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# **Challenging Vavřička: Questioning Compatibility of the Mandatory Tetanus Vaccination with ECHR**

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**ABSTRACT:** The compatibility of mandatory vaccinations with human rights has become a very current issue with the COVID-19 pandemic and the Vavřička ruling by the European Court of Human Rights. This ruling has faced criticism for not conducting examinations related to disease and vaccines based on direct scientific evidence. In this analysis, an assessment will be made based on direct scientific evidence about tetanus and its vaccine.

The prevailing reason for mandatory tetanus vaccination is to protect the health of the vaccinated individual. Competent adults have the right to refuse treatment. This rule also applies to preventive medical interventions, including tetanus vaccination. As a rule, parents are entitled to give consent for medical interventions on their children. If an immediate and serious threat permanently endangers the minor's life, medical intervention can be carried out against the parents' will. The limitation of parental autonomy is more disputed when the minor's life is not immediately threatened. With respect to tetanus vaccination as a preventive medical in-

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tervention, it does not eliminate an immediate and serious risk of harm. As a result, interference with the parent's discretion on tetanus vaccination as a preventive medical intervention should be evaluated for its compatibility with the current legal approach to medical interventions on minors and patient rights.

**Keywords:** best interest, mandatory vaccination, preventive medical intervention, right to reject a medical intervention, vaccine refusal, tetanus

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## I. Introduction

Mandatory vaccinations have long been a topic of debate in relation to the fundamental rights and freedoms enshrined in countries' constitutions and the European Convention on Human Rights (ECHR).<sup>1</sup> This debate has been reignited by the COVID-19 pandemic and the European Court of Human Rights (the Court) *Vavříčka and Others v. The Czech Republic* decision (App. No 47621/13 and five others). In this 2021 decision, the Court questioned the compatibility of the Czech Republic's mandatory vaccination legislation regarding nine childhood diseases comprising diphtheria, tetanus, whooping cough (pertussis), *Haemophilus influenzae* type b infections, poliomyelitis, hepatitis B, measles, mumps, rubella with the European Convention on Human Rights.

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<sup>1</sup> *Boffa v Others v San Marino* Application No 26536/95, Admissibility, 15 January 1998; *Solomakhin v Ukraine* Application No 24429/03, Admissibility, 15 March 2012; *Jacobson v Massachusetts* (1905) 197 US 11; *Zucht v King*, (1920) 225 SW 267; Flanigan, 'A Defense of Compulsory Vaccination', (2014) 26(1) HEC Forum 5; Chemerinsky and Goodwin, 'Compulsory Vaccination Laws Are Constitutional', (2016) 110(3) Northwestern University Law Review 589; Zoltan, 'Jacobson Revisited: Mandatory Polio Vaccination as an Unconstitutional Condition', (2005) 13(3) George Mason Law Review 735.

The Court noted that mandatory vaccination laws aimed at preventing potential outbreaks and protecting the best interest of children and individuals who cannot get vaccinated.<sup>2</sup> The Court considered the Czech Republic's requirement for children to be vaccinated against diphtheria, tetanus, whooping cough (pertussis), *Haemophilus influenzae* type b infections, poliomyelitis, hepatitis B, measles, mumps, rubella to attend nursery schools, and the imposition of fines up to nearly 400 EUR on parents who refused to vaccinate their children, to be a necessary and proportionate intervention in a democratic society. It was also pointed out in the decision that Czech authorities did not exceed their margin of appreciation.<sup>3</sup>

The Court did not conduct a disease and vaccine-specific examination, instead assessing all nine diseases and vaccines targeting them collectively, whereas for example, applicant Mr. Vavříčka refused consent for his children to receive only the poliomyelitis, hepatitis B, and tetanus vaccines. Mr. Vavříčka contended that the regulations in question violated his inherent rights and freedoms, specifically his right to reject medical interventions (as outlined in Articles 5 and 6 of the Convention on Human Rights and Biomedicine). He objected to what he characterized as reckless experimentation with human well-being, underscored the actual and potential adverse effects of vaccines, and asserted that there was no threat to public health in his case, pointing out that the last instance of poliomyelitis dated back to 1960, hepatitis B primarily affected high-risk groups, and tetanus was not communicable among humans.<sup>4</sup> Diphtheria, tetanus, whooping cough (pertussis), *Haemophilus influenzae* type b infections, poliomyelitis, hepatitis B, measles, mumps, rubella and their vaccines have different characteristics that could affect the assessment. Indeed, the dissenting opinion by Judge Wojtyczek also indicated that a separate assessment should be made for each disease.<sup>5</sup>

Tetanus differs from the other diseases considered in the decision as it is not transmitted from person to person and has no potential to cause outbreaks, requiring a separate evaluation. The Court justifies mandatory vaccination on

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<sup>2</sup> *Vavříčka and Others v The Czech Republic* Application No 47621/13, Admissibility, 8 April 2021.

<sup>3</sup> *ibid* 285, 290.

<sup>4</sup> *Vavříčka*, *supra* n 2 at 24.

<sup>5</sup> *ibid* 9-10, Judge Wojtyczek; Some other articles have also criticized the decision on the same grounds. See Ważyńska-Finck, 'Anti-Vaxxers Before The Strasbourg Court: Vavříčka And Others v The Czech Republic', *Strasbourg Observers*, 2 June 2021, available at: [strasbourgobservers.com/2021/06/02/anti-vaxxers-before-the-strasbourg-court-vavricka-and-others-v-the-czech-republic/](https://strasbourgobservers.com/2021/06/02/anti-vaxxers-before-the-strasbourg-court-vavricka-and-others-v-the-czech-republic/) [last accessed 26 October 2023]; Savulescu, Giubilini and Danchin, 'Global Ethical Considerations Regarding Mandatory Vaccination in Children', (2021) 231 *The Journal of Pediatrics*, available at: [www.jpeds.com/article/S0022-3476\(21\)00028-7/fulltext](https://www.jpeds.com/article/S0022-3476(21)00028-7/fulltext) [last accessed 26 October 2023].

the grounds of social solidarity and best interest of the child.<sup>6</sup> In the case of tetanus, social solidarity justification is mostly invalid.<sup>7</sup> Also in the literature, most arguments for compulsory vaccination are based on the need to protect society from infectious diseases.<sup>8</sup> Therefore, compatibility of mandatory tetanus vaccination with the ECHR deserves closer scrutiny.

One criticism of the *Vavříčka* decision is that there was no direct reference to scientific evidence for each disease and vaccine.<sup>9</sup> Referring to the prominent health authorities, the Court accepted that childhood vaccinations in general are one of the most important cost-effective public health measures.<sup>10</sup> The incidence and risks of each disease, content of the relevant vaccines, incidence of complications, and side effects for each rejected vaccine haven't been questioned or explained.

In this study, the authors question the validity of the European Court of Human Rights' decision regarding the mandatory tetanus vaccine by making an analysis based on scientific data. Part II provides scientific information on tetanus disease and its vaccination. Part III analyzes the right to refuse preventive medical intervention and its relationship to vaccination refusal in competent adults. The right of mature minors to refuse medical intervention and tetanus vaccination is discussed in Part IV. Part V evaluates the limits of parental rejection of medical interventions in minors. In the same part, the question is asked whether compulsory tetanus vaccination for minors is compatible with the European Convention on Human Rights.

The issue of the mandatory vaccines' compliance with the European Convention on Human Rights is comprehensive and intricate. It is possible to evaluate this matter from various perspectives. In this article, however, the authors focus on the question of whether an interference with the individual's right to reject tetanus vaccination and the parents' right not to consent to the tetanus vaccination are compatible with ECHR. From this analysis, it is possible to draw conclusions regarding vaccines for other non-communicable diseases. However, the incidence, risks, treatment options, and costs associated with

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<sup>6</sup> Ibid 288, 306; Nugraha, Regules and Vrancken, 'Vavříčka and Others v The Czech Republic', (2022) 116(3) *American Journal of International Law* 579; Nilsson, 'Is Compulsory Childhood Vaccination Compatible with the Right to Respect for Private Life? A Comment on Vavříčka and Others v the Czech Republic', (2021) 28 *European Journal of Health Law* 323, 330.

<sup>7</sup> Nilsson, *supra* n 6 at 334; Archard, Brierley and Cave, 'Compulsory Childhood Vaccination: Human Rights, Solidarity, and Best Interests', (2021) 29(4) *Medical Law Review* 716, available at: [academic.oup.com/medlaw/article/29/4/716/6324237](https://academic.oup.com/medlaw/article/29/4/716/6324237) [last accessed 26 October 2023].

<sup>8</sup> Giubilini, 'An Argument for Compulsory Vaccination: The Taxation Analogy', (2020) 37(3) *Journal of Applied Philosophy*, available at: [doi.org/10.1111/japp.12400](https://doi.org/10.1111/japp.12400) [last accessed 26 October 2023].

<sup>9</sup> *Vavříčka*, *supra* n 2 at 9, Judge Wojtyczek; Archard, Brierley and Cave, *supra* n 7 at 721.

<sup>10</sup> *Vavříčka*, *supra* n 2 at 277.

each non-communicable disease may lead to a different analysis. The authors believe that when assessing the constitutionality of vaccines, each disease and vaccine necessitate a separate analysis.

## II. Information on Tetanus

### A. Brief Facts on Tetanus

The bacteria *Clostridium tetani* produces a toxin that causes tetanus. The disease is marked by muscle spasms and dysfunctions of the autonomic nervous system.<sup>11</sup> Muscle spasms can last for minutes to weeks and begin in the face before spreading to the rest of the body. After infection, weakness begins with a feeling of numbness at the wound site.<sup>12</sup> Initial findings may be trismus and locking in the jaw. Then, because of the involvement of all facial muscles, the sarcastic smile “risus sardonius” appears. Other early signs are sweating and irritability (even small external stimuli can initiate contractions). The contractions are in the form of flexion of the arms and extension of the legs. As a result of constant muscle spasms in the back muscles, the “opustotonus” position occurs. Contractions are very painful. The most common cause of death is asphyxia (suffocation), which is caused by the involvement and contraction of the respiratory muscles. Despite this severe clinical picture, the patient is fully conscious.<sup>13</sup>

*Clostridium tetani* spores are ubiquitous in the environment, especially in soil, cinder, human or animal feces, skin surfaces and rusting objects such as nails, injectors, fence, etc. Due to their extreme capacitance to heat and most detergents, spores can endure for long years.<sup>14</sup> Most tetanus cases result from dirty puncture wounds or contaminated burns, but poor natal hygiene especially involving the umbilical cord can result in neonatal tetanus. Tetanus is not contagious. It does not cause epidemics; it causes deaths one by one.<sup>15</sup> If

<sup>11</sup> Yen and Thwaites, ‘Tetanus’, (2019) 393(10181) *Lancet* 1657, available at: [www.thelancet.com/journals/lancet/article/PIIS0140-6736\(18\)33131-3/fulltext#%20](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)33131-3/fulltext#%20) [last accessed 26 October 2023].

<sup>12</sup> Bae and Bourget, ‘Tetanus’, (2019) StatPearls Publishing, available at: [www.ncbi.nlm.nih.gov/books/NBK459217/](http://www.ncbi.nlm.nih.gov/books/NBK459217/) [last accessed 26 October 2023].

<sup>13</sup> World Health Organization, ‘Tetanus’, (2023), available at: [www.who.int/health-topics/tetanus#tab=tab\\_1](http://www.who.int/health-topics/tetanus#tab=tab_1) [last accessed 26 October 2023]; Rhinesmith and Fu, ‘Tetanus Disease, Treatment, Management’, (2018) 39(8) *Pediatrics in Review* 430, available at: [doi.org/10.1542/pir.2017-0238](https://doi.org/10.1542/pir.2017-0238) [last accessed 26 October 2023].

<sup>14</sup> Dhir, Dewan and Gupta, ‘Maternal and Neonatal Tetanus Elimination: Where are We Now?’, (2021) 12 *Research and Reports in Tropical Medicine* 247, available at: [doi.org/10.2147/RRTM.S201989](https://doi.org/10.2147/RRTM.S201989) [last accessed 26 October 2023].

<sup>15</sup> Centers for Disease Control and Prevention, ‘Tetanus- Causes and How It Spreads’, (2022), available at: [www.cdc.gov/tetanus/about/causes-transmission.html](http://www.cdc.gov/tetanus/about/causes-transmission.html) [last accessed 26 October 2023]; Koc, ‘Neonatal Tetanoz’, (2000) *STED*, available at: [www.ttb.org.tr/sted/sted0400/04004.html#:~:text=NT%den%20her%20y%C4%B1l%20yakla%C5%9F%C4%B1k,50%20ile%2090%20aras%C4%B1nda%20de%C4%9Fi%C5%9Fmektedir](http://www.ttb.org.tr/sted/sted0400/04004.html#:~:text=NT%den%20her%20y%C4%B1l%20yakla%C5%9F%C4%B1k,50%20ile%2090%20aras%C4%B1nda%20de%C4%9Fi%C5%9Fmektedir) [last accessed 26 October 2023].

tetanus vaccine is not administered, tetanus disease, which occurs because of especially dirty injuries, can result in death. In disseminated tetanus disease, 10-30% of patients may die despite the intensive care treatments applied.<sup>17</sup>

### **B. Risk Groups and Risk Factors**

The disease can affect anyone, but newborn infants and pregnant individuals who have not been adequately vaccinated with tetanus-toxoid-containing immunization are particularly susceptible.<sup>16</sup>

Adolescents and adult males undergoing circumcision are at increased risk of tetanus in many countries due to declining immunity and limited access to supplemental doses.<sup>17</sup> Injecting drug addicts are also classified in high-risk group.<sup>18</sup>

Conflicts and natural disasters can raise the prevalence of tetanus even in countries with an effective public health system by uprooting populations, disrupting vaccination campaigns, and increasing injuries that are prone to the disease. For example, 106 cases of tetanus, among adults, were reported in the month following the 2004 tsunami in Indonesia.<sup>19</sup>

In 2016, more than 40 million people were forced to flee their homes due to armed conflicts, which created new difficulties for many international immunization campaigns, including the tetanus vaccination.<sup>20</sup>

### **C. Incidence**

Before vaccination programs, the incidence of deaths caused by tetanus in USA was between 2.5/100,000 and 0.5/100,000.<sup>21</sup> Annually 500-600 cases were reported nationwide in USA before the start of the vaccination program in 1940.<sup>22</sup> It is reported that 140 people died of tetanus in 1951, one year before the

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<sup>16</sup> Due to the limitations on surveillance system in low-income and middle-income countries, it is challenging to determine the full burden of tetanus, Yen, *supra* n 11; In 2015, approximately 34,000 newborns perished of neonatal tetanus, a 96% decrease from 1988, when an estimated 787,000 newborns died of tetanus during their first month of life, Dhir, *supra* n 16 at 247; World Health Organization, *supra* n 15.

<sup>17</sup> World Health Organization, *supra* n 15.

<sup>18</sup> Cherubin, 'Epidemiology of Tetanus in Narcotic Addicts', (1970) 70 NY State Journal of Medicine 267.

<sup>19</sup> Jeremijenko, McLaws and Kosasih, 'A Tsunami Related Tetanus Epidemic in Aceh, Indonesia', (2007) 19(1) Asia Pacific Journal of Public Health 40.

<sup>20</sup> UNHCR, 'Global trends: forced displacement in 2016', (2017), available at: [www.unhcr.org/5943e8a34.pdf](http://www.unhcr.org/5943e8a34.pdf) [last accessed 26 October 2023].

<sup>21</sup> Blain and Tiwari, 'Chapter 16: Tetanus', (CDC, 2020), available at: [www.cdc.gov/vaccines/pubs/surv-manual/chpt16-tetanus.html](http://www.cdc.gov/vaccines/pubs/surv-manual/chpt16-tetanus.html) and, available at: [www.cdc.gov/vaccines/pubs/surv-manual/images/chapt16-figure01.gif](http://www.cdc.gov/vaccines/pubs/surv-manual/images/chapt16-figure01.gif) [last accessed 26 October 2023].

<sup>22</sup> World Health Organization, 'Global Health Observatory Data Repository' (2023), available at: [apps.who.int/gho/data/view.main.1540\\_46?lang=en](https://apps.who.int/gho/data/view.main.1540_46?lang=en) [last accessed 26 October 2023].



start of vaccination in the Czech Republic.<sup>23</sup> In relation to the population of the Czech Republic at that time, this corresponds to an incidence of 1.5/100,000.<sup>24</sup> This data suggests that deaths related to tetanus were infrequent even prior to the introduction of vaccination programs.<sup>25</sup>

The incidence of this disease was reduced because of vaccination. WHO reported that, in 2018, 25000 newborns died from neonatal tetanus, an 88% decrease from the condition in 2000.<sup>26</sup> Since 1947, the number of reported tetanus cases has decreased by over 95%, and the number of tetanus-related deaths has decreased by over 99% in the US. These decreases were partially brought about by the introduction of tetanus immunization in the 1940s as well as use of antitoxin in the treatment of high-risk wounds. Adults who have not had all the advised tetanus immunizations sometime get tetanus today. This includes individuals who have never had a tetanus shot and adults who have not had their 10-year booster shot.<sup>27</sup>

In a study conducted in 2020 on global diseases, it was estimated that more than 73,000 cases of tetanus occurred in 2019. Out of the 34,700 fatalities from tetanus that year, the majority were concentrated in South Asia and Sub-Saharan Africa.<sup>28</sup> Occasional cases of tetanus are reported in high-income countries, most frequently among older persons (60 years) and drug injectors.<sup>29</sup> The estimated global death toll from tetanus has significantly decreased over the last three decades. It is estimated that tetanus killed hundreds of

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<sup>23</sup> EUC, 'Tetanus – People Forget about Prevention of the Disease', (2020), available at: [euc.cz/clanky-a-novinky/clanky/tetanus-people-forget-about-prevention-of-the-disease/](http://euc.cz/clanky-a-novinky/clanky/tetanus-people-forget-about-prevention-of-the-disease/) [last accessed 26 October 2023].

<sup>24</sup> Population Pyramid, 'Population Pyramids of the World from 1950 to 2100', (2022), available at: [www.populationpyramid.net/czech-republic/1951/](http://www.populationpyramid.net/czech-republic/1951/) [last accessed 26 October 2023].

<sup>25</sup> Leading causes of death in Czech Republic, in year 2000, were ischaemic heart disease (328/100.000), stroke (166/100.000), trachea, bronchus and lung cancer (56/100.000), colon and rectum cancers (44/100.000), chronic obstructive pulmonary disease (27/100.000), lower respiratory infections (26/100.000), breast cancer (20/100.000), falls (19/100.000), cirrhosis of the liver (17/100.000), self-harm (16/100.000), available at: <https://www.who.int/data/gho/data/themes/mortality-and-global-health-estimates/ghe-leading-causes-of-death> [last accessed 10 May 2024].

<sup>26</sup> Shimizu, 'Tetanus', (2017), available at: [www.who.int/health-topics/tetanus#tab=tab\\_1](http://www.who.int/health-topics/tetanus#tab=tab_1) [last accessed 26 October 2023].

<sup>27</sup> Centers for Disease Control and Prevention, 'Tetanus- Surveillance', (2023), available at: [www.cdc.gov/tetanus/surveillance.html](http://www.cdc.gov/tetanus/surveillance.html) [last accessed 26 October 2023].

<sup>28</sup> CDC Global Tetanus Vaccination, <https://www.cdc.gov/global-tetanus-vaccination/why/index.html#:~:text=A%202020%20study%20of%20global,are%20increasing%20among%20adult%20men> [last accessed 21 May 2024].

<sup>29</sup> Beeching and Crowcroft, 'Tetanus in Injecting Drug Users', (2005) 330(7485) *BMJ* 208; Filia et al., 'Tetanus in Italy 2001–2010: A Continuing Threat in Older Adults', (2014) 32 *Vaccine* 639.

thousands of people annually in the 1990s. By the 2010s, however, that number has dropped to about 50,000 deaths per year.<sup>30</sup>

#### **D. Treatment**

Tetanus management can be done by preventing toxin absorption, controlling muscle spasms, and providing intensive care. Wounds must be thoroughly cleaned and debrided. The only available treatments for tetanus specifically are antibiotics and antitoxin.<sup>31</sup>

Tetanus is treated according to the severity of the disease. The treatment objectives for all patients should include, prompt wound excision, supportive treatment, antibiotic treatment, early administration of human tetanus immunoglobulin (HTIG) intramuscularly or intravenously, neuromuscular blockade, regulating various manifestations and dealing with complications.<sup>32</sup> In accordance with the tetanus, the patient must be vaccinated for immunization.<sup>30</sup>

Sedation and mechanical ventilation are frequently used during intensive care unit (ICU) hospitalizations for patients with severe tetanus, which increases the risk of mortality and long-term sequelae.<sup>33</sup> Complications that may develop due to tetanus are uncontrolled and involuntary spasm in the vocal cords (vocal cords), bone fractures, hospital infections, pulmonary embolism, aspiration pneumonia due to foreign materials in the respiratory tract, and respiratory distress that is likely to result in death.<sup>34</sup>

#### **E. Immunization as a Preventive Measure**

The infected individual does not become immune. The only way to be immunized is to get vaccinated.<sup>35</sup> A dose of tetanus toxoid (TT) vaccine provides minimal if any, long-term immunity. In approximately 90% of individuals, a second dose confers protection within 2-4 weeks, but immunity is transient in many cases. The protective levels of immunity are induced generally by a primary series of three doses and immunity typically persists for at least five years. After the third primary dose, each additional booster dose given after at least a one-year interval increases tetanus antitoxin levels and further pro-

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<sup>30</sup> Global Burden of Disease Collaborative Network. Global Burden of Disease Study 2019 (GBD 2019) Results. Seattle, United States: Institute for Health Metrics and Evaluation (IHME), 2021.

<sup>31</sup> Yen, *supra* n 13; In cases that are not hospitalized, the mortality is 100%. On which see TC Sağlık Bakanlığı Asi Portali, 'Tetanos Hastalığı', available at: [asi.saglik.gov.tr/liste/48-tetanoz-hastal%C4%B1%C4%9F%C4%B1.html](http://asi.saglik.gov.tr/liste/48-tetanoz-hastal%C4%B1%C4%9F%C4%B1.html) [last accessed 26 October 2023].

<sup>32</sup> Bae, *supra* n 12.

<sup>33</sup> *ibid.*

<sup>34</sup> *ibid.*

<sup>35</sup> Rhinesmith, *supra* n 13.



longs the duration of immunity. Immunity may persist for approximately ten years after the fourth dose and for at least twenty years after the fifth dose.<sup>36</sup>

According to the WHO, children should receive the initial series of tetanus vaccinations. Due to the need for protection against multiple diseases, multi-antigen immunization formulations are usually used.<sup>37</sup> Before turning 7 years old, children must complete the 5-dose DTaP (diphtheria, tetanus, acellular pertussis) immunization series.<sup>38</sup> After the 4- to 7-year-old booster-obtained immunity, Tdap (tetanus, diphtheria, and pertussis) boosters are recommended every ten years (same as DTaP, but with decreased dosages of antigens). A Tdap booster administered ten years after the initial series of vaccines is generally well-tolerated and highly effective.<sup>39</sup> As contrast WHO does not find the adult booster doses for tetanus necessary for individuals who have completed their childhood vaccination series.<sup>40</sup>

## F. Vaccine Content

Many people refrain from getting vaccinated or having their children vaccinated due to doubts and concerns about the content of the vaccine. Therefore, information about the content of the tetanus vaccine will be provided in this section. The content of the vaccine may change depending on the manufacturer and combination with other vaccines. The most commonly used tetanus (T) vaccines for children, which is a pentavalent vaccine contain antigens against four other diseases, usually diphtheria (D or d depending on dose), pertussis (P or aP or ap), polio (IPV), and hepatitis B (HepB) or *Haemophilus influenzae* type B (Hib).<sup>41</sup> There are now seven different types of pediatric DTaP vaccinations licensed and in use around the world.<sup>42</sup> Tetanus vaccine can be administered

<sup>36</sup> World Health Organization, Immunological Basis for Immunization Series Module 3: Tetanus Update 2018, (2018), available at: [apps.who.int/iris/bitstream/handle/10665/275340/9789241513616-eng.pdf?sequence=1&isAllowed=y](https://apps.who.int/iris/bitstream/handle/10665/275340/9789241513616-eng.pdf?sequence=1&isAllowed=y) [last accessed 26 October 2023].

<sup>37</sup> Acres, 'Statement on Tetanus Toxoid', (1987) 137(8) Canadian Medical Association Journal 734.

<sup>38</sup> Liang et al., 'Prevention of Pertussis, Tetanus, and Diphtheria with Vaccines in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP)', (2018) 67(2) MMWR Recommendations and Reports Journal 1.

<sup>39</sup> Halperin, 'Randomized Controlled Trial of the Safety and Immunogenicity of Revaccination With Tetanus-Diphtheria-Acellular Pertussis Vaccine (Tdap) in Adults 10 Years After a Previous Dose', (2019) 8(2) Journal of the Pediatric Infectious Diseases Society 105; Rabadi and Brady, *Tetanus Toxoid* (2022), available at: [www.ncbi.nlm.nih.gov/books/NBK557415/](https://www.ncbi.nlm.nih.gov/books/NBK557415/) [last accessed 26 October 2023].

<sup>40</sup> Slifka et al., 'Incidence of Tetanus and Diphtheria in Relation to Adult Vaccination Schedules', (2021) 72(2) Clinical Infectious Diseases 285, available at: [www.ncbi.nlm.nih.gov/pmc/articles/PMC7840100/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7840100/) [last accessed 26 October 2023].

<sup>41</sup> <sup>38</sup> WHO, *supra* n 44.

<sup>42</sup> In 2013, UNICEF, which provides immunizations to a significant part of the world's children, purchased 100% of the DTP-containing vaccines as pentavalent vaccines. See UNICEF,

as monovalent vaccine or as part of a combination vaccine. For families who refuse the tetanus vaccine, it is also possible for diphtheria and pertussis vaccines to be administered separately. In fact, in the Vavříčka case, despite Mr. Vavříčka refusing the tetanus vaccine, his children have received diphtheria and pertussis vaccines.<sup>43</sup>

In the context of Islam and Judaism, consuming products derived from pigs, such as gelatin, can be a source of concern because these religions prohibit the consumption of pork products. A material called gelatin is made from the collagen of animals like chickens, cattle, pigs, and fish. Tendons, ligaments, bones, and cartilage all contain collagen. Porcine collagen is the source of porcine gelatin. All types of gelatin used in pharmaceutical products are produced in accordance with stringent safety and hygiene standards. Numerous capsules and several vaccinations, among many other medications, contain gelatin. To keep the vaccine stable and safe while being stored, porcine gelatine is utilized in some vaccines. Tetanus vaccines don't contain porcine gelatin.<sup>44</sup>

Aluminum is another material targeted by vaccine opponents due to unsubstantiated claims that it causes certain illnesses. There is no preservative and only a small amount of aluminum in each dose of the DTaP vaccine. DTaP-HepB-IPV (Pediatrix), DTaP-IPV/Hib (Pentacel), DTaP-IPV-Hib-HepB (Vaxelis), DTaP-IPV (Kinrix), and DTaP-IPV (Quadracel) all contain neomycin and polymyxin B as antibiotics, also DTaP-IPV-Hib-HepB (Vaxelis) contains

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'*Diphtheria Tetanus and Pertussis DTP Vaccine*' (2016), available at: [www.unicef.org/supply/documents/diphtheria-tetanus-and-pertussis-vaccine-dtp-price-data](http://www.unicef.org/supply/documents/diphtheria-tetanus-and-pertussis-vaccine-dtp-price-data) [last accessed 21 August 2023]; DTaP (Infanrix, Daptacel) or Tdap (Boostrix and Adacel) vaccines. Tdap (Boostrix) is approved for persons age 10 years or older; Tdap (Adacel) is approved for persons age 10 through 64 years. DTaP vaccine is used in five combination vaccinations. For the first three doses of the DTaP series in children aged 6 weeks to 6 years, DTaP-HepB-IPV (Pediatrix) has a license. For the first four doses of the component vaccinations in children between the ages of 6 weeks and 4 years, DTaP-IPV/Hib (Pentacel) is licensed. Only the fifth DTaP dose and the fourth IPV dose are permitted for use with DTaP-IPV (Kinrix) in children between the ages of 4 and 6 years. Only the fifth dose of DTaP and the fourth or fifth dose of IPV in children between the ages of 4 and 6 are authorized for use with DTaP-IPV (Quadracel). It is legal to administer DTaP-IPV-Hib-HepB (Vaxelis) to kids from 6 weeks old to 4 years old. See Centers for Disease Control and Prevention, '*DTaP (Diphtheria, Tetanus, Pertussis) VIS*', (2021), available at: [www.cdc.gov/vaccines/hcp/vis/vis-statements/dtap.html](http://www.cdc.gov/vaccines/hcp/vis/vis-statements/dtap.html) [last accessed 26 October 2023]; In Turkey, a pentavalent vaccine pentaxim (DTaP-IPV-Hib) (Sanofi Pasteur SA) has been used since 2020. See Elektronik Kamu Alımları Platformu (EKAP), 'Karma Aşı', (2023) Tender Number 2020/32427, available at: [ekap.kik.gov.tr/EKAP/Ortak/IhaleArama/index.html](http://ekap.kik.gov.tr/EKAP/Ortak/IhaleArama/index.html) [last accessed 26 October 2023].

<sup>43</sup> Vavříčka, supra n 2 at 24.

<sup>44</sup> UK Health Security Agency and NHS, '*Vaccines and Porcine Gelatine*' (2015), available at: [assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/1107767/UKHSA-12462-vaccines-porcine-gelatine-English.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1107767/UKHSA-12462-vaccines-porcine-gelatine-English.pdf) [last accessed 26 October 2023].

Streptomycin as an antibiotic. Yeast protein is a component of the DTaP-HepB-IPV (Pediarix) and DTaP-IPV-Hib-HepB (Vaxelis) vaccines. Some vaccines, including the diphtheria toxoid vaccine, are packaged with latex rubber.<sup>45</sup>

### G. Vaccine Side Effects

It is not easy to find official statistics on side effects, although countries should have statistics on serious vaccine side effects. Statistical data for serious side effects were not specified by WHO and CDC.<sup>46</sup> In the Vavříčka case, the Czech Republic reported that serious side effects with lifelong health consequences are very rare, no more than six such incidents per year for 100,000 vaccinated infants.<sup>47</sup> This data applied to side effects from childhood vaccines against nine diseases including pertussis, polio, tetanus, diphtheria, hepatitis B, *Haemophilus influenzae* type b (Hib), measles, rubella and mumps.

Injection site responses from the DTaP vaccine could include discomfort, redness, or swelling. Local reactions were found in 20-40% of infants after each of the first 3 doses. After the fourth and/or fifth dosages, local reactions tend to occur more frequently. Moreover, mild systemic responses including fatigue, anxiety, and fever are possible. A temperature of 101°F or greater was reported in 3-5% of DTaP recipients. These responses are self-contained and can be controlled with acetaminophen or ibuprofen for symptom relief.<sup>48</sup>

Although they have been reported after the administration of DTaP, moderate to severe systemic reactions (such as high fever, febrile seizures, persistent crying, and hypotonic-hyporesponsive episodes) are less common than among kids who received whole-cell DTP. In general, fewer than 1 in 10,000 doses result in moderate or severe systemic responses, though rates change depending on the symptom and the vaccine.<sup>49</sup>

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<sup>45</sup> The same components for poliovirus, diphtheria, tetanus, and pertussis indicated in Infanrix® above, as well as 10 ng of hepatitis B virus surface antigen, are present in each 0.5-mL dosage of Pediarix® (GlaxoSmithKline) (HBsAg). Aluminum salts as adjuvant (not more than 0.85 mg aluminum by assay) and 4.5 mg of sodium chloride are both present in each 0.5-mL dosage. Moreover, each dose contains ≤100 µg of polysorbate 80 and ≤100 µg of residual formaldehyde (Tween 80). Neomycin sulfate and polymyxin B are used in the poliovirus vaccine's production. The final vaccine may contain those components at ≤0.05 ng of neomycin and ≤0.01 ng of polymyxin B per dose. The HBsAg antigen is produced using processes that yield a product with ≤5% yeast protein. To see the ingredients of other vaccines, it is possible to visit the following webpage: [www.cdc.gov/vaccines/vpd/dtap-tdap-tid/hcp/about-vaccine.html](http://www.cdc.gov/vaccines/vpd/dtap-tdap-tid/hcp/about-vaccine.html) [last accessed 26 October 2023].

<sup>46</sup> Centers for Disease Control and Prevention, 'Tdap (Tetanus, Diphtheria, Pertussis) VIS', (2021), available at: [www.cdc.gov/vaccines/hcp/vis/vis-statements/tdap.html](http://www.cdc.gov/vaccines/hcp/vis/vis-statements/tdap.html) [last accessed 26 October 2023]; WHO Tetanus, available at [https://www.who.int/health-topics/tetanus#tab=tab\\_3](https://www.who.int/health-topics/tetanus#tab=tab_3) [last accessed 26 October 2023].

<sup>47</sup> Vavříčka, supra n 2 at 207.

<sup>48</sup> Centers for Disease Control and Prevention, supra n 44.

<sup>49</sup> *ibid.*

In 2017 WHO reported that severe generalized side effects as brachial neuritis and other severe widespread adverse effects are relatively uncommon. It has been documented that peripheral neuropathy, in particular brachial plexus neuritis, can develop hours to weeks following vaccination. According to passive surveillance conducted in the USA, 0.69 incidences of brachial neuritis occurring 0–60 days after vaccination were reported for every 10 million doses. Rare reports of Guillain-Barré syndrome (GBS) after immunization (with tetanus toxoid) have been made, although findings from population-level studies do not corroborate this. Tetanus toxoid-containing vaccines (TTCV) are rarely associated with anaphylaxis. According to recent passive monitoring data, there are 1.6 anaphylactic episodes for every million Td doses delivered.<sup>50</sup> Seldom recorded, but possible are exaggerated local (Arthus-type) reactions after receiving a diphtheria or tetanus toxoid vaccine.<sup>51</sup>

### III. Clash of Right to Refuse Treatment and Tetanus Vaccination Mandate for Competent Adults

According to Article 5 of the Convention on Human Rights and Biomedicine to which many countries are a party “*an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it*”.<sup>52</sup> In many cases, the Court has ruled that imposing medical treatment, even where refusal to receive certain treatment could result in death, without the consent of a mentally competent adult patient would interfere with his or her right to physical integrity.<sup>53</sup> Accordingly, in many jurisdictions, a competent adult has the right to refuse treatment, even if this intervention constitutes an absolutely necessary intervention for the individual’s survival.<sup>54</sup> The right to refuse medical intervention is internationally accepted as a fundamental principle of liberty.<sup>55</sup> Within this framework, a competent adult may

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<sup>50</sup> World Health Organization, ‘Tetanus Vaccines: WHO Position Paper – February 2017’ 92(6) (2017) at 53, available at: [apps.who.int/iris/bitstream/handle/10665/254583/WER9206-53-76.pdf?sequence=1&isAllowed=y](https://apps.who.int/iris/bitstream/handle/10665/254583/WER9206-53-76.pdf?sequence=1&isAllowed=y) [last accessed 26 October 2023].

<sup>51</sup> Centers for Disease Control and Prevention, *supra* n 44.

<sup>52</sup> Convention on Human Rights and Biomedicine 1999, CETS 164, available at: [www.coe.int/en/web/conventions/full-list?module=signatures-by-treaty&treaty=164](https://www.coe.int/en/web/conventions/full-list?module=signatures-by-treaty&treaty=164) [last accessed 26 October 2023].

<sup>53</sup> See *Pretty v UK* Application No 2346/02, Admissibility, 29 April 2002 at paras 63–65; *Glass v UK* Application No 61827/00, Admissibility, 9 March 2004 at paras 82–83; *Jehovah’s Witnesses of Moscow v Russia* Application No 302/02, Admissibility, 10 June 2010 at para 135; *Haas v Switzerland* Application No 31322/07, Admissibility, 20 January 2011.

<sup>54</sup> *Malette v Shulman* 72 OR 417 (CA 1990); Douglas, Forsberg and Pugh, ‘Compulsory Medical Intervention Versus External Constraint in Pandemic Control’, (2021) 47(12) *Journal of Medical Ethics*; *Montgomery v Lanarkshire Health Board* [2004] UKSC 11 [87].

<sup>55</sup> Stern, ‘Parents Patriae and Parental Rights: When Should the State Override Parental Medical Decisions’, (2019) 33(1) *Journal of Law and Health* 82; *Cruzan v Director* 497 US 261 (1990).

make “medically unreasonable” decisions regarding their own health.<sup>56</sup> The purpose of the medical intervention, whether it is preventive, diagnostic, therapeutic, or low risk will not change this rule. Preventive medical interventions such as routine blood tests, check-ups, smear tests, and mammograms can prevent significant health problems from occurring or enable early diagnosis with a significantly higher chance of successful treatment. However, if only the well-being of a mature and competent individual is at stake, as a rule, it is not possible to compel this person to undergo these preventive medical interventions.

On the other hand, patients’ right to refuse treatment can also be restricted.<sup>57</sup> However, for the imposition of a mandatory medical intervention, there must be a particularly strong justification.<sup>58</sup> In the *Jehovah’s Witnesses of Moscow and Others v. Russia* case, the Court stated:

*that free choice and self-determination were themselves fundamental constituents of life and that, absent any indication of the need to protect third parties – for example, mandatory vaccination during an epidemic, the State must abstain from interfering with the individual freedom of choice in the sphere of health care, for such interference can only lessen and not enhance the value of life.*<sup>59</sup>

In this context, a competent adult should also be able to refuse to receive a tetanus vaccine.<sup>60</sup> The tetanus vaccine has a protective effect against tetanus as explained above. Even though adult booster doses are mandatory in few countries like Czech Republic,<sup>61</sup> it is important to reemphasize that after com-

<sup>56</sup> Malette, *supra* n 52.

<sup>57</sup> Rillo, ‘Constitutional Law: The Limits of a Patient’s Right to Refuse Medical Treatment’, (1994) 46 Florida Law Review 347; Wicks, ‘The Right to Refuse Medical Treatment under the European Convention on Human Rights’, (2001) 9 Medical Law Review 19.

<sup>58</sup> *Vavříčka*, *supra* n 2 at 8; *YF v Turkey* Application No 24209/94, Admissibility, 22 July 2003 at paras 33–37; *Solomakhin v Ukraine*, *supra* n 1 at 33–36; Richins, ‘Jacobson Revisited: An Argument for Strict Judicial Scrutiny of Compulsory Vaccination’, (2011) 32(4) Journal of Legal Medicine 409.438.

<sup>59</sup> *Jehovah’s Witnesses of Moscow*, *supra* n 51 at 136.

<sup>60</sup> Richins, *supra* n 56 at 436.

<sup>61</sup> In Czech Republic, tetanus “booster” doses are listed among the regular vaccination programs in the relevant ministerial Decree, while these regular vaccines are compulsory under the Act on the Protection of Public Health. See *Vavříčka*, *supra* n 2 at 205–77; Rozalio, *supra* n 10; ECDC, ‘Czech Republic: Recommended Vaccinations’, (2023), available at: [vaccine-schedule.ecdc.europa.eu/Scheduler/ByCountry?SelectedCountryId=201&IncludeChildAgeGroup=true&IncludeChildAgeGroup=false&IncludeAdultAgeGroup=true&IncludeAdultAgeGroup=false](https://vaccine-schedule.ecdc.europa.eu/Scheduler/ByCountry?SelectedCountryId=201&IncludeChildAgeGroup=true&IncludeChildAgeGroup=false&IncludeAdultAgeGroup=true&IncludeAdultAgeGroup=false) [last accessed 26 October 2023]; It is also important to point that there are few mandatory vaccines for adults even though some sicknesses on vaccination schemes require booster doses for a continuous immunity. This is also the case for tetanus. See McNeill, ‘Mandatory Vaccination for Healthcare Professionals: Preparation for Future Pandemics’, (2022) Master’s Thesis, Durham University 106, available at: [etheses.dur.ac.uk/14742/](https://theses.dur.ac.uk/14742/) [last accessed 26 October 2023].

pletion of a childhood vaccination series, WHO does not recommend adult booster doses for tetanus any more, necessity of the booster dose is disputed<sup>62</sup> In addition, as explained in part II, tetanus vaccine can be applied when this bacterium is encountered. An adult person may refuse application of tetanus vaccination in both cases.

Since tetanus is not transmitted from human to human, there is no risk of epidemic. Protection of the other members of the society cannot be a valid justification for imposition of a tetanus vaccine mandate. Maybe the cost of treatment can be considered a burden for the public. As pointed above, treatment of tetanus will likely require treatment in intensive care units, which is very expensive in many countries.<sup>63</sup> However, if the incidence of the disease

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<sup>62</sup> World Health Organization, 'Immunization, Vaccines and Biologicals', (2017), available at: [www.who.int/teams/immunization-vaccines-and-biologicals/diseases/tetanus](http://www.who.int/teams/immunization-vaccines-and-biologicals/diseases/tetanus) [last accessed 26 October 2023]; In one scientific research analysis of 11 billion person-years of incidence data exhibited decrease associated with performing adult booster vaccinations against tetanus or diphtheria. See Slifka, *supra* n 39.

<sup>63</sup> Intensive care is one of the most expensive categories of hospital-based care worldwide due to the high number of specialized personnel and sophisticated medical equipment required. In the United States (US), intensive care unit (ICU) costs are estimated to account for 13 to 39% of total hospital costs. See Halpern and Pastores, 'Critical care medicine beds, use, occupancy and Costs in the United States: a methodological review', (2015) 43(11) *Critical Care Medicine*, available at: [journals.lww.com/ccmjournal/abstract/2015/11000/critical\\_care\\_medicine\\_beds\\_use\\_occupancy\\_and.23.aspx](http://journals.lww.com/ccmjournal/abstract/2015/11000/critical_care_medicine_beds_use_occupancy_and.23.aspx) [last accessed 26 October 2023]; Coopersmith et al., 'A Comparison of critical care research funding and the Financial Burden of Critical Illness in the United States', (2012) 40(4) *Critical Care Medicine* 1072, available at: [journals.lww.com/ccmjournal/abstract/2012/04000/a\\_comparison\\_of\\_critical\\_care\\_research\\_funding\\_and.4.aspx](http://journals.lww.com/ccmjournal/abstract/2012/04000/a_comparison_of_critical_care_research_funding_and.4.aspx) [last accessed 26 October 2023]; The documented daily ICU costs in high-income countries range from \$1,464 to \$4,518 (adjusted to 2019 prices). See Tan et al., 'Direct cost analysis of intensive care unit stay in four European countries: Applying a Standardized Costing Methodology', (2012) 15(1) *Value Health* 81, available at: [www.valueinhealthjournal.com/article/S1098-3015\(11\)03509-1/fulltext?\\_returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS1098301511035091%3Fshowall%3Dtrue](http://www.valueinhealthjournal.com/article/S1098-3015(11)03509-1/fulltext?_returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS1098301511035091%3Fshowall%3Dtrue) [last accessed 26 October 2023]; Although critical care is less expensive in LMICs (due in part to reduced labor costs), cost information is limited. See Turner et al., 'Achieving affordable critical care in Low-Income and Middle-Income Countries', (2019) 4 *BMJ Global Health*, available at: [gh.bmj.com/content/4/3/e001675](http://gh.bmj.com/content/4/3/e001675) [last accessed 26 October 2023]; The daily ICU costs reported in Thailand, Malaysia, China, and India range from \$292 to \$1,421 (2019 prices adjusted). See Aung et al., 'Determining the Cost and Length of Stay at Intensive Care Units and the Factors Influencing Them in a Teaching Hospital in Malaysia', (2020) 21 *Value in Health Regional Issues* 149, available at: [www.valuehealthregionalissues.com/article/S2212-1099\(19\)30615-6/fulltext](http://www.valuehealthregionalissues.com/article/S2212-1099(19)30615-6/fulltext) [last accessed 26 October 2023]; Peter et al., 'Cost of Intensive Care in India', (2016) 32 *International Journal of Technology Assessment in Health Care* 241, available at: [www.cambridge.org/core/journals/international-journal-of-technology-assessment-in-health-care/article/abs/cost-of-intensive-care-in-india/9FDABCCC59E5AD6332C6C8D85C891D9B?utm\\_campaign=shareaholic&utm\\_medium=copy\\_link&utm\\_source=bookmark](http://www.cambridge.org/core/journals/international-journal-of-technology-assessment-in-health-care/article/abs/cost-of-intensive-care-in-india/9FDABCCC59E5AD6332C6C8D85C891D9B?utm_campaign=shareaholic&utm_medium=copy_link&utm_source=bookmark) [last accessed 26 October 2023]; These costs are equivalent to between 2.2 and 4.0 times the nation's 2018 health care expenditures per capita. See The World Bank, 'Current health expenditure per capita (current US\$) - China,



does not impair the functioning of the health system, the cost and length of treatment or necessity of treatment in ICU should not constitute a reason for a mandatory intervention. Moreover, in the cases of *Vavříčka v. Czech Republic*, *Solomakhin v. Ukraine*, and *Boffa and Others v. San Marino*, the expense of treating unvaccinated individuals was not cited as a justifiable rationale for imposing mandatory vaccination requirements. On the other hand, unvaccinated persons may argue that they are paying high premiums for their social health insurance and cover the cost of a possible tetanus treatment in advance. It's worth mentioning that for preventive medical measures primarily concerned with an individual's well-being, most countries typically do not enforce mandates.<sup>64</sup> Many life-saving preventive medical interventions can be named and most of them have no or very rare side effects.<sup>65</sup> For example, cervical cancer is the fourth most common cancer among women, and routine HPV and pap-smear tests are highly recommended. Regular tests increase the chance of recovery and reduce the cost and the duration of the treatment of cervical cancer due to early diagnosis. However, mostly, these preventive tests are not ruled to be mandatory considering the cost of cancer treatment.<sup>66</sup>

#### IV. Mature Minors' Right to Reject Tetanus Vaccination

According to Article 6 of the Convention on Human Rights and Biomedicine:

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*Malaysia, Thailand, India, Vietnam*, (2023), available at: [data.worldbank.org/indicator/SH.XPD.CHEX.PC.CD?end=2018&locations=CN-MY-TH-IN-VN&start=2017](https://data.worldbank.org/indicator/SH.XPD.CHEX.PC.CD?end=2018&locations=CN-MY-TH-IN-VN&start=2017) [last accessed 26 October 2023]; In a study conducted in Vietnam in 2022, the direct medical cost of tetanus, patients in an intensive care unit is calculated and for patients that did not require mechanical ventilation, the median total ICU cost per patient was found between US\$64.40 and US\$675. The costs were higher for patients that required mechanical ventilation, with the median total ICU cost per patient for the different diseases varying between US\$2,590 and US\$4,250. The main cost drivers varied according to disease and associated severity. See Hung et al., 'Direct Medical Costs of Tetanus, Dengue, and Sepsis Patients in an Intensive Care Unit in Vietnam', (2022) 10 *Frontiers in Public Health*, available at: [doi.org/10.3389/fpubh.2022.893200](https://doi.org/10.3389/fpubh.2022.893200) [last accessed 26 October 2023].

<sup>64</sup> Stubbs, 'Health Matters - Cervical Screening: It's Your Choice', *UKHSA*, 30 August 2017, available at: [ukhsa.blog.gov.uk/2017/08/30/health-matters-cervical-screening-its-your-choice/](https://ukhsa.blog.gov.uk/2017/08/30/health-matters-cervical-screening-its-your-choice/) [last accessed 26 October 2023].

<sup>65</sup> Like routine screening blood tests, check-ups, doctor visits, blood pressure tests.

<sup>66</sup> Public Health England, 'Cervical Screening: Program Overview' (2015), available at: [www.gov.uk/guidance/cervical-screening-programme-overview#:~:text=It%20is%20an%20individual's%20choice,want%20to%20receive%20screening%20invitations](https://www.gov.uk/guidance/cervical-screening-programme-overview#:~:text=It%20is%20an%20individual's%20choice,want%20to%20receive%20screening%20invitations) [last accessed 26 October 2023]; Uruguay enacted mandatory breast cancer screening for working women aged 40-59 in 2006. This rule is challenged. See Rosengurt, 'Uruguay's mandatory breast cancer screening is Challenged' *The BMJ Opinion*, 26 October 2017, available at: [blogs.bmj.com/bmj/2017/10/26/ana-rosengurt-uruguays-mandatory-breast-cancer-screening-is-challenged/](https://blogs.bmj.com/bmj/2017/10/26/ana-rosengurt-uruguays-mandatory-breast-cancer-screening-is-challenged/) [last accessed 26 October 2023].

*Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.*

*The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.*

If a minor is able to make an informed judgment about medical treatment, some countries grant that mature/competent/Gillick competent minor the right to consent to all or some medical procedures.<sup>67</sup> If a state allows mature minors to consent to medical interventions, then these mature minors should also have a right to refuse the medical interventions like competent adults. However, in some countries, it is possible to subject the decision of a mature minor to judicial review if the refusal poses a serious risk to the health of the minor.<sup>68</sup>

A minor accepted as mature to consent to medical interventions in his or her home country should have the same freedom as adults to be not vaccinated as a preventive medical intervention. This freedom can only be interfered

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<sup>67</sup> § 95 Czech Republic Civil Code, No 89/2012: “A minor without full legal capacity may, in usual matters, also give his consent to an intervention on his body himself, if this is adequate to the intellectual and volitional maturity of minors of his age, and if it is an intervention not resulting in any permanent or serious consequences.”; § 36 New Zealand Care of Children Act 2004, No 90: “A consent, or refusal to consent, to any of the following, if given by a child of or over the age of 16 years, has effect as if the child were of full age: (a) any donation of blood by the child: (b) any medical, surgical, or dental treatment or procedure (including a blood transfusion, which, in this section, has the meaning given to it by section 37(1)) to be carried out on the child for the child’s benefit by a person professionally qualified to carry it out.”; §8 UK Family Law Reform Act 1969: “(1) The consent of a minor who has attained the age of sixteen years to any surgical, medical or dental treatment which, in the absence of consent, would constitute a trespass to his person, shall be as effective as it would be if he were of full age; and where a minor has by virtue of this section given an effective consent to any treatment it shall not be necessary to obtain any consent for it from his parent or guardian. (2) In this section “surgical, medical or dental treatment” includes any procedure undertaken for the purposes of diagnosis, and this section applies to any procedure (including, in particular, the administration of an anaesthetic) which is ancillary to any treatment as it applies to that treatment. (3) Nothing in this section shall be construed as making ineffective any consent which would have been effective if this section had not been enacted.”; §173 Austria ABGB: “(1) Consent to medical treatment can only be given by the child who is capable of understanding and judgement; in case of doubt, the existence of this capacity for understanding and judgement is presumed in the case of minors of age. If the child lacks the necessary capacity to understand and judge, the consent of the person entrusted with care and education shall be required.”; § 129 (2-3) South Africa Children’s Act 39, 2005, available at: [www.justice.gov.za/legislation/acts/2005-038%20childrensact.pdf](http://www.justice.gov.za/legislation/acts/2005-038%20childrensact.pdf) [last accessed 27 July 2023].

<sup>68</sup> *Re R (A Minor)* [1991] EWCA Civ J0724-4; *Re W (A Minor)* [1993] EWHC 64 (Fam); *Re X (A Child)* [2021] EWHC 65 (Fam); Critical of these precedents, Birch, ‘Mature Minors and the Refusal of Medical Treatment: A Misuse of Gillick’ (2017) Durham University 104, available at: [etheses.dur.ac.uk/12354/](http://etheses.dur.ac.uk/12354/) [last accessed 26 October 2023].

with if there is an additional justifiable reason, such as the protection of public health. In the case of the tetanus vaccine, there is no such additional justification as explained in the previous part. His children were 13 and 14 years old when Mr. Vavříčka was fined for not vaccinating his children against tetanus, poliomyelitis, and hepatitis B.<sup>69</sup> It is also conceivable that children aged 13 and 14, who have not received any tetanus vaccine before,<sup>70</sup> could decide for themselves about the tetanus vaccination after being informed.<sup>71</sup> As a matter of fact, the legal regulation in the Czech Republic gives minors the right to make their own decisions about medical intervention, according to the maturity of children at certain ages and the severity of the medical intervention.<sup>72</sup> However, the legislation requiring vaccinations in the Czech Republic, it is stated that the consent of the legal representative is required for those under the age of 15.<sup>73</sup> From this point of view, the decision is also questionable in terms of the fact that the parents are fined by the state at an age when the children are mature enough to make their own decisions about vaccination. The child applicants of *Vavříčka* case contended that denying them entry to nursery school due to their parents' refusal was arbitrary. They also invoked their right to personal autonomy in making health-related decisions.<sup>74</sup>

## V. When to Intervene if Parents Object to Children's Tetanus Vaccination?

The *Vavříčka* decision and the discussion on tetanus vaccination mainly concern the age range in which the child is incapable of judgment in such a way as to make his own decision about whether to have the tetanus vaccine. As a rule, the parents, as the legal representatives of the minor, consent to medical interventions on the minor who is incapable of judgment (Article 6 II of the Convention on Human Rights and Biomedicine). In this case, the decision authority is given to the parents, thinking that the best interests of the child will be best determined by the parents. It should be emphasized that the decision authority is vested in parents, not in physicians. Citing this convention too, the Court in *Glass v. The United Kingdom* case ruled that the administration of a high dose of diamorphine to a disabled child against the opposition of his legal representative violated Article 8 of the Convention. In *M.A.K. and R.K. v. The*

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<sup>69</sup> *Vavříčka*, supra n 2 at 23.

<sup>70</sup> *Vavříčka*, supra n 2 at 24, 302

<sup>71</sup> Doležal, 'Informed Consent of Minors with A Special Focus on The Czech Legal Regulation', (2021) 11(1) *The Lawyer Quarterly* 126.130; Weithorn and Campbell, 'The Competency of Children and Adolescents to Make Informed Treatment Decisions', (1982) 53(6) *Child Development* 1589.

<sup>72</sup> §31 Czech Republic Civil Code, No 89/2012; Doležal, supra n 71 at 134-137.

<sup>73</sup> *Vavříčka*, supra n 2 at 11.

<sup>74</sup> *Vavříčka*, supra n 2 at 172-173.

United Kingdom, it was found that taking blood samples and photographing of the nine-year-old child without the consent of his legal representative was contrary to Article 8 of the Convention.

On the other hand, parents' right to consent to medical interventions on minors can be restricted. At this point, a distinction needs to be made based on the nature of medical interventions. An intervention may be aimed at treating the child's existing health problem or preventing a potential health risk the child may encounter in the future. Vaccination is the most important example of the latter type of medical intervention. Additionally, some medical interventions performed on minors with parental consent are neither therapeutic nor preventive in nature. This group, which can be referred to as non-indicated medical interventions, includes circumcision of male minors and cosmetic medical procedures.

In the case of medical interventions on minors, the decision-making authority of parents is debated mostly when it comes to therapeutic medical interventions. However, the assessments regarding the discretion of parents in therapeutic medical interventions also shed light on preventive medical treatments. Therefore, the examination will begin with assessments concerning the discretion of parents in therapeutic medical interventions.

### **A. The Limits of Parental Discretion in Therapeutic Interventions**

As mentioned above, medical interventions on minors will as a rule require parental consent. However, parents' discretion in this matter is not unlimited. The best interest and harm-based principles have been established to determine under which conditions parental authority over medical interventions on minors can be overruled.<sup>75</sup> 'Best interest' refers to making decisions based on what is in the best interest of the child's overall well-being, considering their physical and emotional health. According to this criterion, if the proposed medical intervention serves the best interests of the child, the judge can intervene in the parents' refusal to receive the treatment.<sup>76</sup> However, the best interest of the child does not provide a clear standard. In most cases, physicians are medically more knowledgeable than the child's legal representatives, who are mostly parents, in assessing whether a medical intervention is in the child's best interest. Then, medical best-interest determination might always be based on the physicians' judgment. This is not in line with the ratio legis of legal

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<sup>75</sup> MacDougall, 'Intervention Principles in Pediatric Health Care: The Difference Between Physicians and The State', (2019) 40(4) *Theoretical Medicine and Bioethics* 279, available at: doi.org/10.1007/s11017-019-09497-6 [last accessed 26 October 2023]; Other different standards are suggested for decision making in such cases. See DeMarco, Powell and Stewart, 'Best Interest of the Child: Surrogate Decision Making and the Economics of Externalities', (2011) 8 *Bioethical Inquiry* 289, available at: doi.org/10.1007/s11673-011-9315-1 [last accessed 26 October 2023].

<sup>76</sup> NHS, '*Children and young people: Consent to Treatment*', (2022), available at: www.nhs.uk/conditions/consent-to-treatment/children/ [last accessed 26 October 2023].

regulations that grant parents the decision-making authority over medical interventions on minors. Hence, it is suggested that the best interest evaluation should be subjected to restrictive interpretation.<sup>77</sup> Furthermore, it is stated that this criterion does not offer physicians a clear guideline on when to initiate legal proceedings to override the refusal of the legal representative. Therefore, it is emphasized that the ‘significant risk of serious preventable harm’ principle should be considered as an alternative.<sup>78</sup> “Harm-based” principles focus on preventing or minimizing potential harm or risks to the child. Within the framework of this principle, if there is a high probability of significant harm to the child’s health when medical intervention is not applied, and the recommended medical intervention can mitigate this danger without substantial risks on its own, the legal representative’s decision to withhold medical intervention can be overridden in favor of the intervention.<sup>79</sup> It is interesting to note that childhood vaccinations are used as an example when discussing when a “significant risk of serious harm” can be addressed.<sup>80</sup> According to this example, many physicians may advise parents to have their child vaccinated during childhood, but they do not resort to legal measures against parents who refuse vaccination for their child. This is because in countries where vaccination is widespread, the likelihood of contracting vaccine-preventable diseases and thus suffering serious harm is low. As a result, utilizing such criteria and legal regulations, efforts are made to determine the limits of parental discretion. Some case samples are established to limit parental discretion.

In emergency cases where minors’ life is at high risk, physicians can proceed with necessary medical intervention without parental consent or legal authorization.<sup>81</sup> This is in accordance with Article 8 of the Convention on Human Rights and Biomedicine.<sup>82</sup>

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<sup>77</sup> Stern, *supra* n 65 at 88; Buchanan and Brock, *Deciding for Others: The Ethics of Surrogate Decision Making* (1989) at 145.

<sup>78</sup> Kopelman, ‘The Best-Interests Standard as Threshold, Ideal, and Standard of Reasonableness’, (1997) 22 *Journal of Medicine and Philosophy* 271.275; Buchanan, *supra* n 87, Ekundayo, ‘Legal Basis for the Court’s Intervention over Medical Treatment of Children’, (2022) 121 *Journal of Law Policy and Globalization* 39.49.

<sup>79</sup> Diekema, ‘Parental Refusals of Medical Treatment: The Harm Principle as Threshold for State Intervention’, (2004) 25 *Theoretical Medicine and Bioethics* 243.

<sup>80</sup> UW Medicine Department of Bioethics and Humanities, available at <https://depts.washington.edu/bhdept/ethics-medicine/bioethics-topics/detail/72> [last accessed 23 October 2023]

<sup>81</sup> Guadarrama-Orozco et al., ‘Informed Consent and Parental Refusal for Medical Treatment in Childhood. The Threshold of Medical and Social Tolerance: Part II’, (2015) 72(4) *Boletín Médico del Hospital Infantil de México* 184, available at: [www.elsevier.es/en-revista-boletin-medico-del-hospital-infantil-201-articulo-informed-consent-parental-refusal-for-X244434091543972X](http://www.elsevier.es/en-revista-boletin-medico-del-hospital-infantil-201-articulo-informed-consent-parental-refusal-for-X244434091543972X) [last accessed 26 October 2023].

<sup>82</sup> Emergency situation “When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned.”

In many legal systems, if the recommended medical intervention is a life-saving measure for the child, but the parents refuse to consent for reasons other than the medical intervention's higher risks, the court or a similar authority may intervene and authorize the necessary treatment.<sup>83</sup>

In cases where medical intervention is necessary to prevent significant health problems for the child, and the risks associated with the medical intervention are low while the chances of successful treatment are high, courts often intervene when parents refuse the treatment. The court's intervention aims to ensure that the child receives the necessary medical care for their well-being and health.<sup>84</sup>

If the likelihood of success of a medical intervention is low or the treatment process is risky, prolonged, or painful, there is a tendency not to interfere with parental discretion. In such cases, more respect is given to the parents' preferences.<sup>85</sup>

### **B. Limits of Parents' Decisive Authority in Preventive Medical Interventions**

Compared to therapeutic medical interventions, preventive medical intervention is performed with the aim of protecting the minor from a health problem that may occur in the future. In preventive medical interventions, consent for this treatment will also be given by the parents as a rule, for the minors who are incapable of judgment.

In the case of preventive medical interventions, healthcare practitioners or state authorities may deem a medical intervention necessary, but parents may refrain from giving consent. In such situations, whether the parental discretion can be overridden should be determined considering factors such as the seriousness and incidence of the health risk being addressed, the effectiveness of the preventive medical intervention, and the risks associated with the intervention itself, and the reasons behind the parents' refusal of the treatment.

Among preventive medical interventions, vaccines are considered the most effective in terms of cost and impact. The risk of a child contracting tetanus depends on the family's lifestyle and can vary from one country to another. Neonatal tetanus is very unlikely with hospital births and circumcisions and is also much less likely to occur in non-hospital settings when mothers have received at least two doses of tetanus vaccine before and during pregnancy.

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<sup>83</sup> *Willmann* 493 N E 2d 1380 (OH 986); *Matter of D R* 20 P 3d 166 (OK 2001); *Custody of a Minor* 379 N E 2d at 1056 (Mass 1978); Townsend, 'Judicial Limitations on Parental Autonomy in the Medical Treatment of Minors', (1980) 59(4) *Nebraska Law Review* 1093.1094.

<sup>84</sup> *Guadarrama-Orozco*, supra n 89; *Stern*, supra n 65 at 88; *Custody of a Minor*, supra n 93; *Ekundayo* supra n 88 at 49; *Sampson* 37 AD 2d 668 (NY 1971).

<sup>85</sup> *Guadarrama-Orozco*, supra n 89; *Newmark v Williams* 588 A 2d 1108 (DE 1990); *Re Greene* 448 PA at 348 292 A 2d at 392 (PA 1972).



Additionally, if there is no drug use in the child's vicinity, the likelihood of the child encountering this disease significantly decreases. According to the data mentioned above, the incidence of tetanus was not high even without any vaccination programs. Additionally, as described earlier, when an unvaccinated person contracts tetanus, early diagnosis allows for effective treatment. Therefore, the refusal of the tetanus vaccine does not expose the child to an immediate risk of harm.

The pentavalent vaccine when administered in recommended doses and at specific intervals, as explained above, provides effective protection against tetanus disease.<sup>86</sup> On the other hand, as mentioned earlier, the likelihood of the vaccine causing serious harm to the child is told to be low. However, considering the low incidence of tetanus itself, the states should make more specific and transparent declarations on the incidence of the serious side effects. This information is crucial for parents who want to give informed consent to this medical intervention.

The content of the tetanus vaccine is provided in the section above. According to manufacturers, despite possible variations in content, tetanus vaccine types do not contain porcine gelatin, which shouldn't be consumed in accordance with Jewish and Islamic beliefs. Even though the level of aluminum is also very low in vaccine contents, parents' concerns about vaccines may arise due to the use of aluminum as an adjuvant in vaccines. The use of aluminum as an adjuvant in vaccines raises doubts in some parents about potential negative effects on human health. On the other hand, some parents may refuse the vaccine due to their lack of trust in vaccine manufacturers and their country's health authorities.

As a result, parents' doubts about the safety or effectiveness of vaccines, concerns about the ingredients in vaccines, and/or religious beliefs may lead them to decide against vaccinating their children. These concerns of parents may not be justified according to medical science.<sup>87</sup> However, in this case, it should be considered whether parental discretion can be overridden regarding the risk mitigated by the tetanus vaccine. There can be several other preventive medical interventions for a child's health besides the tetanus vaccine. Regular blood tests and developmental check-ups by a pediatrician may be more effective health measures to prevent many potential health issues for the child compared to the tetanus vaccine. Parents influence their children's psychological and physiological health through the many decisions they make every day. Choices such as their dietary preferences, not encouraging their children to engage in sports, not restricting screen time, allowing biking or scooter riding

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<sup>86</sup> *Troxel v Granville* 530 US 57 (2000) [65].

<sup>87</sup> Rhinesmith and Fu, 'Tetanus Disease, Treatment, Management', (2018) *Pediatrics in Review* 430, 430-432; Slifka, *supra* n 39, 285-292.

without helmets, neglecting basic safety measures at home, and not knowing first aid can negatively impact a child's health and may be deemed inappropriate by experts. However, it is not feasible to intervene in every decision that is perceived as incorrect as parents are raising their children. On the contrary, intervention in parental rights should be possible in exceptional cases.<sup>88</sup> The relatively low risk of encountering tetanus, the possibility of early diagnosis and treatment, and the principle of intervention in parental rights in exceptional cases make mandatory preventive tetanus vaccination for young children not a proportionate measure.<sup>89</sup> On the other hand, parents have the right to make informed decisions. There is no transparency about the incidence of tetanus in unvaccinated persons and frequency of the serious side effects of tetanus vaccine. Countries should ideally already have this information and make it available to parents so they can make informed decisions.

In the *Acmanne and Others v Belgium* case, the European Court of Human Rights ruled that the regulation subjecting children to routine tuberculosis testing and chest X-rays is lawful, as it is in the best interest of the child and society.<sup>90</sup> However, it is important to point out that mandatory vaccination is a much more serious intervention in the body than a test since vaccination injects a substance in the the body.<sup>91</sup> Additionally, unlike tuberculosis, tetanus does not spread from person to person. Therefore, mandatory tetanus vaccination as a preventive measure requires a different analysis than the one in *Acmanne* case.

## Conclusion

A competent adult may refuse treatment, even if the result is death. This is a general rule accepted by the European Court of Human Rights in many of its decisions. Therefore, adults and mature minors who are authorized to decide on such medical interventions should have the right to refuse tetanus vaccination. At this point, sanctioning an adult for not getting vaccinated against tetanus will not be in line with the Oviedo Convention and ECHR.

A more controversial legal situation arises when mandatory tetanus vaccine is intended for minors who are incapable of judgment. In the case of therapeutic medical interventions, parents' right to refuse a suggested medical treatment is set within the framework of the 'best interests of the child' or 'significant risk of serious harm' criteria. However, the intervention to be made according to these criteria should be exceptional and should not transfer the

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<sup>88</sup> *Strand Lobben and others v Norway* Application No 37283/13, Admissibility, 10 September 2019 at para 211; *Vavříčka*, supra n 2 at 13.

<sup>89</sup> Vaccinating each child is not justified by its being in their best interests alone. On which see Archard, Brierley and Cave, supra n 7 at 7.

<sup>90</sup> *Acmanne and Others v Belgium* Application No 10435/83, 10 December 1984.

<sup>91</sup> Douglas, Forsberg and Pugh, supra n 52.

discretion of the parents regarding the proposed medical intervention to the physicians. The likelihood that a child will have tetanus will vary depending on the environment, country, and family attitudes. If the child lives in hygienic conditions, the probability of getting infected with tetanus is not high. Despite its high mortality rate, tetanus is treatable especially when it is diagnosed in a timely manner and when intensive care services including mechanical ventilation is available. There are many other preventive medical interventions for minors, such as routine blood tests and pediatrician check-ups, and some of them may be even more effective than the tetanus vaccine. On the other hand, countries are not transparent with the specific incidence of the serious side effects of the vaccines. In our opinion, due to the rarity of tetanus, its non-contagious nature, and parents' rights to choose what they believe is best for their children, even if it goes against medical advice, it is not in accordance with the European Convention on Human Rights (ECHR) to interfere with parents' discretion regarding preventive tetanus vaccination.