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Key Issues in Vaccine-Based Tuberculosis Prevention for Children within Family Medicine Systems in Ukraine

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Abstract

The article examines the key challenges surrounding childhood vaccination in Ukraine and suggests solutions to address them. It presents the findings of a survey assessing parental and prospective parental awareness of the importance of childhood vaccinations and identifies the main reasons for vaccine refusal. A SWOT analysis was conducted that outlined the strengths, weaknesses, advantages, and drawbacks of the vaccination process from the perspective of parents or potential parents. Several strategies were proposed, including the implementation of pre-vaccination express tests for vaccine tolerance, the development of an online vaccination schedule or a dedicated application with individualized vaccination reminders for each child, and the enhancement of the free vaccination system. In addition, it emphasizes the need for improving the information and health education provided by medical and pharmaceutical institutions, increasing parental accountability regarding vaccine refusal, and ensuring the availability of high-quality vaccines at the national level. The study also tracks trends in tuberculosis incidence and investigates the availability of anti-tuberculosis vaccines in Ukraine's pharmaceutical market. By understanding the social challenges faced by patients, healthcare providers can not only address some of these issues but also encourage a more informed approach to the necessity of children's vaccination and revaccination.

Keywords: Family medicine, Tuberculosis, Vaccination of children, Pharmacy

Introduction

Vaccination plays a critical role in preventing a variety of bacterial and viral diseases, particularly in protecting children from birth through adolescence. In Ukraine, the calendar of preventive vaccination of children (CPVC) has been revised since 2020 to align more closely with the CPVC of the EU and the US [1-3]. However, complete alignment may not always be suitable, as the epidemiological conditions for some diseases differ significantly between countries and regions. For instance, the World Health Organization reports that approximately nine million people worldwide are affected by tuberculosis (TB) each year, with only six million receiving treatment, and around 1.7 million dying from the disease annually. The primary objective of national health programs globally is to prevent TB, which involves interrupting the transmission of the disease from infected individuals to healthy ones [4]. In Ukraine, TB rates are above average, with an increasing incidence of the disease year after year [5].

Despite these concerns, the CPVC has removed the BCG revaccination for children at the age of seven [2, 6]. According to the updated guidelines, children are initially vaccinated against TB within the first three to five days of life, but revaccination at the age of seven is no longer performed. Additionally, some newborns with specific developmental issues are transferred to specialized healthcare facilities for treatment within the first few days of life, where the BCG vaccine is not administered

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due to its unavailability. Furthermore, children over the age of seven, who no longer receive the vaccine, are also excluded from vaccination in children's departments of healthcare facilities. This has led to the initiation of a study focused on vaccination practices in Ukraine. It is important to note that the research began before the COVID-19 pandemic, yet even at that time, a generally negative perception toward vaccination among parents was evident.

We believe that this negative view is partly because family medicine practitioners fail to adequately engage in educational efforts with parents. Moreover, according to current legislation, pharmacies should also be involved in public education regarding vaccination, but unfortunately, this responsibility is often neglected by pharmacists [7].

The purpose of the study was to examine the trends in TB incidence within Ukraine, evaluate the availability of anti-tuberculosis vaccines on the country's pharmaceutical market, explore the issues surrounding the negative attitude towards child vaccination, and propose solutions to address these challenges.

Materials and Methods

The study utilized data from official Ukrainian statistical sources regarding tuberculosis incidence, the State Register of Medicines, and survey responses from employees and students at higher education institutions concerning vaccination. The research employed methods such as meta-analysis, statistical evaluation, marketing office techniques, field research, and SWOT analysis.

Results and Discussion

Each year, the Public Health Center of Ukraine's Ministry of Health, in collaboration with the Center for Medical Statistics, compiles an analytical and statistical report titled "Tuberculosis in Ukraine," along with documentation detailing tuberculosis incidence in various Ukrainian regions [4]. We have analyzed the statistical data on tuberculosis rates in the population over the past 4 years **(Table 1)**.

Table 1. Statistics on the incidence of tuberculosis in Ukraine

№	Nosology/years	2018*	2019	2020	2021
1.	Total number of TB patients (ICD-10-CM code)	8306	8103	6738	9825
	1.1. Pulmonary tuberculosis (ICD-10-CM code: A15.0-3, A16.0-2, A19)	7668	7461	6238	9014
	1.2. Extrapulmonary tuberculosis (ICD-10-CM code: A15.0-3, A16.0-2, A19)	638	642	500	811
2.	Relapses	1447	1315	1121	1863
3.	New cases	5775	5852	4944	7096
4.	Others	1084	936	673	866
5.	Men/women	6011/2295	5989/2114	4849/1889	7167/2658

*1st quarter of 2018

Data on the disease trends in the adult population indicates a reduction in the recurrence of TB, though the trend for new cases remains unstable. The decline in morbidity and improvement in patient recovery is largely tied to the availability of new medications that target resistant strains of the bacteria. Notably, most of the adult population in Ukraine was vaccinated in their early childhood, with a booster shot administered around the age of seven, and occasionally at fourteen when deemed necessary.

Diagnostic data on TB up until 2019 remain reliable, although the focus shifted in recent years toward addressing the challenges posed by the COVID-19 pandemic [8-10]. Preventive screening in the adult population dropped to 45.9% in 2017, while the percentage of children aged 4-14 years receiving tuberculin testing decreased from 64.4% in 2012 to 49.7% in 2017 [3]. In 2017, the percentage of TB patients detected during preventive screenings fell to 51.1%. While the detection rate for patients testing positive for tuberculosis increased to 51.1%, the preventive coverage for children under 14 remained insufficient, with just 49.7% of children in that age group being tested in 2017. The proportion of children under one-year-old receiving

the BCG vaccination fell to 83.6%, and for those over seven years old, the figure dropped to 46.0%. Furthermore, the number of TB-related deaths grew significantly, with the death rate among TB patients who were not hospitalized rising to 32.8% by 2017, signaling late diagnoses and missed cases of TB [4].

In 2014, the TB incidence rate for children (0-17 years) decreased by 15% compared to 2013, with the figures dropping from 11.9 to 10.1 per 100,000 population (from 948 to 770 cases). However, by 2018, the incidence increased by 2.9% compared to 2014, with the rate rising from 10.1 to 10.4 per 100,000 population (770 to 788 cases) [11].

The incidence rates in 2021 **(Table 1)** showed a positive trend across various indicators, which we attribute to increased diagnostic testing during the COVID-19 pandemic, leading to a rise in new diagnoses and recurrences.

This prompts a discussion on whether it is justified to end BCG revaccination for children at the age of seven, or even at fourteen if needed. There is also an urgent need to ensure that outpatient pediatric clinics are supplied with the BCG vaccine. As per the 2019 CPVC, vaccinations for ten diseases are mandatory, and they are free of charge for all children under 18. Those at higher risk, such as medical professionals, students, military personnel, and educators, are eligible for free vaccinations against diseases like measles, rubella, and mumps. However, when the BCG vaccine is unavailable in pediatric clinics, parents must purchase it privately. A market analysis of the BCG and tuberculin vaccines in Ukraine revealed that both vaccines are listed in the State Register of Medicines and are available for purchase in pharmacies, though at varying costs **(Table 2)** [12].

Table 2. Availability of BCG vaccine and tuberculin according to the state drug registry

Name/dosage form	The composition of active substances	Producer	The applicant
RC № UA/14884/01/01, validity RC unlimited from 16.12.2020:			
TUBERCULOSIS PREVENTION VACCINE LIVE, DRY BCG 10 powder and solvent for suspension for intradermal injection, 0.5 mg (10 doses), 5 ampoules of powder, and 5 ampoules of solvent in 1 ml (isotonic sodium chloride solution) in a cardboard box	Each ampoule of the BCG vaccine 10 (containing 10 doses) contains 0.5 mg of live BCG mycobacteria. Each dose (0.1 ml) consists of 50 µg of semi-dried BCG mycobacteria, with a range of 150,000 to 600,000 viable BCG mycobacteria.	BIOMED-LUBLIN, Poland POLPHARMA SA Pharmaceutical Works (solvent manufacturer), Poland	BIOMED-LUBLIN, Poland
RC № UA/16739/01/01, the validity of RC from 06/05/2018 to 06/05/2023:			
TUBERCULIN PPD RT 23 SSI solution for injection 2 TO / 0.1 ml of 1.5 ml of solution (15 doses) in a vial; 1 or 10 vials in a cardboard box	Each dose (0.1 ml) includes 0.04 µg of tuberculin PPD RT 23 (2 TO). A single vial (1.5 ml) holds 15 doses of Tuberculin PPD RT 23 SSI (2 TO per 0.1 ml).	AJ Vaccines A / EU, Denmark	AJ Vaccines A / EU, Denmark
RC № UA/16761/01/01, the validity of the RC from 06/15/2018 to 06/15/2023:			
TUBERCULIN PPD RT 23 SSI solution for injection 2 TO / 0.1 ml of 1.5 ml in bulk: in vials № 1300-1400 in a plastic bag	Each 0.1 ml dose contains 0.04 µg of tuberculin PPD RT 23 (2 TO). A 1.5 ml vial provides 15 doses of Tuberculin PPD RT 23 SSI (2 TO per 0.1 ml).	AJ Vaccines A / EU, Denmark	AJ Vaccines A / EU, Denmark
RC № UA/16762/01/01, the validity of the RC from 06/15/2018 to 06/15/2023:			
TUBERCULIN PPD RT 23 SSI solution for injection 2 TO / 0.1 ml; 1.5 ml of solution (15 doses) in a vial; 1 vial complete with 15 self-locking syringes in contour honeycomb packaging or without contour honeycomb packaging in a cardboard box	Each 0.1 ml dose provides 0.04 µg of tuberculin PPD RT 23 (2 TO). A 1.5 ml vial contains 15 doses of Tuberculin PPD RT 23 SSI, with each dose containing 2 TO per 0.1 ml.	LUMIER PHARMA LLC (production in bulk packaging of the manufacturer AJ Vaccines A / ES, Denmark), Ukraine	LUMIER PHARMA LLC, Ukraine

RC № UA/15772/01/01, RC validity is unlimited from 15.02.2017:			
BIOLIC TUBERCULIN PPD-L solution for injection with an activity of 2 TO/dose in bulk: 30 ampoules of 0.6 ml (6 doses), or 1 ml (10 doses), or 20 ampoules of 3 ml (30 doses) in a cardboard cell packaging; 10 or 20 cardboard honeycomb packages in a cardboard package	Each 0.1 ml dose includes 2 TO (tuberculin units) of allergen-tuberculoprotein.	JSC "BIOLIK", Ukraine	JSC "BIOLIK", Ukraine
RC № UA/15771/01/01, RC validity is unlimited from 15.02.2017:			
BIOLIC TUBERCULIN PPD-L Solution for injection with an activity of 2 TO/dose of 0.6 ml (6 doses), 1 ml (10 doses), 3 ml (30 doses) in ampoules № 10; or set: 1 ampoule of 0.6 ml (6 doses), 3 syringes with needles for extraction, 3 needles for injection; or set: 1 ampoule of 1 ml (10 doses), 5 syringes with needles for extraction, 5 needles for injection	A 0.1 ml dose consists of 2 TO (tuberculin units) of allergen-tuberculoprotein.	JSC "BIOLIK", Ukraine	JSC "BIOLIK", Ukraine

In Ukrainian pharmacies, the price of tuberculin ranges between 176 and 189 UAH, approximately €6. The price for the BCG vaccine is not available as it is delivered directly to maternity wards. The Uro-BCG vaccine, priced at 3,000 UAH (~€95), is the only one available for purchase at pharmacies. Private healthcare facilities offer vaccinations as part of a service that includes a pediatrician's consultation, with costs ranging from 100 to 1,000 UAH, although BCG vaccination is not included. Several studies addressing the negative perceptions of some individuals toward preventive vaccinations led to the creation of a specialized electronic questionnaire [13-15] **(Table 3)**.

Table 3. Questionnaire on parents' awareness of the expediency of vaccination in childhood

Questionnaire on vaccination of children (16 questions)			
The purpose of the survey according to this questionnaire is to analyze the degree of awareness of parents and future parents about the feasibility of vaccination in childhood and determine the main reason for refusal of vaccination.			
1.	Your age:	a) 18-21 years b) 22-35 years	c) 35-50 years d) over 50 years
2.	Highest level of education attained:	a) Student b) Ph.D. student c) Academic	d) Associate professor e) Professor
3.	Where do you reside?	a) A big city b) A small town	c) A village (settlement, urban-type settlement)
4.	Are you currently a parent or planning to become one?	a) Yes, I have a child (ren). b) No, but I plan to shortly. c) No, and not planning.	
5.	Have you received vaccinations for the 10 diseases provided free of charge in childhood clinics?	a) Yes b) No	
6.	If not, what was the reason?	a) Parental refusal b) Lack of availability of free vaccines c) Vaccine intolerance	

7.	If you were vaccinated, did you experience any adverse reactions?	a) Yes b) No
8.	If there were reactions, did they lead to serious consequences?	a) Yes b) No adverse reactions were minor.
9.	Do you believe vaccinating your children is necessary?	a) Yes b) No
10.	What is the main reason you would refuse to vaccinate your child?	a) Religious beliefs b) The risks of vaccination outweigh the potential benefits c) Fear of side effects d) No perceived need for vaccination e) Belief that vaccination should be delayed until a certain age f) Other (please specify): _____
11.	Would you prefer paid or free vaccinations?	a) Payment. b) Free of charge.
12.	Are you well-informed about the advantages of vaccination?	a) Yes, enough. b) No.
13.	Where do you typically get your information about vaccinations?	a) Media (TV, radio, internet, newspapers) b) Healthcare professionals c) Not informed about vaccination needs d) Other (please specify): _____
14.	Would you be willing to vaccinate your child if you received comprehensive and trustworthy information about the vaccine?	a) Yes b) Difficult to answer. c) No
15.	Do you comprehend the potential consequences of an infection outbreak without vaccination?	a) Yes b) No c) Difficult to answer.
16.	Are you open to consulting with a healthcare professional for adequate information on vaccination?	a) Yes b) No

The survey was composed of 16 questions, which were divided into three sections. The first section aimed to gather demographic information about the respondents, the second focused on their personal experiences with vaccination, and the third explored their current and future attitudes and intentions regarding childhood vaccinations.

The questionnaire was conducted electronically, maintained anonymity, and participation was voluntary. It was distributed to students, faculty members, administrative staff, researchers, and other personnel at two universities: Lviv Polytechnic National University (NU LP) and Danylo Halytsky Lviv National Medical University (LNMU).

The survey collected responses from 246 individuals in total, with 173 participants from NU LP and 73 from LNMU. Based on the demographic data from the questionnaire, including age, education level, and gender, we conclude that the sample is representative. **Figures 1 and 2** show the breakdown of respondents by age and education level at both universities.

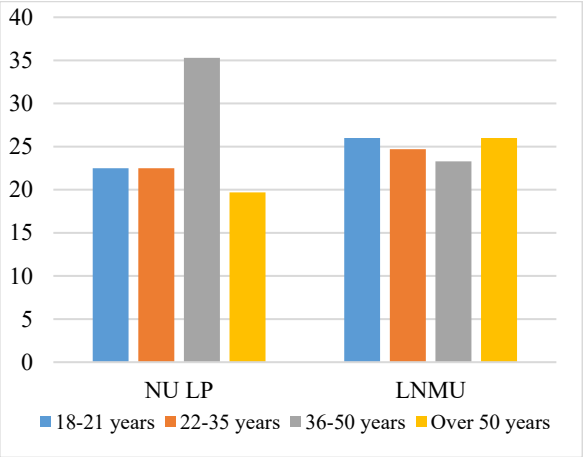

Figure 1. Distribution (%) of respondents by age of NU LP (173 answers) and LNMU (73 answers).

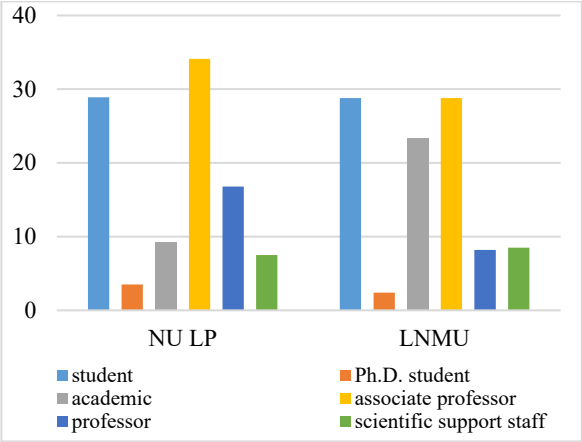

Figure 2. Distribution (%) of respondents of NU LP (173 answers) and LNMU (73 answers) by the level of education.

The distribution of respondents by education level at NU LP and LNMU, shown in **Figure 2**, reveals significant participation from students and associate professors at both institutions. These two groups are primarily composed of individuals who are parents or plan to become parents shortly.

By analyzing the responses to all survey questions, we were able to perform a SWOT analysis, highlighting both the strengths and weaknesses, as well as the benefits and challenges associated with childhood vaccination, according to the perspectives of parents or prospective parents. The results of this SWOT analysis are summarized in **Table 4**.

Table 4. Matrix of SWOT-analysis of vaccination of children in Ukraine

Component SWOT analysis	**Possibility**	**Threats**
	A. The government ensures the availability of high-quality, cost-free vaccines.	a) Higher child mortality rates if parents refuse vaccination, especially during outbreaks.
	B. Educating parents and prospective parents about the advantages and benefits of vaccination.	b) Inadequate supply of vaccines to healthcare facilities.
	C. Assessing children for any potential vaccination contraindications.	c) Low-quality vaccines that could pose a risk of severe reactions, leading parents to decline vaccination for their children.
Strengths	**SO - strategies**	**ST - strategies**
I. Immunization safeguards children from infections and mitigates the severity of illnesses and their complications if exposure occurs.	- Create a digital platform or mobile app to educate parents on vaccination (B, a). -Share detailed information with the public regarding the advantages and importance of immunization (I, IV). - Perform thorough medical assessments, including required tests, to ensure vaccination safety (B, V).	- Implement state-level oversight to ensure the availability of high-quality, free vaccines (II, III, b, c). - Organize discussions between prospective parents and healthcare providers about the importance of childhood immunization (I, V, a).
II. The necessary vaccinations for children against 10 diseases are provided free of charge at clinics.		
III. Only vaccines certified by the World Health Organization (WHO) are purchased in Ukraine.		
IV. Vaccination is the only option for preventing these diseases.		
V. If a child has missed vaccinations according to the standard schedule, an individualized vaccination plan is created by a healthcare provider, following the guidelines of Ukraine's Ministry of Health.		
Weak sides	**WO – strategies**	**WT – strategies**
1. There are situations where vaccination is not recommended for certain children.	1) Development of quick tests to assess vaccine tolerance (1, B). 2) Implementation of an online vaccination calendar or a	1) Increase parental accountability for refusing 2) vaccination (2, a). Guarantee the availability of high-quality vaccines at the national level (4, b, c).
2. Children who have not completed their vaccinations (due to parental refusal) may be restricted from		

attending daycare or school during outbreaks of specific vaccine-preventable illnesses.	dedicated app that provides reminders for vaccination dates (3, 4, B).
3. Timely adherence to the vaccination schedule is essential, as certain vaccines, like those for rotavirus and Haemophilus type b infection, must be started or completed by a specific age.	3) Establishment of a high-quality system for free vaccination and improvement of the performance of healthcare facilities (4, A).
4. Some challenges with free vaccination include long waiting times at clinics, a shortage of vaccines, and the high cost of private vaccines.	

The development of a SWOT analysis matrix for vaccination has highlighted five key strategies that could enhance the outlook of parents toward the vaccination process for children in Ukraine. These strategies include: the establishment and adoption of rapid tests for assessing vaccine tolerability; the creation of an online vaccination tracker or application that sends personalized notifications about upcoming vaccine appointments; the enhancement of a high-quality free vaccination system, alongside improvements in the informational and educational outreach of medical and pharmaceutical services; the reinforcement of parental accountability for opting out of vaccinations; and ensuring the provision of quality vaccines at the state level. It is also worth noting that there have been occurrences of misdiagnosis of tuberculosis in adults, which can lead to significant social and mental health challenges for the affected individuals [16].

Our research did not focus on the medications used for the treatment of tuberculosis in adults [17], nor did it address the issue of drug-resistant tuberculosis strains [18]. However, numerous studies are being conducted to develop new anti-tuberculosis vaccines and enhance existing ones [19], areas that remain highly relevant and hold potential for future advancements.

Conclusion

There is an urgent need to rethink the approach to BCG vaccination, especially for newborns who are transferred to specialized hospital departments shortly after birth and do not receive the vaccine in maternity wards. Gaining insight into the social challenges that patients face can help in addressing some of their concerns and also foster a more informed approach towards the need for childhood vaccination and revaccination.

Timely and early detection of tuberculosis patients is essential to ensure prompt treatment and prevent further spread of the disease, especially since those with pulmonary tuberculosis pose a significant public health risk.

The role of medical and pharmaceutical professionals in educating the public on vaccination is vital, as misleading information from unreliable online sources often influences public opinion. Implementing the strategies discussed, such as creating an online vaccination reminder system, improving the quality of the free vaccination program, and enhancing the work of medical professionals, will significantly aid in increasing childhood vaccination rates.

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