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REVIEW ARTICLE PREGLEDNI RAD

Health Policy in Medical Waste Management - an Analysis of the Regulatory Framework

Zdravstvena politika u oblasti upravljanja medicinskim otpadom – analiza regulatornog okvira

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Abstract
Medical waste represents a major challenge for public health and environmental protection within modern healthcare systems. Inadequate regulation and weak enforcement of existing legislation may increase health risks for patients, healthcare workers, and the general population. The aim of this study is to analyze the health policy and regulatory framework for medical waste management in the Republic of Serbia, with a particular focus on its alignment with international recommendations and standards. A descriptive-analytical approach was applied, including a review and comparative analysis of relevant national laws and by-laws, in comparison with guidelines issued by the World Health Organization and directives of the European Union. The national regulatory framework recognizes the importance of medical waste management; however, inconsistencies remain regarding institutional responsibility, regulatory oversight, and the practical implementation of legislation. More effective implementation of health policy in the field of medical waste management requires strengthened intersectoral cooperation, continuous training of healthcare personnel, and consistent enforcement of existing regulations in order to protect public health.

Keywords: medical waste, health policy, public health, regulation, healthcare system

Apstrakt
Medicinski otpad predstavlja ključni izazov za javno zdravlje i zaštitu životne sredine unutar modernih zdravstvenih sistema. Slaba primena propisa i neadekvatna regulativa mogu povećati rizik po zdravlje pacijenata, osoblja i širu populaciju. Cilj rada je analiza zdravstveno-političkog i regulatornog okvira upravljanja medicinskim otpadom u Republici Srbiji, sa posebnim osvrtom na usklađenost sa međunarodnim preporukama i standardima. Primenjena je deskriptivno-analitička metoda koja uključuje pregled i komparativnu analizu relevantnih nacionalnih zakona i podzakonskih akata, u poređenju sa smernicama Svetske zdravstvene organizacije i direktivama Evropske unije. Nacionalni regulatorni okvir prepoznaje značaj upravljanja medicinskim otpadom, ali postoje nedoslednosti u institucionalnoj odgovornosti, nadzoru i primeni propisa u praksi. Efikasnije sprovođenje zdravstvene politike u oblasti medicinskog otpada zahteva jačanje međusektorske saradnje, kontinuiranu edukaciju osoblja i doslednu primenu propisa radi zaštite javnog zdravlja.

Ključne reči: medicinski otpad, zdravstvena politika, javno zdravlje, regulativa, zdravstveni sistem

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Introduction

Medical waste encompasses all waste generated during the provision of healthcare services, including diagnostic, therapeutic, laboratory, and research activities, as well as patient care. Its heterogeneous composition, which includes infectious, pathogenic, chemically contaminated, or physically hazardous materials, makes it potentially harmful to human health and the environment if not managed properly (1–2). Although medical waste constitutes a relatively small proportion of the total waste generated by the healthcare sector, the risks it poses may have a significant impact on the safety of healthcare workers, patients, and the wider population (1, 3).

Medical waste management involves a series of procedures, ranging from segregation at the point of generation and collection, through transportation and temporary storage, to treatment, processing, and final disposal. An effective system requires clearly defined regulations and policies aimed at minimizing the risks of infections, injuries, and environmental pollution (4–6). According to the guidelines of the World Health Organization, inadequate handling of medical waste may contribute to the spread of infectious diseases, compromise the safety of healthcare personnel, and cause serious environmental problems, particularly in large healthcare facilities and urban settings (1, 2, 5).

In addition to health and environmental consequences, improper medical waste management may significantly increase remediation costs and healthcare expenditures in the event of incidents or contamination (7, 8). Studies conducted in Serbia and the wider region indicate that the main practical challenges are related to insufficient staff training, inconsistent oversight, and limited resources, especially in smaller healthcare institutions (6).

In the Republic of Serbia, medical waste management is regulated by several key legal acts, including the Law on Waste Management, the Law on Health Care, and the Rulebook on Medical Waste Management, which define the responsibilities of healthcare institutions, waste classification, and procedures for treatment and disposal (9). Nevertheless, the implementation of these regulations is not always uniform, particularly in smaller hospitals and rural primary healthcare centers, where limited capacity and inadequate staff training increase the risk of injuries and infections (10).

Comparisons between national legislation and international guidelines, including recommendations of the World Health Organization and European Union directives, indicate that the technical aspects of medical waste management are largely addressed. However, the enforcement of regulations and oversight of their implementation remain key challenges (1, 3, 6). The literature further emphasizes that integrating medical waste management into broader public health strategies can contribute to risk reduction for the population and enhance the environmental sustainability of healthcare systems (4, 7, 8).

Given these challenges, the aim of this study is to conduct a detailed assessment of the national regulatory framework and practical implementation of medical waste management in Serbia, identify existing gaps, and propose specific measures to improve policy and practice. Such an analysis contributes to the protection of public health, the safety of healthcare workers, and the preservation of the environment (5, 10).

National Regulatory Framework for Medical Waste Management

Medical waste management represents an important component of health policy, as improper handling may pose risks to patients, healthcare personnel, and the environment. In Serbia, the regulatory framework governing this area includes laws and by-laws that define types of medical waste, responsibilities of healthcare institutions, and the competencies of supervisory authorities (5–7).

The Law on Waste Management defines the basic categories of waste, including medical and hazardous waste, and establishes guidelines for its treatment and disposal. The Law on Health Care obliges healthcare institutions to protect the health of patients and staff, including ensuring the proper handling of medical waste. The Rulebook on Medical Waste Management provides a detailed description of waste classification, segregation procedures, transportation, temporary storage, treatment, and final disposal, thereby ensuring a comprehensive legal framework for the safe management of medical waste (5–7).

Although the legal framework is clearly defined, its implementation in practice is not uniform. Limited resources, weak coordination between inspection authorities and healthcare institutions, and insufficiently trained personnel often result in inconsistent enforcement of regulations, particularly in smaller and rural healthcare facilities. These factors increase the risk of injuries, infections, and potential adverse environmental impacts.

The national regulatory framework of the Republic of Serbia is largely aligned with international guidelines, particularly the recommendations of the World Health Organization (WHO) and EU Directive 2008/98/EC (1, 3). These guidelines mandate the segregation of medical waste, safe transportation and storage, and the application of environmentally sound treatment and final disposal methods (1, 3). A comparison of national regulations with international standards indicates that technical requirements are generally met, while oversight and practical implementation remain ongoing challenges (2, 6, 7).

A review of the literature suggests that the main challenges in the enforcement of regulations include insufficient staff education and risk awareness, limited control over private medical waste transport operators, and a lack of appropriate equipment for waste treatment in

smaller healthcare institutions (2, 6, 7). These findings highlight the need for continuous improvement of oversight mechanisms, increased resources, and strengthened capacities to ensure that the medical waste management system is both effective and sustainable (7, 8).

Materials and Methods

For the purposes of this study, a combination of descriptive and comparative analysis was applied in order to systematically examine the regulatory framework and practical implementation of medical waste management in the Republic of Serbia. The analysis was conducted through the following steps:

1. Analysis of National Legislation

Key laws and by-laws regulating medical waste management were reviewed, with a focus on the definition of waste types, responsibilities of healthcare institutions, oversight mechanisms, and procedures for waste treatment and disposal. Specifically, the following legal documents were analyzed:

- Law on Waste Management (Official Gazette of the Republic of Serbia No 109/2025 (4)
- Law on Health Care (Official Gazette of the Republic of Serbia Nos. 25/2019, 92/2023) (5)
- Rulebook on Medical Waste Management (Official Gazette of the Republic of Serbia No. 110/2025) (6).

2. Comparison with International Standards

National regulations were compared with the guidelines of the World Health Organization (WHO) and EU Directive 2008/98/EC in order to identify areas of alignment as well as potential gaps in implementation (1, 3).

3. Review of Scientific Literature

Domestic and international scientific publications addressing medical waste management practices were reviewed, including studies by D. Ugrinov and collaborators, with particular emphasis on regulatory implementation, occupational safety, and the environmental sustainability of the system (7, 8, 10, 11).

4. Descriptive-Comparative Evaluation

Key components of the medical waste management system were identified as segregation, transportation, storage, treatment, staff training, and oversight. For each component, a comparison between national legislation and international standards was conducted to assess practical challenges and implementation gaps. The results were presented in tables, highlighting differences among large hospitals, primary healthcare centers, and rural healthcare facilities.

5. Data Validation

Data obtained from legislative documents and the scientific literature were cross-checked to ensure accuracy and reliability. Particular attention was paid to the application of regulations in different types of healthcare institutions and their impact on the safety of healthcare workers and patients.

This methodological approach enables a critical evaluation of the regulatory framework, identification of implementation challenges, and formulation of recommendations for improving medical waste management policy and practice in accordance with public health principles and international standards.

Results

The analysis of national legislation in the Republic of Serbia, combined with a review of relevant literature, shows that regulations in the field of medical waste management are clearly defined and cover all key activities: segregation, transportation, storage, treatment, and disposal of waste (4–6, 12).

Comparison with international standards (WHO and EU) indicates that technical norms mostly cover all areas; however, implementation in practice varies, particularly in smaller and rural healthcare facilities, where capacity, equipment, and staff training are often insufficient (7, 8, 10, 11).

Table 1 National regulations in relation to international standards and main implementation challenges

Area	National Regulations	WHO / EU Standards	Main Implementation Challenges
Waste Segregation	Rulebook 110/2025	WHO 2014, EU 2008	Variable implementation in smaller facilities
Transport and Storage	Law on Waste Management 109/2025	WHO 2014	Lack of controlled routes and oversight
Treatment and Disposal	Rulebook 110/2025	WHO 2014	Insufficient sterilization and treatment capacity
Staff Training	Law on Health Care 25/2019	WHO recommendations	Low awareness and inconsistent training

Sources: Rulebook 110/2025; Law on Waste Management 109/2025; WHO 2014; EU Directive 2008/98/EC; Ugrinov D et al., 2025 (4–8, 9)

Table 2 Main challenges by type of healthcare facility

Facility Type	Main Challenges
Large hospitals	Occasional non-compliance in waste segregation; need for additional staff training
Primary healthcare centers	Lack of sterilization capacity; limited oversight; weak waste transport
Rural facilities	Minimal equipment; absence of dedicated disposal sites; insufficient staff training

Sources: Rulebook 110/2025; Ugrinov D et al., 2025; analysis of practices in healthcare centers and hospitals (6–8, 9)

Proposed Measures for Improvement

Based on the identified challenges and literature analysis, the following interventions are proposed:

Area	Proposed Measures
Staff Training	Regular workshops and seminars; development and distribution of manuals; practical simulations and knowledge evaluation
Treatment and Disposal	Expansion of sterilization capacity; introduction of modern waste treatment technologies
Transportation and Oversight	Monitoring of private transport operators; standardization of routes and documentation; periodic inspections
Implementation Monitoring	Regular evaluation of regulation application; monitoring effects on safety and environmental protection

Sources: WHO 2014; Rulebook 110/2025; Ugrinov D. et al., 2025 (1, 6–9)

Discussion and Conclusion

The analysis of Serbia's legal framework and available literature indicates a solid legal basis for medical waste management. National regulations, including the Law on Waste Management, the Law on Health Care, and the Rulebook on Medical Waste Management, cover all key activities: segregation, transportation, storage, treatment, and disposal of waste (4–6, 12). This framework is largely aligned with the international guidelines of the World Health Organization (WHO) and EU Directive 2008/98/EC (1, 3).

However, in practice, the implementation of regulations is not uniform. The greatest challenges occur in smaller healthcare facilities and rural institutions, where the lack of adequate equipment, waste treatment capacity, and trained personnel leads to variable compliance (7, 8, 10, 11). These findings align with domestic studies, including research by Ugrinov et al., which emphasize that technical coverage of regulations alone is insufficient without effective supervision and resource support (7, 8).

Key gaps in regulatory implementation were identified:

1. **Transportation and supervision of private operators** – although the law prescribes obligations, systematic control is not always present, which can lead to improper waste handling and increased risk of injuries and infections (2, 6, 7).
2. **Waste treatment capacity** – smaller facilities often lack adequate sterilization equipment, increasing the risk of improper disposal (6, 7).
3. **Staff education** – educational programs are not uniform and do not cover all levels of healthcare institutions, although regulations prescribe responsibilities in this area (7, 8, 10).

Results clearly indicate that continuous staff education is a key factor in reducing the risk of injuries and infections. Insufficient awareness of hazards and improper handling of medical waste directly threatens public health, especially in the context of pandemic and infectious risks (1, 2, 6).

Comparison of national and international frameworks shows that technical standards in Serbia meet basic requirements, but implementation in practice requires additional systemic interventions, improved coordination, and adequate resources. Particular attention should be given to smaller and rural facilities, where the risk of improper handling is highest (7, 8, 10, 11).

Recommendations for Improvement

1. **Increase capacity and resources in smaller healthcare facilities**
   - Introduce adequate medical waste treatment equipment (sterilizers, autoclaves).
   - Renovate or construct facilities for temporary storage and safe disposal of waste.
2. **Standardize and enhance staff education**
   - Regular training on proper handling, segregation, and treatment of waste.
   - Development and distribution of manuals and guidelines for all types of healthcare institutions.
   - Evaluate staff knowledge through tests and practical simulations.
3. **Improve oversight and control of waste transportation**
   - Monitor private medical waste transporters.
   - Standardize transport routes, documentation, and protocols.
   - Conduct regular inspections and audits in cooperation with competent authorities.
4. **Implement modern waste treatment technologies and methods**
   - Introduce environmentally friendly treatment methods (microwave and thermal disinfection) in accordance with WHO and EU recommendations.
   - Promote circular economy innovations to reduce waste volume and recycle safe materials.
5. **Integrate medical waste management with public health and sustainability strategies**
   - Continuous review and alignment of national regulations with international guidelines.
   - Monitor the impact of regulations on healthcare worker and patient safety, as well as environmental protection.
   - Include medical waste management in public health and sustainable development plans.

In conclusion, Serbia has a solid legal basis for medical waste management, but the effectiveness of regula-

tions in practice depends on resources, staff training, and oversight. Implementation of the proposed measures can significantly improve healthcare worker and patient safety, protect the environment, and contribute to sustainable medical waste management in accordance with public health principles (1–9, 12).

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