ORIGINAL ARTICLE

CONTENTS

Legal regulation of health care management based on forensic medical assessment of early in-hospital mortality

Alina O. Pletenetska[1], Anzhela B. Berzina[1], Ruslan A. Volynets[2], Oksana O. Cherniak[3], Oleksandr V. Felyk[3], Valentyn V. Halunko[3]

[1]BOGOMOLETS NATIONAL MEDICAL UNIVERSITY, KYIV, UKRAINE
[2]TARAS SHEVCHENKO NATIONAL UNIVERSITY OF KYIV, KYIV, UKRAINE
[3]KYIV UNIVERSITY OF INTELLECTUAL PROPERTY AND LAW, KYIV, UKRAINE

ABSTRACT

Aim: To analyze the legal regulation of health care management based on the analysis of forensic medical examinations concerning the quality of medical care in cases of early in-hospital mortality.

Materials and Methods: A retrospective forensic medical examination was conducted of 51 cases of patient mortality occurring within the first 24 hours after hospital admission in a multidisciplinary hospital in Kyiv. Organizational and legal aspects of medical care delivery were analyzed for compliance with legislation and clinical protocols.

Results: Systemic deficiencies included the absence of electrocardiographic examination in 90,2 ± 4,2% of cases, regardless of diagnostic accuracy. Significant trends were identified as the hospital stay duration increased: the absence of oxygen therapy showed a downward trend (from 86,7 ± 8,8% to 38,5 ± 13,5%; $p_{trend} = 0,006$), while diagnostic discrepancies demonstrated an upward trend (from 6,7 ± 6,4% to 46,2 ± 13,8%; $p_{trend} = 0,016$). The median number of deficiencies doubled from 2 (1–3) in the <3 h group to 4 (3–4) in the 12–24 h group ($p = 0,002$). A moderate direct correlation was established between patient age and the total number of deficiencies ($\rho = 0,462$; $p < 0,001$).

Conclusions: The identified deficiencies correlate with non-compliance with mandatory regulatory requirements. The accumulation of medical errors with increasing length of stay and patient age indicates systemic violations of organizational and legal standards, necessitating stricter public administration control over medical care quality.

KEY WORDS: forensic medicine, public administration, medical care

Wiad Lek. 2026;79(2):355-361. doi: 10.36740/WLek/218721 DOI

INTRODUCTION

Early in-hospital mortality (death occurring within the first 24 hours after hospital admission) is an integral indicator of the quality, effectiveness, and organization of medical care [1]. It reflects not only the severity of the patient's clinical condition but also the timeliness of diagnosis, the adequacy of the pre-hospital care pathway, and adherence to clinical protocols.

International guidelines of the European Society of Cardiology (ESC) and the American Heart Association (AHA) identify early diagnosis, particularly electrocardiography (ECG), risk stratification, and timely initiation of therapy as important factors in reducing in-hospital mortality in acute conditions [2–5]. Contemporary studies employing machine learning methods further confirm the critical role of the completeness of early diagnostic data in predicting mortality outcomes [6–9]. Non-compliance with these requirements significantly worsens prognosis and constitutes a defect in the provision of medical care.

Early in-hospital mortality serves as an indicator of public administration and regulatory frameworks in health care and as a marker of the quality of medical care delivery within the system of state governance in the health sector. Health care management is a component of public administration, a normatively regulated process based on a system of standards in the health care sector, which, in accordance with the Law of Ukraine "Fundamentals of the Legislation of Ukraine on Health Care" (1993), includes medical standards, clinical protocols, drug formularies, and related instruments. These standards are mandatory for all health care institutions [10]. Forensic medical examination is a main tool for assessing the quality of medical care, enabling

the establishment of a causal relationship between the actions (or omissions) of medical professionals and a fatal outcome [11,12].

AIM

The aim of the study was to analyze the legal regulation of health care management based on the analysis of forensic medical examinations concerning the quality of medical care in cases of early in-hospital mortality; to identify associations between violations of regulatory requirements and adverse medical outcomes; and to determine directions for improving the legal regulation of health care management, including in the context of ensuring quality control of medical care.

MATERIALS AND METHODS

A retrospective forensic medical examination was conducted of 51 cases of patient mortality occurring within the first 24 hours after hospital admission to a multidisciplinary hospital in Kyiv during the pre-war period. Patients were divided into four groups according to the length of hospital stay: up to 3 hours (n = 15), 3–6 hours (n = 7), 6–12 hours (n = 16), and 12–24 hours (n = 13).

The forensic medical assessment of compliance of the provided medical care was performed based on applicable regulatory legal acts, including the Law of Ukraine "Fundamentals of the Legislation of Ukraine on Health Care" (1993) [10], the Criminal Code of Ukraine (2002) [13], and multiple orders of the Ministry of Health of Ukraine.

Statistical analysis. Data were processed using IBM SPSS Statistics v. 27.0 (Armonk, NY: IBM Corp., USA). Quantitative variables are presented as M ± SE (mean ± standard error of the mean) or median (Me) with interquartile range (IQR [Q_1-Q_3]), and qualitative indicators as percentages with standard error of the percentage (SE%). Normality of distribution was assessed using the Shapiro–Wilk test. The comparisons of two independent groups were performed using Student's t-test (for normally distributed quantitative variables) or the Mann–Whitney U-test (for non-normally distributed data). Four independent groups were compared by the use of ANOVA with the post hoc Tukey HSD test (for normally distributed quantitative variables), or Kruskal-Wallis test with the post hoc Mann–Whitney U-test (for non-normally distributed data) (considering the Bonferroni correction). The Associations between categorical variables were evaluated using the Fisher's exact test. The strength of association between binary variables was assessed using the phi-coefficient (φ). The binary qualitative data in four independent groups were compared by the use of χ^2 test (including the χ^2 test for trend), with the post hoc Marascuilo-Liakh-Gurianov procedure. The correlation analysis was performed by the use of Spearman's rank correlation coefficient (ρ). Differences were considered statistically significant at $p<0,05$ (considering the multiple comparisons correction).

ETHICS

The study was conducted in accordance with provisions of Helsinki Declaration of World Medical Association, Council of Europe Convention on Human Rights and Biomedicine, and Ukrainian legislation. Aggregated statistical data without disclosure of personal information were used. Analysis of clinical cases was conducted in generalized form, without possibility of identifying specific persons.

FRAMEWORK

The study was performed within framework of initiative research work "Expert-diagnostic system for objectification of forensic medical examination of traumatic brain injury" (state registration number 0123U101528; term 2023-2026), as a fragment of the complex scientific project of the Educational and Scientific Institute of Law Taras Shevchenko National University of Kyiv «Legal support for the sustainable development of the economy of Ukraine in the context of European integration» (state registration number 0124U003297; term: 2024-2029).

RESULTS

The general characteristics of the cases subjected to forensic medical examination are presented in Table 1. The mean age of the deceased patients was 67,5 ± 1,7 years. Sex distribution was as follows: males – 49,0% (25 persons), females – 51,0% (26 persons). The mean age of males was 66,2 ± 2,6 years, being comparable to that of females (68,6 ± 2,3 years).

The cardiovascular diseases were the leading cause of death identified by forensic medical examination, accounting for 37 cases (72,6 ± 6,2%).

Deficiencies in the provision of medical care identified during the forensic medical examination are presented in Table 2.

The most critical deficiency identified during the forensic medical examination was the failure to perform ECG in 90,2 ± 4,2% of cases.

ANALYSIS OF THE ASSOCIATION BETWEEN DEFICIENCIES AND DIAGNOSTIC ERRORS

An analysis of the association between the identified deficiencies and adverse outcomes was conducted

Table 1. General characteristics of cases subjected to forensic medical examination of early in-hospital mortality

Indicator	Absolute number (n = 51)	Frequency (% ± SE%)	Forensic medical assessment
Demographic structure			
Men	25	49.0 ± 7.0	-
Women	26	51.0 ± 7.0	-
Mean age (years. M ± SE)	-	67.5 ± 1.7	Consistent with the epidemiology of ACD*
Nosological structure			
Diseases of the cardiovascular system	37	72.6 ± 6.2	Typical structure for EIHM**
Other diseases	14	27.4 ± 6.2	-
Path of hospitalization			
Emergency medical service	43	84.3 ± 5.1	Meets the standard (> 80%)
Outpatient and polyclinic facilities	8	15.7 ± 5.1	Requires optimization***
Quality of diagnostics			
Diagnostic concordance	40	78.4 ± 5.8	Below standard (standard >88%)
Diagnosis discrepancy	11	21.6 ± 5.8	Violation of quality standard

Notes: * ACD – acute cardiovascular diseases; ** EIHM – early in-hospital mortality; *** According to the results of the forensic medical examination, some patients required hospitalization by the emergency medical service (EMS)
Source: compiled by the authors of this study

Table 2. Deficiencies in medical care identified by forensic medical examination

Diagnostic and Therapeutic Intervention	Performed n (% ± SE%)	Deficiency Identified n (% ± SE%)	Regulatory Requirement, %	Legal Qualification of the Deficiency
Electrocardiography (ECG)	5 (9.8 ± 4.2)	46 (90.2 ± 4.2)	100	Gross violation of the CC* (Article 140)
Venous access	32 (62.7 ± 6.8)	19 (37.3 ± 6.8)	95	Violation of the EMC** standard
Pharmacotherapy	39 (76.5 ± 5.9)	12 (23.5 ± 5.9)	90	Incomplete scope of care
Oxygen therapy	16 (31.4 ± 6.5)	35 (68.6 ± 6.5)	85	Violation of the clinical protocol despite medical indications

Notes: * CC – Criminal Code; ** EMC – emergency medical care
Source: compiled by the authors of this study

within the framework of the forensic medical examination (Table 3).

The analysis showed that ECG was not performed in 90,9% of cases with diagnostic discrepancies and in 90,0% of cases with diagnostic concordance. The lack of a statistically significant difference indicates that the failure to perform an ECG was a universal systemic deficiency in medical care delivery, rather than a factor specific only to diagnostic errors.

A statistically significant moderate association was identified between the absence of pharmacotherapy and diagnostic discrepancies ($\varphi = 0,38$; $p = 0,013$). Moreover, the absence of venous access tended to be more frequent in the diagnostic discrepancy group. The association between the absence of oxygen therapy and diagnostic discrepancies did not reach statistical significance (Table 4).

ANALYSIS OF DEFICIENCIES ACCORDING TO THE DURATION OF HOSPITAL STAY

The analysis revealed significant temporal variations in medical care quality (Table 5). A trend in age distribution was observed ($p = 0,052$), with the oldest patients in the 3–6 h group (75,6 ± 1,8 years) and the youngest in the 12–24 h group (62,9 ± 3,1 years). The absence of oxygen therapy showed a significant downward trend (from 86,7 ± 8,8% to 38,5 ± 13,5%; $p_{trend} = 0,006$), whereas diagnostic discrepancies demonstrated a significant upward trend as the duration of stay increased, reaching 46,2 ± 13,8% in the 12–24 h group ($p_{trend} = 0,016$). The median number of deficiencies per patient significantly increased with the duration of stay, doubling from 2 (1–3) in the earliest group to 4 (3–4) in the 12–24 h one (Table 5). Furthermore, a moderate direct correlation

Table 3. Association between the absence of ecg examination and diagnostic discrepancies

Parameters	Diagnostic Discrepancy	Diagnostic Concordance	Total
ECG not performed	10 (90.9 ± 8.7%)	36 (90.0 ± 4.7%)	46
ECG performed	1 (9.1 ± 8.7%)	4 (10.0 ± 4.7%)	5
Total	11	40	51

Source: compiled by the authors of this study

Table 4. Association Between Other Deficiencies and Diagnostic Discrepancies

Deficiency	With Diagnostic Discrepancy (n = 11)	With Diagnostic Concordance (n = 40)	Fisher's Exact Test	φ
Absence of venous access, n (% ± SE%)	7 (63.6 ± 14.5 %)	12 (30.0 ± 7.2 %)	p = 0.075	0.29
Absence of pharmacotherapy, n (% ± SE%)	6 (54.5 ± 15.0 %)	6 (15.0 ± 5.6 %)	p = 0.013	0.38
Absence of oxygen therapy, n (% ± SE%)	9 (81.8 ± 11.6 %)	26 (65.0 ± 7.5 %)	p = 0.466	0.15

Source: compiled by the authors of this study

Table 5. Deficiencies According to the Duration of Hospital Stay

Indicator		Up to 3 h (n = 15)	3-6 h (n = 7)	6-12 h (n = 16)	12-24 h (n = 13)	p
Age, years, M ± SE		68.7 ± 2.8	75.6 ± 1.8	72.3 ± 2.1	62.9 ± 3.1	0.052
Age group, years, n (% ± SE)	<60	4 (26.7 ± 11.4)	0	2 (12.5 ± 8.3)	6 (46.1 ± 13.8)	0,071
	60-75	6 (40.0 ± 12.6)	4 (57.1 ± 18.7)	9 (56.3 ± 12.4)	4 (30.8 ± 12.8)	0,484
	>75	5 (33.3 ± 12.2)	3 (42.9 ± 18.7)	5 (31.3 ± 11.6)	3 (23.1 ± 11.7)	0,832
Females, n (% ± SE%)		9 (60.0 ± 12.6)	1 (14.3 ± 13.2)	10 (62.5 ± 12.1)	6 (46.2 ± 13.8)	0.156
Absence of ECG, n (% ± SE%)		13 (86.7 ± 8.8)	6 (85.7 ± 13.2)	14 (87.5 ± 8.3)	13 (100)	0.590
Absence of venous access, n (% ± SE%)		5 (33.3 ± 12.2)	4 (57.1 ± 18.7)	4 (25.0 ± 10.8)	6 (46.2 ± 13.8)	0.432
Absence of pharmacotherapy, n (% ± SE%)		2 (13.3 ± 8.8)	2 (28.6 ± 17.1)	3 (18.8 ± 9.8)	5 (38.5 ± 13.5)	0.427
Absence of oxygen therapy, n (% ± SE%)		13 (86.7 ± 8.8)	6 (85.7 ± 13.2)	11 (68.8 ± 11.6)	5 (38.5 ± 13.5)	0.033*
Diagnostic discrepancy, n (% ± SE%)		1 (6.7 ± 6.4)	1 (14.3 ± 13.2)	3 (18.8 ± 9.8)	6 (46.2 ± 13.8)	0.075**
Total deficiencies count per patient, Me (IQR)		2 (1-3)	2 (2-4)	2 (1-3***)	4 (3-4)	$p_{1-4} = 0.002$ $p_{3-4} < 0.001$

Notes: * $p_{trend} = 0{,}006$; ** $p_{trend} = 0{,}016$; *** Q_3 rounded from 2,5 (an average value between 2 and 3) to 3; p_{1-4} – the significance of difference between «up to 3 h» and «12-24 h» groups; p_{3-4} – the significance of difference between «6-12 h» and «12-24 h» groups
Source: compiled by the authors of this study

was established between patient age and the total number of deficiencies ($\rho = 0{,}462$; $p < 0{,}001$), suggesting that older age was associated with a higher accumulation of organizational and diagnostic shortcomings.

DISCUSSION

Early in-hospital mortality, as an integral indicator of the quality of medical care, enables the identification of systemic organizational and legal gaps regardless of the nosological structure [1]. In the context of this study, early in-hospital mortality is considered not only a statistical indicator but also a marker of the quality of medical care delivery. The identified deficiencies indicate the absence of effective public administration in the health care sector. The lack of managerial decisions regarding interaction between the stages of medical care, insufficient regulatory specification of the scope and sequence of diagnostic and therapeutic interventions, violations of medical documentation requirements, as well as ineffective quality control and accountability of medical professionals, require in-depth analysis.

Medeiros et al. (2020) demonstrated that early mortality is a sensitive indicator of organizational problems within the health care system [1]. Our findings are consistent with these conclusions. Hernesniemi et al. (2019), Li et al. (2021), Soleimani et al. (2025), and Liu

et al. (2024) showed that the accuracy of mortality prediction critically depends on the completeness of early diagnostic data [6–9].

Statistical Interpretation of Diagnostic Omissions. The ubiquitous absence of ECG examination (90,2% of all cases) resulted in the lack of a statistically significant association with diagnostic discrepancies. However, this does not diminish its clinical importance. According to the systematic analysis, such a mass omission of a fundamental diagnostic standard across all study groups indicates a "ceiling effect" of organizational failure. Rather than being a variable factor, the absence of ECG has become a constant systemic deficiency that fundamentally undermines diagnostic reliability. The fact that ECG was not performed in 90,9% of cases with diagnostic discrepancies confirms that this omission is a foundational barrier to accurate clinical assessment, regardless of the length of hospital stay.

Ukrainian studies have substantiated that forensic medical examination is an important instrument for identifying systemic gaps in legal regulation [11,12]. Our study confirms these findings: the identified gross violations of clinical protocols qualify as actions containing elements of offenses stipulated in Articles 139 and 140 of the Criminal Code of Ukraine.

LEGAL LEVERS FOR IMPROVING HEALTH CARE MANAGEMENT

International guidelines mandate ECG performance within 10 minutes in 100% of cases [2–5]. In developed countries, this indicator reaches 95–98%. Our data (9,8%) demonstrate a critical gap, necessitating the improvement of public administration mechanisms in health care through the legal establishment of mandatory ECG performance within a defined time frame as a managerial quality indicator integrated into systems of state control, accreditation, and accountability of health care institution managers.

ORGANIZATIONAL AND MANAGERIAL ASPECTS

The Ministry of Health of Ukraine should legislatively mandate 100% equipment of emergency medical service teams with ECG devices with autonomous power supply. Digitalization through the Electronic Health Care System (EHCS) should include automated monitoring of compliance with mandatory procedures and automatic notification of supervisory authorities in case of violations.

REGULATION OF MEDICAL PRACTICE

Licensing conditions for conducting medical practice should include mandatory availability of ECG equipment as a prerequisite for obtaining and renewing a medical practice license. Legislative establishment of mandatory forensic medical examination of all cases of early in-hospital mortality is required.

PATIENT RIGHTS PROTECTION AND FINANCIAL MECHANISMS

The National Health Service of Ukraine should monitor quality and safety indicators of medical care and apply financial and organizational sanctions to health care institutions with high mortality rates. Wang et al. (2021) demonstrated the economic feasibility of investments in diagnostic methods [14], while Ho et al. (2023) showed the critical impact of diagnostic timeliness on mortality [15]. In our study, 74,5% of patients sought medical care later than the optimal therapeutic window, indicating the need for legal regulation of public information campaigns.

LEGAL REGULATION UNDER MARTIAL LAW

Novakivskyy et al. (2023) analyzed the impact of the war in Ukraine on the health care system, including infrastructure destruction, power outages, logistical disruptions, shortages of medications, and personnel deficits [16]. Galea et al. (2020) and Daniels et al. (2021) demonstrated that emergencies exacerbate organizational deficiencies [17, 18].

If, in the pre-war period, the identified deficiencies resulted in mortality within 24 hours in 100% of cases, under wartime conditions these deficiencies become critically aggravated. Infrastructure destruction renders equipment non-operational; power outages transform the deficit in ECG performance (90,2%) into an almost complete absence of diagnostics; logistical disruptions prolong transport times, increasing the number of deficiencies; medication shortages exacerbate inadequate pharmacotherapy; and staff shortages prevent the use of available equipment.

Required Special Legal Regulation:

1. *Protected infrastructure*. Amendments to the Code of Civil Protection of Ukraine [19] mandating placement of diagnostic equipment in underground facilities with autonomous power supply, particularly operating rooms. For Kyiv, the obligation is to establish at least 10 underground diagnostic centers.
2. *System redundancy*. Amendments to licensing conditions require reserve diagnostic equipment, generators with fuel supply for 72 hours, and medication reserves for 21 days.
3. *Evacuation priority*. Amendments to traffic regulations [20] and the Law of Ukraine "On the Legal Re-

gime of Martial Law" [21] establish absolute priority passage for ambulances, even during air raid alerts, with predefined alternative routes.

4. *Decentralization*. Amendments to building regulations to create a network of small protected diagnostic units in populated areas.
5. *Enhanced control*. Legislative establishment of an automated system for analysis of all cases of early in-hospital mortality.

Future research perspectives include expanding the sample to a multicenter level, implementing a prospective design with continuous monitoring through the EHCS, and evaluating the effectiveness of the proposed legal and public administration mechanisms in reducing early in-hospital mortality both in peacetime and during armed conflict.

The study is limited by its single-center design and pre-war data. However, statistical power was sufficient to detect significant associations, and the identified patterns reflect systemic problems of the entire health care system of Ukraine.

CONCLUSIONS

1. Critical organizational and legal gaps were identified in early in-hospital mortality cases, characterized by systemic non-compliance with clinical protocols (ECG, venous access, oxygen therapy). These gross violations of medical standards qualify as actions containing elements of offenses stipulated in Articles 139 and 140 of the Criminal Code of Ukraine.
2. The absence of ECG examination (90,2 ± 4,2%) is a universal systemic failure that persists regardless of the diagnostic outcome or length of stay. This fundamental breach of health care legislation reflects profound gaps in the existing quality control and legal regulation of medical management.
3. Diagnostic discrepancies (21,6 ± 5,8%) significantly exceed acceptable medical standards, showing a significant upward trend as the length of hospital stay increases. The cumulative effect of deficiencies, and their moderate correlation with patient age, confirm that the longer a patient remains in the facility, the higher the risk of legal and clinical omissions.
4. Legal mechanisms for health care quality must be strengthened through the legislative establishment of 100% diagnostic equipment coverage, automated monitoring via the Electronic Health Care System (EHCS), and the implementation of stringent financial sanctions by the National Health Service of Ukraine for protocol violations.
5. Under wartime conditions, identified systemic deficiencies are critically exacerbated. Special legal regulation is required to ensure medical resilience, including the legislative establishment of autonomous underground diagnostic centers with 100% redundancy of critical systems, which is projected to reduce preventable mortality during large-scale infrastructure disruptions.

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CONFLICT OF INTEREST

The Authors declare no conflict of interest

CORRESPONDING AUTHOR

Alina O. Pletenetska
Bogomolets National Medical University
5 Mechnikov St., 01133 Kyiv, Ukraine
e-mail: fantasyalinka@gmail.com

ORCID AND CONTRIBUTIONSHIP

Alina O. Pletenetska: 0000-0002-7029-3377 A B C D E
Anzhela B. Berzina: 0000-0002-9885-309X A B D E F
Ruslan A. Volynets: 0000-0002-8134-8572 A D F
Oksana O. Cherniak: 0000-0003-0991-4477 A E F
Oleksandr V. Felyk: 0000-0003-0862-1453 A E F
Valentyn V. Halunko: 0000-0002-8133-6766 A D F

A – Work concept and design, B – Data collection and analysis, C – Responsibility for statistical analysis, D – Writing the article, E – Critical review, F – Final approval of the article

RECEIVED: 09.08.2025
ACCEPTED: 20.01.2026