Union's internal market) adequately promotes support for ailing and vulnerable individuals. Sadly, as of now, the answer cannot be in the affirmative. Until now, contrary to the CJEU's ruling in *Commission of the European Communities v Federal Republic of Germany* and the subsequent case law (e.g. the Court's judgments in *Commission of the European Communities v Republic of Austria* or *Commission of the European Communities v Kingdom of Belgium*) Germany continues to require TCNs to obtain the so-called Vander Elst visas from German embassies (in some cases they are virtually impossible to obtain – as examples of Lithuania or Poland clearly demonstrate) before a third-country national may be posted (also within the framework of live-in care) to Germany (Danaj et al., 2023, p. 4).

4 Live-in Care– De-Institutionalisation of Care in the EU – 'Building Back Better'?

One of the major trends that could be inferred from the recent EU policy documents is de-institutionalization of live-in care (combined with the promotion of autonomy and independent living in all long-term care settings). It represents a fundamental reorientation of social and health policy in the Union, a signal of moving away from large residential institutions towards community-based, home-based, and person-centred services. Such reorientation is strongly driven by most care recipients' desire to be cared for at home, as demonstrated in literature, reflecting in this regard the opinions of the persons being taken care of[6] (Kuhn & Seidlein, 2023, p. 384). From

[6] Those persons are also referred to as 'people in need of long-term care' – see e.g., para 4(c) of the 2022 Council Recommendation or 'recipients of care'

this perspective, institutionalized long-term care is not seen as a 'good alternative', e.g. to care provided at home, but as a sort of 'final option' to be avoided at all costs (Höpflinger & Van Wezemael, 2014).

At the heart of this policy shift arguably lies the UN Convention on the Rights of Persons with Disabilities (CRPD[7]), which obliges Member States not only to ensure (to persons with disabilities) the opportunity to choose their place of residence but also that they are not obliged to live in a particular living arrangement (Article 19 CRPD). Within the framework of the EU law, this concept has been first mirrored by the EU's Charter of Fundamental Rights[8], which recognised the rights of older adults to lead a life of dignity and independence (Communication from the Commission, 2022, p. 8).[9] The very concept has then been further developed (this time, it has also been extended to other categories of persons) in the European Pillar of Social Rights. Its Principle 18 spells out the right to access quality and affordable long-term care, in particular home care (and community-based services) (Communication from the Commission, 2022, pp. 8-9; Grossi et al., 2024, p. 55; Sabato & Vanhercke, 2017). It indeed verbalizes a preference for home-based and community-based solutions over institutional settings.

A document that expands upon the Pillar, including its Principle 18 (and which is also firmly rooted therein) in this regard is the European Care Strategy. The Strategy has arguably been the most significant and evolved EU policy programme ever in the field of 'care' – seen as an overarching concept, suggesting, as some authors rightly note, another sort of recognition by the EU of care as a broader social phenomenon (Daly, 2025, p. 11). Hardly did the EU speak in such terms beforehand, especially in terms of policy.

Such a relationship between the Pillar and the Strategy has also helped to define the latter's aim (the goal which had not been envisaged to such an extent beforehand in the EU documents, either) - 'integrated and person-centred long-term care that is accessible, affordable and of high quality' (Daly, 2025, p. 12; Commission Staff Working Document 2022). The Commission emphasized that '*person-centredness entails*

[7] Adopted at the sixty-first session of the General Assembly by resolution A/RES/61/106, entry into force: 3 May 2008.
[8] OJ, C-326/391.
[9] This concept has been taken up by e.g. the Council Recommendation of 8 December 2022 and 2023 Council Conclusions.

offering a choice of services in line with people's needs and improving the transition from institutional care to home care and community-based services'. At the same time, it acknowledged the '*approaches that are person-centred and conducive to independent living are often lacking, exacerbated by insufficient integration between long-term care and healthcare, or between informal care, home care, community-based and residential care'* (Communication from the Commission, 2022, pp. 10-11).

The Commission proposes to plug those holes *inter alia* by '*offering direct technical support from the Technical Support Instrument to the Member States under a new flagship project "Towards person-centred integrated care"*. Such support aims at *'facilitating reforms in line with the proposal for a Council Recommendation (…)*. That flagship is meant to help Member States, upon demand, to design and implement relevant reforms aimed, e.g. at '*putting the person at the centre of services to ensure (…) better quality of care at every stage of life'* (Communication from the Commission, 2022, p. 11).

In parallel, the Commission acknowledges the plethora of challenges to successfully implementing the above-mentioned 'person-centredness' of care. Among them are labour shortages, caused *inter alia* by frequently difficult working conditions and the reduction of the working age population (Communication from the Commission, 2022, p. 12). According to the Commission, one of the key drivers to remedy labour shortages in care can be 'legal migration'; including from third countries.[10]. Indeed, as the EC conceded, '*already today, many people from non-EU countries work in the care sector'*. To attract them, the Commission, *inter alia* recommended that Member States, in collaboration with respective stakeholders, address skills needs and worker shortages in long-term care by *'exploring legal migration pathways for long-term care workers'* (Council Recommendation of 8 December 2022, para. 8(d), p. 7). Moreover, the Commission then proposed a series of new initiatives in a Skills and Talent Mobility package to make the EU more attractive to talent from outside the EU, and to facilitate mobility within.[11] Significantly, the acts proposed within the very package, and especially the Proposal for a Regulation establishing an EU Talent Pool, provides for a direct employment of third-country nationals (Proposal for a Regulation of the European Parliament and of the Council Establishing an EU

[10] That is countries from outside the EU/EEA/Switzerland. The Commission rightly points out that '*these opportunities may also be valuable to people fleeing the Russian aggression in Ukraine, especially experienced care workers, who want to seek employment while residing in the EU'* – Communication from the Commission, 2022, p.14.

[11] Commission proposes new measures on skills and talent to help address critical labour shortages, Press release, 15 Nov. 2023, retrieved from: https://ec.europa.eu/commission/presscorner/detail/en/ip_23_5740.

Talent Pool, 2023; the proposed Article 4(1)(3) refers to '*jobseekers from third countries*', who, when registered in the the EU Talent Pool IT platform may search for job vacancies – see also Article 11(4) thereof). Indeed, the wording of the solutions envisaged within the package presupposes that such third-country nationals would become migrant worker-carers (within the framework of Article 45 et seq. of the TFEU), instead of becoming posted workers (within the framework of Article 56 *et seq*. TFEU). I am pointing to this legal basis as the evidence collected by doctrine demonstrates, that long-term care is mostly provided by posted workers (including third-country nationals), and that employment contracts are not used in principle in the field of posted live-in care (especially in the Polish-German context, which arguably constitutes the most significant flow of such live-in carers in the EU) (Leiber, Matuszczyk & Rossow, 2019, p. 377).

Moreover, the Skills and Talent Mobility Package is yet to be adopted. Accordingly, what actually makes a robust impact and fills in the void caused by labour shortages in this area is freedom to provide services and posting of workers and not migration.

Yet, it is the Council Conclusions on the transition of care systems of 27 November 2023, where deinstitutionalisation of care had been mentioned on such a scale in an EU polity document for the first time. The Council firstly referred to the EESC Opinion of 2022[12], affirming the need to respond 'to the *call to generally deinstitutionalise care for older people in care homes by promoting dependent older people's autonomy, independence, ability to look after themselves, and social relations'* (Council Conclusions of 27 November 2023, 2023, para. 15, p. 9).

Further, the Council in its Conclusions acknowledged that '*greater awareness of the right of all persons to enjoy a full and dignified life have led to the questioning of institutional care models, which in many cases entail segregation and limit fundamental freedoms. This paradigm shift has been accompanied by (…) changing ideas of what care should look like. It has also been supported by scientific evidence confirming many inadequacies of institutional care, by heightened social awareness (…) of gender mainstreaming (…) and by increasing social sensitivity and a widespread preference for person-centred and community-based models'* (Council Conclusions of 27 November 2023, 2023, para. 1, p. 2; its para. 15 cited the EESC Opinion '*Towards a*

[12] *Opinion of the European Economic and Social Committee. Towards a new care model for older people: learning from COVID-19,* adopted at plenary on 19 January 2022, SOC/687.

New Care Model for the Elderly: learning from the Covid-19 pandemic' (2022) affirming *'the need to respond to the call to generally deinstitutionalize care for older people in care homes'*). Therefore, arguably for the first time in such an EU text, the Council invited the Member States to *'[r]ecognise the individual right to be cared for, under equal conditions, (…), that holistically define and ensure the right to sufficient, appropriate and affordable high-quality, person-centred and community-based care. It is important that this care is in accordance with the choice of the person, who has the right to be accompanied in that process and that decision. The right to care implies supporting care givers (e.g. by providing social protection and training, counselling and respite care), and recognising their right to make decisions about how much, and whom to care for'* (Council Conclusions of 27 November 2023, para. 18, p. 10).[13] The Council also invited the Member States to ensure *'person-centered long-term care and support that enable those who require it, and who so wish, to prevent institutionalization, to live dignified lives, to life in self-determination, to conserve their autonomy, to live independently in the community and to be able to freely exercise control over where, with whom and how they want to live'* (Council Conclusions of 27 November 2023, para. 19a), p. 10) – thereby upholding the choice of the recipient of care (and not, e.g., the needs of the system alone).

It is indeed this particular aspect that undoubtedly constitutes a breakthrough in both social and medical law. It changes the perception of how care to elderly, ailing and helpless should be provided, as it puts in the spotlight both the choice of the recipient of care and their will. Therefore, they have their (substantive) say on the conditions of that stage of their lives and they become subjects (and not objects) of care. Such a choice also determines the manner in which the care is to be carried out, directly influencing also medical procedures and the manner in which they are provided (in some cases making it swifter and more accessible to the recipient of care) and influencing also the mobility of medical practitioners (who are to take care of persons in their familiar, home environments, different from sometimes depersonalized hospital settings).

One significant downside of the European Care Strategy, the Council Recommendation of 8 December 2022, and the Council Conclusions of 27 November 2023, is that they lack binding force. Instead, they have a power to exhort and to persuade – but they do not offer an enhanced protection (Andone & Coman-

[13] Arguably for the first time, the EU document also refers *'to combating 'undeclared work in care services, paying particular reference to domestic care work, which is often carried out by migrant workers'* (Council Conclusions of 27 November 2023, para. 24 a), p. 13).

Kund, 2022, p. 31 *et seq.*; *Belgium v Commission, 2016*, para. 26 *et seq.*). Yet, considering the use of soft law in the context of social and labour law, they '*can be used as a fulcrum against the standstill of European social policies, when hard law seems to be a faraway achievement.*' (Caracciolo di Torella, 2023, p. 68). Accordingly, they have the potential to lay the groundwork for more authoritative commitments.

5 Women Providing Live-in Care – 'Unsung Heroes' or Victims of Daughterhood Penalty?

Another crucial issue (and a challenge at the same time) in the latest discussions on care is women's participation in caregiving. Indeed, as the phenomenon of live-in care in the EU has grown into a pivotal pillar of contemporary long-term care systems, it remains predominantly carried out by women, many of whom are third-country nationals. Sometimes referred to 'unsung heroes' (Opinion of the AG Cosmas in *Molenaar v Allgemeine Ortskrankenkasse Baden-Württemberg* (1997, footnote 3, p. I-848) where he stated that *'they are the unsung heroes in the case of persons reliant on care, in particular where the latter remain at home'*, 'true angels' or 'silent heroines' (Steiner et al., 2020, p. 69), women carry out the burden of care – both internationally and within the EU. According to the latest ILO global and regional estimates presented in an ILO brief, care responsibilities remain the main reason for women to be outside the labour force. In 2023, 748 million people aged 15 and above (708 million women and 40 million men) cited care responsibilities as the reason for being outside the labour market. The deeply entrenched gendered division of care responsibilities continues to limit women's access to decent work, restricting their ability to engage in paid work and to advance in their career (International Labour Organization Statistical Brief, 2024, p. 2).[14] The same holds true also for the EU, where care responsibilities often act as a barrier to women's participation in the labour market. According to estimates, 7.7 million women across the EU remain outside the labour market due to care responsibilities, compared to just 450,000 men. The authors of the International Labour Organization Statistical Brief (2024, p. 19) demonstrated that the share of women and men outside the labour force due to care responsibilities varies between the countries (for example, for Poland that share for women

[14] Of the more than 37 million Americans who are providing unpaid care to adults aged 65 or older, 59% are women, according to 2023 data from the U.S. Bureau of Labor Statistics – Travis, 2025.

amounted to 9.6%, while for men to merely 1.3%; in the case of Slovenia – it was lower, amounting to 4.7% for women and 0.6% for men only.

The above also impacts women's ability to undertake full-time employment, with many reducing their working hours to perform care duties. This has further implications both for the gap in earnings between men and women and long-term impacts, e.g. on women's pension payments (Grossi et al., 2024, p. 6; Communication from the Commission, 2022, p. 2).

Apart from the above-described challenges, one could devise at least two further (yet related) phenomena. Firstly, the so-called '*daughterhood penalty*' – capturing the disproportionately adverse economic and career effects experienced by women, particularly daughters, who assume caregiving responsibilities (often – unpaid) for elderly or disabled relatives. While such caregiving, by and large, does not cause women to exit the workforce (Glauber, 2019, p. 417 *et seq*.), it is very likely to have real economic consequences for women at the height of their careers.

A longitudinal American study (whose results are universal and perfectly transferable to the EU context), published in 2024 (Brady, 2024), examined the professional trajectories of 460 employed women aged between 50 and 60 who undertook caregiving responsibilities for an ageing parent or parent-in-law. The findings reveal that these women experienced, on average, a 4.2% decline in inflation-adjusted hourly wages, with the decrease reaching 9.5% among those providing high-intensity eldercare. By contrast, the study compared those results with 966 women in the same age group who were not caring for ageing parents. The women without eldercare responsibilities experienced a 2.7% increase in inflation-adjusted hourly wages during the same period (Travis, 2025).

From a legal and policy perspective at the EU level, the imbalance in unpaid family care duties contributes to persistent labour market inequalities. The European Parliamentary Research Service (2022, p. 1 and 4) estimated that women providing unpaid care earn roughly 3 % less per hour than women without such responsibilities, whereas no comparable wage penalty was observed for men. The so-called '*unpaid care penalty*' amounts to an annual loss of at least €242 billion across the EU - an astonishing amount that underscores the economic magnitude of caregiving inequality.

In the context of live-in care, these findings suggest a structural risk: daughters, who disproportionately undertake continuous, informal caregiving within households, face compounded disadvantages. The interplay of enduring societal norms, fragmented EU regulation of long-term care, and insufficient legal protection frameworks perpetuates this '*daughterhood penalty*'.

The second phenomenon has been described as the '*motherhood penalty'* (further exacerbated in the case of the so-called '*sandwich generation'*[15]) with a corresponding '*fatherhood bonus'*. When women become mothers, they are viewed as less committed to their careers and tend to receive less pay, smaller raises, and fewer promotions. In contrast, when men become fathers, their breadwinner status often results in higher raises and more promotions than other men (Travis, 2025).

Consequently, it is no wonder that it has been acknowledged that the EU action in the care sector has the potential for high returns for society. Fostering the 'equal earner – equal carer model' could generate benefits of between €24 billion and €48 billion a year. EU action to promote affordable, high-quality care could produce an additional €90 billion to €160 billion in benefits each year (European Parliamentary Research Service, 2022, p. 1).

How do the EU policies aim to respond to these challenges, as evidenced by the latest EU policy documents? Do they provide effective solutions?

The latest EU policy documents, analysed above, refer to those challenges – arguably the first of such documents to date. First, the Commission in the European Care Strategy stated that inadequate care services have a disproportionate impact on women, as supplementary or informal care responsibilities still fall predominantly on them, and this affects their work-life balance and options to take on paid work. This leads to women reducing working time and withdrawing early from the labour market. For many women, it results in fewer career opportunities and lower wages and pensions than those enjoyed by their male peers (Communication from the Commission, 2022, p. 2). These considerations were largely reiterated in the Council Recommendation of 8 December 2022, where the Council confirmed (a rather

[15] This notion is being referred to persons who are simultaneously taking care of elderly parents and children (Rogalewski & Florek, 2020, p. 26).

obvious truth) that women make up most carers and shined a light on '*the gender-based gap in the distribution of care work*', claiming it '*one of the key drivers of gender inequality in the labour market*' (Council Recommendation of 8 December 2022, 2022, motive 4 of the Preamble, p. 1) and that among informal carers – most of them are women, who '*traditionally carry out the bulk of caregiving, often due to a lack of accessible and affordable formal long-term care*' (Council Recommendation of 8 December 2022, motive 20 of the Preamble, p. 4). As one of (relatively scarce) solutions, the Council recommends that Member States, in '*in collaboration, where relevant, with social partners, long-term care providers and other stakeholders*' *inter alia* '*address skills needs and worker shortages implementing measures to tackle gender stereotypes and gender segregation*' (Council Recommendation of 8 December 2022, para. 8(f), p. 8).

Finally, considerations in the Council Conclusions of 27 November 2023, were set out in the similar vein, reiterating the statement on '*a significant gender dimension*' of care as well as consequences of that fact for career development projects, labour market participation and labour shortages in the EU; while putting the *ratio* of women gainfully employed in the sector at nearly 90% of all working therein, estimated at 9.1 million in Europe.[16]

To sum up this thread, it is important to underline that while so many of the issues discussed above were taken up for the first time in the documents I have identified, it is also true that they contain no significant attack on prevailing gender norms, the feminisation of the sector or the widespread gender-asymmetrical distribution of care. In essence, the underlying model of the distribution of care is essentially *status quo*. It is connected with the fact that carers' rights in the EU are employment-related rights (Daly, 2025, p. 14) (which in turn does not mean that carers need to be employed on the basis of a contract of employment – e.g., in Polish conditions it could well be – and in the majority of occasions it actually is – a so-called 'civil law contract' (Danaj et al., 2023, p. 22).

[16] And with the number of jobs that could be created over the coming 10 years (from 2023) estimated at eight million and potential earnings foregone by women due to this unbalanced distribution of unpaid care work has been found to total at least 242 billion euros per year (Council Conclusions of 27 November 2023, 2023, para 2, p. 3).

6 Conclusions

The phenomenon of live-in care provided by posted workers, including third-country nationals, epitomises the opportunities, ,the indispensability of such arrangements and the profound tensions they generate within the EU legal and policy framework. On the one hand, the freedom to provide services and the social security coordination system underpin the functioning of this transnational care model, ensuring that thousands of households across Europe can meet urgent long-term care needs. On the other hand, the Union's lack of explicit competences in the field of care has resulted in a fragmented and largely soft-law approach. While the framework of free movement of services and Regulation 883/2004 enables the transnational provision of indispensable care, it also exposes the structural limits of the Union competences in social policy.

Recent Union initiatives, most notably the European Pillar of Social Rights, the European Care Strategy, and other documents resulting from them and analyzed herein, signal a shift towards recognising care as a legal and policy priority. Yet, they remain mainly anchored in soft law essentially exhortative rather than enforceable. If these policy instruments had been able to create judicially enforceable rights, they would have offered a more robust protection (Caracciolo di Torella, 2023, p. 68). At the same time, these documents mark a significant discursive shift: they firmly place care - and especially person-centred, community-based and home-based care - on the EU agenda, aligning European policy with global commitments such as the UN Convention on the Rights of Persons with Disabilities and broader human rights discourses.

Simultaneously, the care sector (and especially live-in care) remains profoundly gendered. Women, many of them migrants, bear the overwhelming share of caregiving responsibilities, both in unpaid family care and in live-in care, leading to phenomena such as the '*daughterhood penalty*' and '*motherhood penalty*' which systematically depress women's earnings, career prospects, and pensions and underscore the need for more robust guarantees of fairness and equality. The EU's challenge is to reconcile the logic of dignified care which is so desperately needed with the imperative of women's prospects and , ensuring that both carers and care recipients are afforded genuine rights rather than aspirational rhetoric. One of the manners to achieve that aim could be to allow to posted workers (including third-country nationals) to be able to carry out live-in care work under the existing EU law framework. Maintaining available live-in care services, which are affordable to both persons being taken care of and their families will result in that numerous relatives, mostly women, will be able to practice their learned professions or carry out their business ventures, thereby benefitting both themselves (and their future) and the society.

Finally, the developments surveyed suggest that the EU has entered a new stage in recognising care as a legal and policy priority. Indeed, the above-analyzed policy documents have unequivocally put care (including live-in care) quite firmly on the EU agenda. This is the case both of the care as such, but especially of the deinstitutionalizing of the live-in care. Nevertheless, the Union's sphere of interventions remain constrained by soft-law instruments. The Union's central challenge in this regard seems therefore to be to reconcile the economic freedom that enables live-in care through posting of workers (which enables to meet the ever-rising care needs, caused by population ageing) with the imperative of safeguarding local (domestic) competences of national legal orders. Achieving truly person-centred and equitable care will require not only rhetorical recognition, but also binding legal guarantees capable of addressing structural inadequacies.

While the present framework offers only indirect legal impact, the influence the EU policies exert may be particularly useful (especially for the persons taken care of). It is precisely within the previously delineated spheres that the policy instruments under consideration may provide for an 'indirect legal impact,' serving, simultaneously as a precursor to more formal and binding measures to be adopted in due course. Such measures should start with the phenomena described herein, including especially person-centred live-in care as well as addressing gendered dimension of care by.

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Legal Acts, Case-law

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Povzetek v slovenskem jeziku

Ta članek obravnava rastoči pojav oskrbe na domu v Evropski uniji, s posebnim poudarkom na storitvah, ki jih opravljajo napoteni delavci, vključno z državljani tretjih držav. Oskrbo na domu umešča v širši socialnopravni okvir EU ter sledi razvoju nedavnih političnih pobud, kot so Evropski steber socialnih pravic, Evropska strategija za oskrbo in dokumenti, ki iz njih izhajajo. Članek analizira najnovejše pojave na področju čezmejne oskrbe na domu, vključno z deinstitucionalizacijo oskrbe, ter poudarja, kako modeli, usmerjeni v posameznika in skupnost, preoblikujejo to področje. Posebna pozornost je namenjena spolnim dimenzijam, med katerimi izstopata nesorazmerno breme za ženske

ter tako imenovani "kazni hčerinstva" in "kazni materinstva." Z povezovanjem pravnih, ekonomskih in socialnih vidikov članek ocenjuje, ali politike EU učinkovito obravnavajo trenutne izzive na tem področju in kakšen bo njihov prihodnji vpliv na bolj trajnostno zagotavljanje oskrbe.

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Musgrave, M. R. (1959) *The Theory of Public Finance* (New York: McGraw-Hill).

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