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REPORTING OF ADVERSE MEDICAL EVENTS IN POLAND WITH PARTICULAR FOCUS ON CRIMINAL LAW ASPECTS

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Abstract. The article examines the criminal law aspects of implementing the idea of reporting adverse events in medicine into the Polish legal system. An analysis of the organisational factors underlying treatment errors leads to the conclusion that, given the increasing complexity of healthcare delivery, it is essential to implement systemic mechanisms for monitoring, analysing and improving clinical and management processes. Improvements in the quality of healthcare and patient safety cannot be realised without establishing a system for reporting and analysing adverse events, which enables the identification of multifactorial causes of errors, including organisational errors. The concept of an adverse event register is intended to reflect a shift away from a punitive model towards a culture of safety. Sometimes, refraining from criminal sanctions may, paradoxically, improve patient safety and thus prove more cost-effective than punishment. The fear of stigmatisation is one of the major obstacles to the reporting of adverse events. Minimising this fear by introducing mechanisms that encourage openness in discussing adverse events may contribute to increasing detection rates, and thus to greater effectiveness in minimising the scale of medical errors. The aim of this article is to demonstrate that, although the matter is complex from the perspective of criminal law principles, it is nevertheless possible to find solutions that would serve the objectives of the incident reporting system whilst remaining consistent with the Polish criminal law system.

Keywords: medical error; organisational error; safety culture; near misses; quality in healthcare; patient safety.

INTRODUCTION

An analysis of organisational factors contributing to treatment irregularities may lead to the conclusion that, considering the current complexity of the healthcare provision process, it is necessary to introduce systemic solutions aimed at improving the quality of the working environment for medical professionals and increasing patient safety, achieved through continuous monitoring, analysis and improving clinical and management processes. Error reporting and analysis are particularly important in the context of detecting systemic, organisational, ergonomic and management flaws that may

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be more widespread than individual cases. Nevertheless, it should be noted that the problem highlighted is not limited to organisational errors, although in these circumstances the need for comprehensive solutions to prevent such adverse events from occurring in the future is particularly evident.

The outlined expected state of affairs cannot be implemented without establishing a system that allows for the continuous assessment of the indicated factors and drawing conclusions from the assessment, serving to identify, collect and analyse data on so-called 'adverse events', with a particular emphasis on using the conclusions from the analyses and focusing on learning from the identified irregularities rather than on punishment. An adverse event in medicine can be defined as an event that occurs during the provision of healthcare services, or as a result of the provision or failure to provide such services, causing or likely to cause a negative effect on the health or life of a patient, in particular death, damage to health or health disorder, illness, life-threatening situation, the need for hospitalisation or its prolongation, as well as bodily injury or health disorder of the unborn child.

This article is devoted to presenting the legal conditions in the Polish legal system, with particular emphasis on issues relating to criminal law, for the introduction of a system for reporting such incidents in healthcare, including near misses, which may be helpful in understanding and reducing the phenomenon of medical error. This paper refers largely to criminal aspects because sometimes refraining from criminal prosecution may increase patient safety and thus prove more cost-effective than punishment. The fear of stigmatisation is the main barrier to reporting adverse events and thus an obstacle to increasing their detectability, obtaining information about the root causes of such incidents and learning from mistakes. Meanwhile, the adverse event reporting system is a strategic tool in the fight against medical errors on a larger scale than individual cases. Nevertheless, the introduction of such a system encounters difficulties in the area of criminal law, as the consequences of these events may be classified as a crime (e.g., unintentional causing of death, bodily harm or exposure to direct danger of loss of life or serious bodily harm – Articles 155, 156-157 and 160 of the Criminal Code[1]). Therefore, the issue is complex, interesting, and worth exploring.

In order to conduct research for the purposes of preparing the thesis, the formal-dogmatic method was chosen as the dominant research method (analysis of the Polish legal situation and views presented in literature), with elements of the historical method (analysis of the evolution of selected institutions as a phenomenon over time) and the comparative law method (analysis of foreign literature and reports in search of models for solving the problems under study).

[1] The Act of 6 June 1997 – the Criminal Code, Journal of Laws of 2025, item 383.

1. THE CORRELATION BETWEEN STRICTER CRIMINAL LIABILITY FOR MEDICAL PERSONNEL AND THE EFFECTIVENESS OF MEDICAL ERROR PREVENTION

The above-mentioned postulates for the introduction of an adverse event reporting system have been presented by many experts in Polish and foreign publications.[2] As emphasised in the cited works, criminal law institutions are not effective instruments for solving the complex problem of medical error. It is worth outlining below why this may be the case.

Medical errors are usually associated by the public with negligence on the part of a member of staff. However, there are cases where the deterioration of a patient's health or their death should be linked to organisational irregularities [Chowaniec, Jabłoński, Kobek, et al. 2007, 79]. In this context, it is noteworthy that medical cases are becoming more and more complex, as observed by forensic specialists, who point out that nowadays, there are almost no simple expert medical opinions that can be prepared by a single specialist [Świątek 2000, 40]. As is highlighted in the medical community, it is becoming increasingly rare for medical care to be provided from start to finish by one and the same person, who independently provides medical assistance to the patient and at the same time takes care of the entire spectrum of conditions in which this care is provided. In view of the contemporary complexity of the process of providing healthcare services, an interdisciplinary treatment process is becoming the typical method of providing healthcare services. The old model, based on the individual relationship between the patient and the independently working doctor, is giving way to a new system, where patient care is provided by a team of people, which may include doctors of various specialities, nurses, midwives, laboratory diagnosticians, paramedics, perfusionists or physiotherapists, working together to provide comprehensive healthcare services. They may act simultaneously, e.g., during complex surgery or intervention by an emergency medical team, or in a specific sequence dictated by the need to transfer the patient to subsequent stages of diagnosis, treatment and rehabilitation.

There is no doubt that cooperation in the treatment process can bring obvious benefits to the patient and may even prove necessary. After all, a number of health services are simply impossible to perform by a single, even

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[2] See, for example: Pokorski, Pokorska, and Zawłodzki 2010, *passim*; Kutryba, Kutaj-Wąsikowska, and Tombarkiewicz 2015, *passim*; Berwick 2003, 2570-572; Leap. 2002, 1633-638; Leape, Berwick, and Bates 2002, 501-507; Leape and Berwick 2005, 2384-390; Kohn, Corrigan, and Donaldson 1999, *passim*; Henriksen, Battles, Keyes, et al. 2008, *passim*; Millenson 2017, 103-12; Waxman, Greenberg, Ridgely, et al. 2014, 1518-525; Weingart, Callanan, Ship, et al. 2001, 809-14; Niżankowski 2012, 103-105; Kutryba and Kutaj-Wąsikowska 2012, 140-47.

outstanding, medical professional, or their provision as a team allows for a reduction in the time needed to perform a specific procedure or an increase in the quality and safety of its performance. The above-mentioned conditions therefore seem to open up new perspectives for effective and efficient treatment. However, like any joint activity, the provision of healthcare services as a team involves not only benefits but also risks, which may be caused by a lack of adequate organisation, coordination or communication within a given medical team, or by poor work ergonomics. The source of these irregularities may be inappropriate staffing, failure to ensure adequate technical, equipment and sanitary conditions, or faulty organisational procedures.

As J. Pokorski emphasises, referring to data published in an American report entitled "To err is human. Building a safer health system", confirming the observations made by the aforementioned forensic specialists, the traditional attribution of all responsibility to the last link in the chain of causation, i.e., the direct performer of medical actions, usually a rank-and-file employee, is an anachronism in view of the contemporary realities of the functioning of the healthcare system [Pokorski 2008, 3-4]. Adverse events usually have multiple causes and a multifactorial aetiology. These may include errors hidden in the system (so-called 'latent errors'), which, under unfavourable circumstances, can lead medical staff to commit visible errors (so-called 'active errors') that has little or nothing to do with medical errors in the traditional sense, resulting from a lack of knowledge, skills or due diligence [Pokorska, Pokorski, Nitecka, et al. 2015, 546].

Punishing the perpetrators of 'active errors' may satisfy the sense of social justice and public expectations, but it does not eliminate the 'latent errors' that result from improper organisation and management in the healthcare system. Therefore, punishing those responsible for disclosed errors does not solve the problem. It does not even touch on its core. Nor does it have anything to do with analysing the root causes, which is necessary to effectively solve the problem. Stigmatising those responsible does not help much. After all, once the case has been closed, the original causes of the situation (system-hidden defect so-called 'latent error') remain in the system, so that in the event of an unfavourable combination of circumstances, they may manifest themselves in the form of another adverse event, this time probably involving another person employed in the same position [ibid.]. Stigmatising those responsible may even contribute to worsening the situation. As already mentioned in this paper, the fear of stigmatisation and criminal liability is the main barrier to reporting adverse events and thus constitutes an obstacle to increasing their detectability and the possibility of drawing conclusions from a given situation for the future, which consequently hinders the prevention of medical errors.

Solutions aimed at preventing adverse events, based on the idea of reporting errors and learning from them, are identified as adequate measures

to combat medical errors. They are collectively referred to as Reporting and Learning Systems, whose main purpose is to identify, understand, correct and prevent errors from occurring in the future, rather than stigmatising those responsible for them. The fear of stigmatisation, particularly in terms of criminal liability, is one of the major obstacles to the reporting of adverse events. Minimising this fear by introducing mechanisms that encourage openness in disclosing such circumstances may contribute to increasing detection rates and thus the effectiveness of the system of reporting errors and learning from them, which is a strategic tool in the fight, on a larger scale than individual cases, against a social phenomenon that is detrimental to the most valuable legally protected goods, namely medical error [Wróbel 2010, 155-56].

The fear of stigmatisation, particularly in the context of criminal liability, constitutes a principal barrier to the reporting of adverse events. Reducing such fear, through the introduction of mechanisms that encourage openness in disclosing the circumstances of such cases, may contribute to an increase in detectability and, consequently, to the effectiveness of the system for reporting errors and learning from them. Such a system constitutes a strategic instrument in the fight, conducted on a scale broader than that of an individual case, against the socially detrimental phenomenon of medical error, viewed from the perspective of the protection of the most valuable legally protected interests.

Accordingly, it is argued that the system for monitoring adverse medical events should primarily be: 1) non-repressive, voluntary and confidential, in order to encourage the medical community to be open about disclosing such matters; 2) take into account cases referred to as near misses, close calls and sentinel events in order to be effective and efficient; 3) assuming regular and reliable root cause analysis to ensure reliability; 4) providing for the development of professional feedback in the form of conclusions and recommendations (standards of conduct) for the future, so that it is fully useful and practical; 5) ensuring a sufficiently large research scale so that the results concerning the identified phenomenon are measurable and the conclusions are relevant to reality.

After introducing the idea of a system for reporting adverse events in medicine, it is worth looking at how this idea has been adopted in Poland and transposed into Polish law.

2. CRIMINAL LAW ASPECTS OF INTRODUCING A REGISTER OF ADVERSE EVENTS

2.1. Considerations *de lege lata*

Without conducting a detailed analysis, as this would go beyond the scope of this article, it is worth noting that the impact of the concept

of adverse event reporting can be identified in can be identified in a number of laws.[3] However, although the implementation of the idea of reporting adverse events is not entirely new in the Polish legal system, there is still a lack of criminal law regulations linked to and synchronised with the institution of reporting adverse events. None of the aforementioned acts mentions the possibility of mitigating or waiving criminal liability as a reward for self-denunciation or other forms of reporting errors. This gap was to be filled by the proposed Act on Quality in Healthcare and Patient Safety, which provides for the development and implementation of legal and organisational solutions that will comprehensively and co-ordinately implement health policy priorities in the area of quality, including through the introduction of systematic monitoring of adverse events. However, according to the Act of 16 June 2023 on quality in healthcare and patient safety,[4] finally passed in June 2023, the proposals contained in its July 2021 draft[5] were largely rejected.

On the one hand, the adoption of the first act in the Polish legal system regulating the issue of quality in healthcare and patient safety should be viewed positively. Although, as can be concluded from an analysis of the legislative process, the legislator decided to implement the idea of reporting medical events gradually, the final adoption of the act after years of discussion on its form should be welcomed. It brings the Polish healthcare system closer to implementing tools that enable the improvement of clinical and management processes and increase patient satisfaction with the services received. It is worth noting that, pursuant to Article 3(2) in conjunction with Article 18, it introduces an internal quality and safety management system. An entity providing medical services under a contract for the provision of publicly funded healthcare services is required to have such a system in place. It consists of rules, procedures, methods and job descriptions to prevent adverse events. The operation of this system by an entity providing medical services consists in implementing, maintaining and improving

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[3] Article 14 and 21 of the Act of 5 December 2008 on preventing and combating infections and infectious diseases in humans, Journal of Laws of 2025, item 1675; Articles 36d-36n of the Pharmaceutical Law Act of 6 September 2001, Journal of Laws of 2025, item 750; Article 12a of the Act of 6 November 2008 on patient rights and the Patient Rights Ombudsman, Journal of Laws of 2025, item 750; Articles 52-54 of the Act of 1 July 2005 on the collection, storage and transplantation of cells, tissues and organs, Journal of Laws of 2023, item 1185; Articles 28 and 31a of the Act of 25 June 2015 on infertility treatment, Journal of Laws of 2020, item 442; The adverse event reporting institution is also known for its certification process, which for years was based on the Act of 6 November 2008 on accreditation in healthcare, Journal of Laws of 2009, No. 52, item 418, archived, repealed on 1 January 2024.

[4] Journal of Laws of 2023, item 1692.

[5] Draft Act on Quality in Healthcare and Patient Safety of 22 July 2021, published on the official website of the Government Legislation Centre: https://legislacja.rcl.gov.pl/projekt/12349305/katalog/12804503#12804503 [accessed: 25.03.2026].

the system on the basis of an assessment of its effectiveness and the results of patient opinion and experience surveys. An entity providing medical services within the internal system, among other things, implements solutions for identifying the risk of adverse events and managing that risk within the scope of the healthcare services provided, identifies priority areas, etc., implements solutions for identifying the risk of adverse events and managing this risk in the provision of healthcare services, identifies priority areas for improving the quality and safety of healthcare services, periodically monitors and evaluates the quality and safety of healthcare services, and monitors adverse events. On the other hand, however, it is worth expressing the hope that solutions that have not yet been adopted, in particular those defining the criminal law situation of a person who self-reports through the adverse event reporting system, will be reconsidered after gaining initial experience with the operation of the aforementioned Act in medical practice.

2.2. Considerations *de lege ferenda*

2.2.1. Comment on the rejected bill

In this section of the paper, it is worth taking a look at the solutions proposed so far and commenting on them briefly, while also proposing conclusions *de lege ferenda*.

Let us begin by outlining what the most important proposals looked like and what form they ultimately took, especially with regard to criminal law. In accordance with the aforementioned draft bill on quality in healthcare and patient safety of 22 July 2021 monitoring of adverse events is activities carried out by a healthcare entity providing hospital services, consisting of ensuring the reporting of adverse events, their systematic analysis and the implementation of conclusions from the analysis, with the aim of preventing the occurrence of the same and similar adverse events in the future (Article 2(3)). However, as can be seen from the rest of the draft, not only adverse events in the strict sense of the term, i.e., those that have occurred, but also near misses, referred to in the draft act as non-compliance with standard procedures (Article 18(2)(7)-(10)), were to be reported. The proposal should be assessed positively, but it was not reflected in the text of the adopted act. In addition to the internal quality and safety management system, the draft bill also provided for a central (external) level of monitoring, using an ICT system developed and made available by the National Health Fund (Article 19(2)(2), Article 23(1)). The proposal was ultimately limited to the internal level (medical entity), which restricts the global study of medical errors on a national scale. A separate issue is whether the National Health Fund was rightly identified as the monitoring entity. On the one hand, it has the

resources to carry out projects on such a scale, on the other hand, as has been rightly pointed out, this should rather be done by an independent entity, e.g., a scientific one, as the National Health Fund is an entity providing services financed from public funds, which inevitably reduces the openness of healthcare entities to talk about their own shortcomings and inefficiencies.

Moving on to the criminal aspects, it is worth noting that reports to the reporting system were to be made 'also anonymously'; and, in addition, 'adequate protection was provided to prevent the identification of personal data of patients, persons involved in the event and persons reporting non-compliance or adverse events by anonymising them' (Article 20(2) and Article 21(2)). Importantly, 'the reporting of an adverse event would not constitute grounds for initiating disciplinary proceedings, misdemeanour proceedings or criminal proceedings against the person who made the report, unless, as a result of an analysis of the root causes, the event turned out to be an intentional act' (Article 20(3)). Importantly, 'the reporting of an adverse event would not constitute grounds for initiating disciplinary proceedings, misdemeanour proceedings or criminal proceedings against the person who made the report, unless, as a result of an analysis of the root causes, the event turns out to be an intentional act' (Article 20(3)). These proposals should be viewed positively, but it is worth adding a few words by way of comment. Although the draft reflects the idea of avoiding condemnation and stigmatisation of persons who actively participate in reporting errors, the solution in its proposed form seems too cursory and incomplete. The wording of Article 20(3) suggests, at most, that discretion should be exercised in relation to law enforcement authorities towards a person who has self-reported. This wording does not correspond to any of the circumstances excluding criminal liability (unlawfulness, punishability, reprehensibility or guilt), which means that there are no normative grounds for mitigating or waiving criminal liability for a person who has made a mistake and wishes to report it. Meanwhile, according to the explanatory memorandum to the draft, the intention was to 'introduce regulations on the absence of sanctions against medical personnel in connection with the reporting of an adverse event'. Unfortunately, the provision in its current wording can only be understood to mean that facts disclosed through the system in question are not subject to reporting to the competent law enforcement authorities, but the fact of their disclosure in this way does not in itself preclude prosecution. According to the draft, their occurrence does not constitute a negative procedural premise as referred to in Article 17 of the Code of Criminal Procedure.[6] It does not protect against criminal liability, even if the law enforcement authorities obtain information about criminal facts in a separate manner, from another

[6] The Act of 6 June 1997 – Code of Criminal Procedure, Journal of Laws of 2025, item 46.

source. Furthermore, only the person who made the report themselves can benefit from the provision, and it should not be forgotten that another person with relevant knowledge may also report the incident, pre-empting the (potential) perpetrator's self-reporting.

In the context outlined above, it is also appropriate to refer to Article 240 of the Criminal Code, as, given the characteristics of the prohibited act articulated therein, it seems impossible to take into account the postulate of anonymity of the register of adverse events without the legislator intervening in the catalogue contained in the aforementioned provision. This provision includes, as subject to mandatory reporting under penalty of law, the offence specified in Article 156 of the Criminal Code, without specifying that it refers exclusively to intentional acts. Therefore, given that causing serious damage to health is inevitably linked to the issue of incorrectly provided health services, the system administrator, having reliable information about the commission of the aforementioned prohibited act, could not refrain from disclosing the circumstances of the case to the authorities responsible for prosecuting crimes without exposing (himself) to criminal liability for such an omission. It is worth noting a certain inconsistency, manifested in the fact that the obligation to report also covers information about causing serious bodily harm, even if unintentional, while at the same time the aforementioned list of prohibited acts does not include an act resulting in a more serious consequence, such as unintentional causing of death, as defined in Article 155 of the Criminal Code. Therefore, the assumptions for the efficient functioning of the monitoring system should take into account the criminal law situation not only of the potential perpetrator, but also of the person who, in this way, i.e., in the circumstances of performing duties related to the operation of the system, would learn about the incriminated behaviour.

2.2.2. Proposals for amendments to the Act

The above confirms what has already been indicated, namely that although the direction of the discussed solutions should be assessed positively, they require further consideration, which could form the basis for drafting an amendment to the Act as soon as we gain initial experience in the practical application of this regulation. However, in order not to stop at criticism and to try to contribute to the discussion, it is worth recalling the concepts of criminal law that could serve as inspiration in the situation in question.

Firstly, it is worth mentioning the institution of the crown witness, described in the Act of 25 June 1997 on crown witnesses,[7] as well as Article 60(3-5) of the Criminal Code, introducing the concept of the so-called

[7] Journal of Laws of 2016, item 1197.

minor crown witness. For example, according to Article 60(3) of the Criminal Code at the request of the public prosecutor, the court shall apply extraordinary mitigation of the penalty and may even conditionally suspend its execution in relation to a perpetrator who has cooperated with other persons in committing a crime, if he discloses to the authority appointed to prosecute crimes information concerning the persons participating in the commission of the crime and the relevant circumstances of its commission. How can this be assessed in this context, given that obtaining strategic information needed to fight crime and achieve a preventive effect has come to be accepted as a basis for mitigating the liability of so-called 'ordinary criminals', it can be concluded that it would be acceptable to use this type of construction in relation to unintentional acts, which are typically (model) cases of incorrectly provided health services, which are by their nature less serious than those committed intentionally. Of course, Article 60 would have to be modified accordingly to bring its content into line with the circumstances of criminal liability for medical personnel. The condition for exclusion or mitigation of liability would not have to be the denunciation of another person; it could be a reward for self-denunciation and disclosure in a specific manner of the relevant circumstances of the prohibited act committed by oneself.

Secondly, one may resort to the concept of so-called active repentance, referring to the provisions of Articles 15, 17 and 23 of the Criminal Code, as well as the provisions contained in the special part of the Criminal Code. For example, according to Article 229(1) of the Criminal Code, whoever grants or promises to grant a financial or personal benefit to a person performing a public function in connection with the performance of that function shall be subject to imprisonment for a term of between 6 months and 8 years. However, according to para. 6, the perpetrator of the offence shall not be subject to punishment if the financial or personal benefit or the promise thereof was accepted by a person performing a public function and the perpetrator notified the law enforcement authority of this fact and disclosed all relevant circumstances of the offence before the authority became aware of it. It is worth noting that the Fiscal Penal Code[8] is also a good source of normative models in this area. Voluntary disclosure regulated in Article 16 allows one to avoid punishment for a fiscal offence or misdemeanour by voluntarily notifying the law enforcement authority of the act (before the tax office initiates an inspection or proceedings) and paying the arrears.

Thirdly, a healthcare worker's admission of guilt through self-reporting within the adverse event reporting system could be considered as grounds for extraordinary mitigation of punishment, as referred to in Article 60(2) of the Criminal Code. The description of the case in the report may

[8] The Act of 10 September 1999 – Fiscal Penal Code, Journal of Laws of 2025, item 633.

be treated as an attempt to bring about reconciliation between the victim and the perpetrator by the perpetrator making efforts to remedy the harm or prevent it. Disclosure of the case may help prevent further adverse health consequences for the patient, enabling the patient to react quickly and undergo, for example, necessary reoperation or rehabilitation. Disclosure of the case may also help to expedite the evidentiary proceedings in a civil action brought by the patient for damages and compensation for the harm suffered.

CONCLUSIONS

There is no doubt that receiving healthcare services of an appropriate standard of quality and safety is a fundamental right of the patient. To achieve this, it is necessary to continuously improve clinical and management processes and to assess patient satisfaction. A key tool for this is the operation of an adverse event reporting system, designed to learn from past mistakes and, consequently, prevent them in the future. A prerequisite for ensuring the effectiveness of adverse event reporting, and thereby achieving a preventive effect against the negative consequences of inappropriate treatment, is a shift away from a culture of repression and stigmatisation towards a safety culture that encourages openness about mistakes. Such openness can be achieved by changing the social mindset of both patients and doctors, which may be facilitated by appropriate legislative measures allowing for the mitigation of liability for a perpetrator who has admitted to a mistake. A key issue in this context is the foundation of criminal law, which imposes an obligation to impose criminal sanctions for the violation of the most fundamental legal rights. Nevertheless, the Polish criminal law system recognises mechanisms for mitigating or even waiving criminal liability where specific considerations of criminal policy so warrant. Examples include active remorse, making efforts to bring about reconciliation between the victim and the perpetrator by apologising to the victim of a crime and providing compensation for the harm caused, as well as the institution of the state witness, who receives a reward for providing information of strategic importance from the point of view of crime prevention.

It is to be hoped that, having gained initial experience with the implementation of the recently enacted Act on Quality in Healthcare and Patient Safety, the legislator will reconsider proposals for appropriate amendments to criminal law that support the development of a system for reporting adverse events in medicine. Especially since, as this article has sought to demonstrate, such solutions would not be a novelty. Given that instruments for mitigating criminal liability can currently be applied to perpetrators of more serious offences, guided by the interests of justice, the reduction of crime and the aim of safeguarding society against it in the future,

it is entirely reasonable to consider such solutions in relation to healthcare professionals who, acting unintentionally, cause harm to a patient and who, wishing to make amends for the harm caused, come forward voluntarily.

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