

VALUE OF INFORMATION ANALYSIS IN THE PHARMACOECONOMIC EVALUATION OF DIAGNOSTIC TECHNOLOGIES FOR RESPIRATORY VIRAL INFECTIONS

S. Soloviov^{1,2}, D. Horodetskyi², O. Kovaliuk¹, V. Mykhalchuk¹, N. Pryputa¹, L. Babintseva¹, M. Sidorenko³, S. Mickevičius³, M. S. Hakim⁴

¹ Shupyk National Healthcare University of Ukraine, Kyiv, Ukraine

² National Technical University of Ukraine "Igor Sikorsky Kyiv Polytechnic Institute", Kyiv, Ukraine

³ Vytautas Magnus University, Research Institute of Natural and Technological Sciences, Kaunas, Lithuania

⁴ Department of Biology and Immunology, College of Medicine, Qassim University, Buraydah, Saudi Arabia

Corresponding author: dgoldetsky37@gmail.com

Received 15 July 2025; Accepted 10 April 2026

Background. Respiratory infections remain a major global health burden with significant economic impact. The diversity of viral pathogens and variability in diagnostic approaches complicate etiological verification in laboratory practice. As diagnostic technologies evolve, there is a growing need for economically justified approaches that integrate analytical performance, operational characteristics, and costs. Value of Information (VOI) analysis provides a formal framework for evaluating the impact of uncertainty on decision-making.

Objective. To develop and apply a methodology for assessing the cost-utility and value of information of diagnostic technologies for viral respiratory infections from a laboratory perspective.

Methods. The study compared immunochromatographic rapid tests and PCR-based diagnostics for viral infections. Diagnostic utility was quantified using expert elicitation based on four operational criteria: automation, turnaround time, reproducibility, and accessibility. A multi-criteria decision-tree model was constructed, incorporating sensitivity, specificity, diagnostic spectrum, and cost parameters. Uncertainty was modeled using beta and gamma distributions. The framework enabled estimation of expected utility, Net Monetary Benefit (NMB), Expected Value of Perfect Information (EVPI), and Expected Value of Sample Information (EVSPI).

Results. A multi-criteria cost-utility methodology for evaluating etiological diagnostic technologies was developed and applied. Within the defined model, PCR-based diagnostics demonstrated higher expected utility, primarily due to their broader diagnostic spectrum and higher analytical sensitivity. In probabilistic simulations (10,000 iterations), PCR showed an average positive Net Monetary Benefit of approximately \$854 per clinical sample compared to rapid tests. VOI analysis indicated low decision uncertainty, with EVPI estimated at \$0.25 per patient. EVSPI for the diagnostic spectrum of PCR was negligible, and EVSI reached a maximum of \$2.69 at a sample size of 40, suggesting limited additional value of further data collection under current assumptions.

Conclusions. The integration of multi-criteria cost-utility modelling with VOI analysis provides a consistent framework for evaluating diagnostic technologies in laboratory medicine. Within the assumptions of the model, PCR-based diagnostics demonstrated higher economic utility compared to rapid tests. However, the results should be interpreted within the defined laboratory perspective and modeling assumptions, including limitations related to the diagnostic spectrum of rapid tests and the absence of downstream clinical outcomes. The proposed approach supports evidence-based and economically justified selection of diagnostic technologies under uncertainty.

Keywords: viral respiratory infections; laboratory diagnostics; polymerase chain reaction; rapid diagnostic tests; cost-utility analysis; decision tree, modelling; value of information.

Introduction

Viral respiratory infections remain a major public health challenge and contribute substantially to global morbidity and mortality [1]. Despite advances in clinical management, accurate etiological identification of viral pathogens remains a complex task in routine laboratory practice due to the diversity of viruses, variability in their circulation, and differences in access to diagnostic technologies [2, 3]. In this context, laboratory diagnostics plays a central role in the verification of etiological agents and in supporting broader healthcare processes, including epidemiological sur-

veillance, diagnostic standardization, and resource planning. In recent years, significant progress has been made in laboratory methods for the etiological diagnosis of viral respiratory infections. These include molecular techniques such as polymerase chain reaction (PCR), as well as point-of-care rapid diagnostic tests based on immunochromatographic principles [3–5]. From the perspective of laboratory medicine, these technologies represent alternative diagnostic tools that differ in diagnostic spectrum, sensitivity, specificity, reproducibility, turnaround time, operational complexity, and cost [5–7]. As a result, laboratory specialists are increasingly faced with the task of se-

lecting the most appropriate diagnostic technology under conditions of limited resources and uncertainty. Importantly, the evaluation of diagnostic technologies in laboratory practice cannot rely solely on conventional analytical indicators such as sensitivity and specificity [8, 9]. Although these parameters characterize the technical performance of tests, they do not fully reflect the overall utility of a diagnostic technology within the laboratory workflow. The value of etiological diagnostics depends on the integrated performance of diagnostic technologies, including the balance between true-positive, false-positive, true-negative, and false-negative results, as well as operational characteristics such as reproducibility, accessibility, time requirements, and the possibility of automation [9]. Therefore, the assessment of diagnostic technologies requires a comprehensive framework that links analytical performance with operational and economic characteristics within the laboratory setting. In practice, such relationships are complex and often not directly observable. The effectiveness of etiological diagnostics is influenced by pre-analytical conditions, variability in laboratory processes, differences in testing strategies, and limitations in available data. Consequently, the evaluation of diagnostic technologies is frequently based on modeling approaches that integrate analytical characteristics, epidemiological parameters, and cost data [9, 10]. These factors introduce uncertainty into decision-making and complicate the selection of optimal diagnostic technologies from a laboratory perspective.

Despite the increasing role of laboratory diagnostics in viral respiratory infections, pharmacoeconomic evaluation of diagnostic technologies in this field remains limited [2, 6, 7]. In many cases, decision-making is still focused on maximizing analytical performance, without sufficient consideration of the balance between diagnostic utility, operational feasibility, and economic efficiency [6, 8]. However, in the context of modern laboratory medicine and constrained healthcare resources, there is a need for structured approaches that support rational and evidence-based selection of diagnostic technologies. Value of information (VOI) analysis has emerged as a methodological tool for addressing uncertainty in decision-making. Within the framework of laboratory diagnostics, VOI analysis extends traditional pharmacoeconomic approaches by quantifying the expected benefit of reducing uncertainty in key parameters related to diagnostic performance, operational characteristics, and costs. Measures such as the expected value of perfect information and the expected value of sample information allow for the formal assessment of whether additional data collection would improve the selection of diagnostic technologies [11]. In the context of etiological diagnosis of viral respiratory infections, VOI analysis is

particularly relevant due to uncertainty in parameters such as diagnostic spectrum, sensitivity, specificity, and variability of laboratory conditions [5, 11]. By integrating these elements within a unified modeling framework, VOI analysis provides a basis for comparing diagnostic technologies as laboratory tools and for optimizing their use under resource constraints [11].

Therefore, the aim of this study was to develop and apply a pharmacoeconomic modeling framework incorporating value of information analysis to evaluate diagnostic technologies for the etiological diagnosis of viral respiratory infections from a laboratory perspective and to support economically justified selection of diagnostic tools.

Materials and Methods

1. Study design

This study develops a pharmacoeconomic methodology for comparing two diagnostic technologies for respiratory viral infections: immunochromatographic rapid tests and PCR-based diagnostics. Both have gained wide clinical adoption, yet differ substantially in cost, accuracy, and operational characteristics. The analysis was conducted within the Ukrainian healthcare setting, a middle-income country with functional molecular diagnostic infrastructure that nonetheless operates under significant budget constraints, further compounded by the ongoing Russian full-scale invasion.

The analytical framework proceeds in three sequential steps. First, a multi-criteria utility assessment derives utility values for each technology through structured expert elicitation across four criteria: automation, time, reproducibility, and accessibility. Each expert independently assigns weights and scores to each criterion, and the values are aggregated across the panel. Second, a decision-tree model estimates the expected utility of each technology as a function of sensitivity, specificity, diagnostic spectrum, and expert-derived utility values. Diagnostic spectrum sets the prior probability of a positive result, while sensitivity and specificity determine the distribution of true- and false-positive outcomes, each weighted by the corresponding utility value. Third, a probabilistic simulation propagates parameter uncertainty across all model inputs to calculate cost-utility and value of information metrics, specifically EVPI, EVPPI, and EVSI. Beta distributions are fitted to proportional parameters (sensitivity, specificity, diagnostic spectrum, utility), and gamma distributions to cost parameters, with distribution shape derived from empirical means and standard deviations. All proportional parameters are bounded within [0, 1], while cost parameters are strictly positive.

2. Multi-criteria cost-utility framework

The use of pharmacoeconomic analysis in the practice of laboratory medicine is substantiated in cases that involve a comparison of two or more diagnostic technologies and the choice of a more appropriate (acceptable) technology of laboratory diagnostics, considering their utility and cost [12].

Different levels for evaluating the utility of etiological diagnostic technologies demonstrate that performance at each lower level is logically necessary, but not sufficient, to ensure performance at higher levels. These levels in ascending order of importance are:

- technical quality
- accuracy, sensitivity, specificity
- the influence of diagnostic results on the doctor's diagnostic thinking
- the impact on clinical management of viral disease
- the impact on social costs and benefits.

Achieving the maximum effect from use of a diagnostic test is possible under the condition of finding a balance between the indicators of three areas that partially overlap: the productivity of etiological diagnostic methods, features of the epidemiology of a viral disease, and costs (Fig. 1)

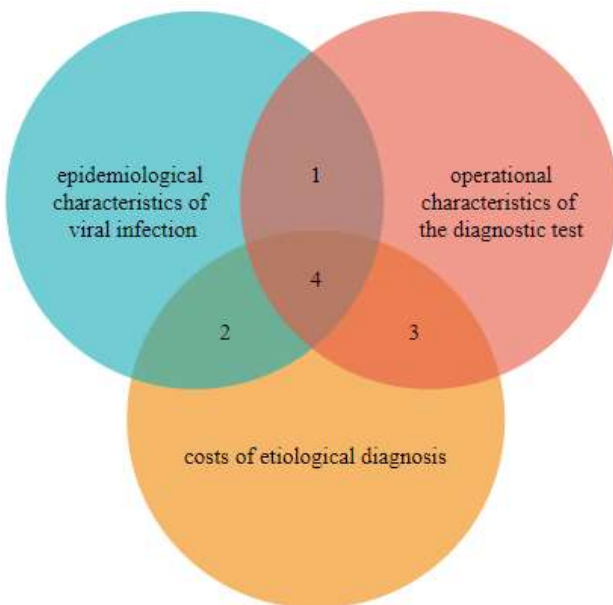


Figure 1: Balance between indicators of the productivity of the technology for etiological diagnosis, the epidemiology of the viral agent, and costs

The main operational characteristics of diagnostic technologies are sensitivity, specificity, reproducibility, accuracy, quality control and turnaround time. Most clinical and diagnostic laboratories strive to maximise these indicators, thus specialists sometimes tend to focus on these indicators alone. This approach was considered sufficient in the past, but budget con-

straints today require a broader examination of the problem [13]. The second important area is the epidemiological characteristics of viral disease, which are determined by its prevalence, the presence of clinical symptoms, and demographic, behavioural and clinical risk factors. The intersection of operational characteristics of etiological diagnostics and epidemiology (Fig. 1, section 1) determines requirements for the timing of sample collection and its type. The third major area is the cost of diagnostic tests. The intersection of diagnostic costs and epidemiological characteristics (section 2) determines the possibility of disease prevention. The intersection of cost and productivity (section 3) determines the requirements for equipment, its throughput, material resources and correspondingly qualified personnel. The intersection of all three areas determines the utility of spending (section 4). A balanced model of this kind for evaluating modern diagnostic technologies is especially appropriate for the identification of infectious agents based on PCR, ligase chain reaction, the use of biochips etc. Since such diagnostics are fairly expensive, the question of their cost-effectiveness naturally arises.

The criteria for the utility of diagnostic technologies are their operational characteristics of sensitivity, specificity and numerous other indicators based on the statistical analysis of datasets of clinical and laboratory studies [14]. Statistical analysis in the etiological diagnostics of viral infections in particular, and in laboratory medicine in general, is one of the tools for analysing laboratory data, as well as the language used to express research results. However, for a practical virologist, it is also necessary to improve knowledge dynamically about some aspects of the interpretation of operational characteristics of the utility of diagnostic tests and their interrelationships. Evaluating the utility of various diagnostic technologies relies on several operational characteristics based on statistical analysis and arranged into three groups that determine diagnostic (or analytical) accuracy, clinical accuracy and clinical utility.

The main operational characteristics that determine the diagnostic accuracy of a laboratory test include diagnostic sensitivity (Se), diagnostic specificity (Sp) and accuracy (Ac). The diagnostic utility of a laboratory test is one of the key elements of decision-making regarding the need for further diagnosis, monitoring and forecasting of viral disease development. Today, statistical analysis is widely used for diagnostic purposes, solving classification tasks, identifying new regularities, and advancing new scientific hypotheses. Sensitivity, specificity and accuracy are statistical indicators of the utility of a certain diagnostic test. The utility of predicting the presence of a viral infection or disease can be improved by enhancing these characteristics, and therefore the quality of management decision-making in diagnosing and treating patients

improves, thus reducing the burden on the healthcare resources available [15].

Until recently, it was believed that achieving the maximum sensitivity and specificity of diagnostic tests were sufficient criteria of medical utility for their implementation in healthcare practice. Nowadays, determination of the usefulness (utility) of the methods of etiological diagnosis of viral pathogens is much wider, which requires continually providing the practising physician with up-to-date information. In early works on cost-effective technologies in laboratory diagnostics, the usefulness of the method was assessed as the proportion of correctly diagnosed people, i.e. the sum of the proportions of true-positive and true-negative results [16].

The level of utility of any medical (particularly diagnostic) technology from the point of view of laboratory diagnostics can be determined using qualitative and quantitative indexing of criteria and gradation scales. Depending on the requirements and purpose of the laboratory research, the utility of the diagnostic test considers its reproducibility, availability, time spent on diagnostics, the possibility of automating the process, and other indicators. In this case, the expert assessment is a table in which a virologist or other expert assigns a certain weight (w_i) and score (r_i) from 1 to 5 for a certain diagnostic technology to each utility criterion (Tab. 1).

According to the expert judgment, the utility of the actual diagnostic results is determined by formula (1):

$$U_i = \frac{w_{1i}r_{1i} + w_{2i}r_{2i} + w_{3i}r_{3i} + w_{4i}r_{4i}}{r_{\max}} \quad (1)$$

At the same time, the utility of false-positive and false-negative diagnostic results is considered to be zero. In the case where the utility U_i is evaluated by several of k involved experts, after calculating the utility according to the table completed by each expert, the average utility of the diagnostic technology is calculated according to the opinions of all the experts involved (2):

$$\underline{U} = \frac{\sum_i^k U_i}{k} \quad (2)$$

The root-mean-square deviation σ is an indicator of the degree of dispersion of utility values around its average value, i.e. the degree of consistency of expert judgments in evaluating a certain diagnostic technology by all utility indicators such as variance (D) and standard deviation (σ) (3, 4):

$$D = \frac{\sum_i^k (U_i - \underline{U})^2}{k} \quad (3)$$

$$\sigma = \sqrt{D} \quad (4)$$

As a tool for analysing the expected utility of etiological diagnosis in the presence of incomplete or insufficiently reliable clinical and laboratory information, a diagnostic method has been proposed. This method is based on the construction of a probabilistic decision-tree model similar to that used in cost-utility analysis [17, 18]. The branches of the tree represent alternatives of events (diagnostic results) with certain probabilities of the occurrence of these events and the final result (usefulness of each result) (Fig. 2).

Table 1: Multi-criteria analysis of the medical utility of diagnostic technologies

Indicator	Weight of the indicator w_i	Assigned mark r_i
Reproducibility: poor reproducibility - 1, excellent reproducibility - 5	w_{1i}	r_{1i}
Accessibility: low availability - 1, high availability - 5	w_{2i}	r_{2i}
Working time costs: high expenses - 1, low expenses - 5	w_{3i}	r_{3i}
The possibility of automating the process: automation is impossible - 1, the process is fully automated - 5	w_{4i}	r_{4i}

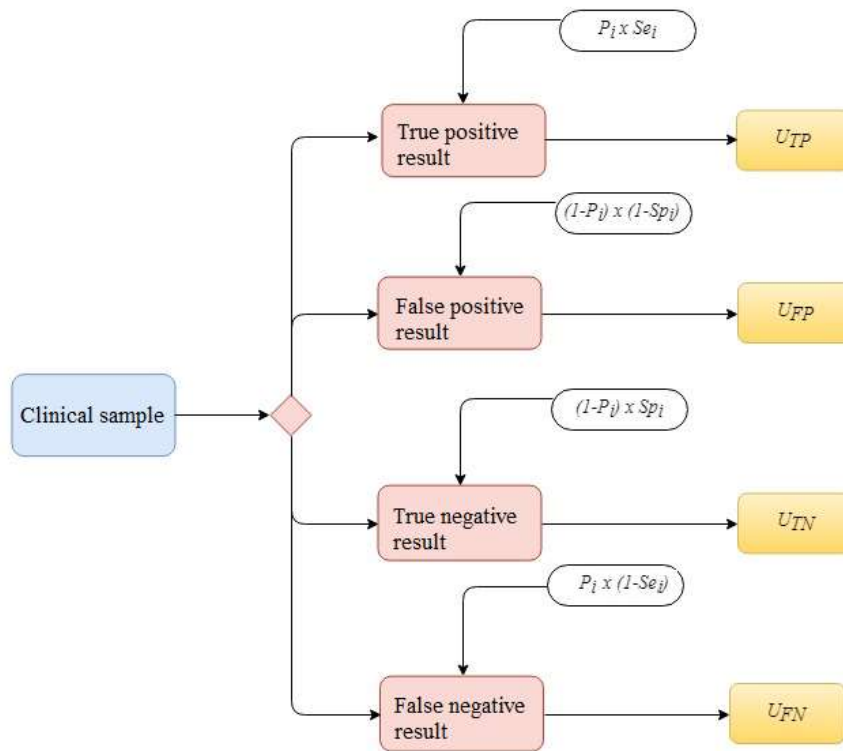


Figure 2: Decision-tree model of the expected utility of diagnostic technology

The decision tree framework was selected as the primary analytical approach for several reasons. First, it explicitly models the sequential nature of diagnostic decision-making and allows transparent representation of diagnostic pathways. Second, it facilitates integration of expert-derived utility assessments across multiple criteria (automation, time, reproducibility, accessibility) that extend beyond simple diagnostic accuracy metrics. While alternative approaches such as Markov models could capture long-term disease progression and treatment pathways, the decision tree framework was deemed most appropriate for this analysis focused on the immediate diagnostic decision episode, given data availability and the objective of establishing a methodological foundation for diagnostic technology evaluation applicable across diverse healthcare contexts.

In such a model, the criteria are the diagnostic spectrum of the diagnostic technology (P), the sensitivity of the diagnostic technology (Se), the specificity of the diagnostic technology (Sp), the utility of a true-positive diagnostic result (U_{TP}), the utility of a false-positive diagnostic result (U_{FP}), the utility of a true-negative diagnostic result (U_{TN}) and the utility of a false-negative diagnostic result (U_{FN}). The determination of the expected utility result (EU) based on the constructed tree of alternatives, as the sum of products of efficiencies is decisive in the results of diagnostics and their corresponding probabilities (5):

$$EU = P_i \cdot Se_i \cdot U_{TP} + (1 - P_i) \cdot (1 - Sp_i) \cdot U_{FP} + (1 - P_i) \cdot Sp_i \cdot U_{TN} + P_i \cdot (1 - Se_i) \cdot U_{FN} \quad (5)$$

In addition to expected utility, direct medical and non-medical costs should be considered when analysing diagnostic technology. Indirect costs in this case are not usually considered. Direct medical costs include all costs of a clinical diagnostic laboratory, e.g. the cost of the purchase and storage of diagnostic test systems, payment for the work undertaken by the doctor, laboratory technician and other personnel, costs related to the use of medical equipment, space, facilities etc [19]. To determine the amount of direct costs for the use of each diagnostic technology in monetary terms, it is sensible to use the following sources of information:

- tariffs for diagnostic test systems valid in a certain region
- the cost of diagnostic services of a specific institution
- prices of paid diagnostic services within the limits of one or another commercial activity
- average tariffs of several diagnostic centres (at least 3-5, with justification for their choice)
- the results of economic calculations of prices of diagnostic services (with a description of the calculation methodology).

To determine the direct costs for diagnostic tests in monetary terms, the manufacturer's retail prices

and the wholesale prices of distributor companies (at least 3-5 distributors, with justification for their choice) are used. Average price indicators should be used in the analysis.

In the practice of a diagnostic laboratory, it is often possible to choose a diagnostic test for the diagnosis of a certain viral disease from several available. It becomes appropriate to compare the ratios of expected utility and costs in the case of using each diagnostic technology and then choose the one that gives the lowest ratio. The basis of the study is the determination of indicators that affect the utility of the diagnosis of respiratory viral infections and the costs of using each technology, which is the “cost-utility” method.

The development of methods and models of the economic utility of technologies for the etiological diagnosis of viral infections is based on the above Venn diagram (Fig. 1) and the aggregation into a single methodology of epidemiological indicators, operational characteristics of diagnostic technologies, and costs associated with their use. The ultimate goal of an analysis methodology of this kind is to perform numerical modelling based on the principles of pharmacoeconomic analysis and to determine pharmacoeconomically justified rules for the optimal choice of etiological diagnosis technology (Fig. 3).

These calculations use utility and cost data to determine the “cost-utility” ratio of the diagnostic technology, i.e. the cost of a unit of utility provided by the compared technologies (6):

$$CUR(P_i, Se_i, Sp_i) = \frac{Cost_i}{EU(P_i, Se_i, Sp_i)} \quad (6)$$

where is CUR is a cost-benefit ratio; $Cost_i$ is the expenses for the i th diagnostic technology etc.; EU_i is an indicator of the expected efficiency of the i th diagnostic technology; P_i is the diagnostic spectrum of a labor-

atory test; Se_i is the sensitivity of the laboratory test; Sp_i is the specificity of the laboratory test.

From the point of view of the “costs utility” method, pharmacoeconomic diagnostic technology can be recognised as:

- “dominant” if it demonstrates better utility at lower costs, i.e. it is characterised by a lower value of the “cost-utility” ratio and cost savings compared with other technologies

- “effective” in the case when the diagnostic technology with a lower value of the “cost-utility” ratio involves spending more funds than other alternatives, but demonstrates better diagnostic utility or vice versa

- “useless” if the diagnostic technology has a greater value of the “cost-utility” ratio with lower diagnostic utility.

The value of CUR_i (CUR_i) decreases with an increasing sensitivity or specificity of the diagnostic test. Therefore, if a diagnostic technology is more effective in some of these prevalence intervals relative to its costs, then it is dominant and better than others.

Extending the decision-making analysis, the sequence of use of the two diagnostic tests is considered. Since the first diagnostic test is used for all individuals and the second is used for a certain subgroup of patients, and if diagnostic costs are considered during diagnosis, it is important to decide which test to use first. All things being equal, using the more expensive test first is disadvantageous and it is therefore expected that the decision maker should commence the diagnosis with the less expensive test. This reflects the benefits of using a specific test first, as a negative diagnostic result will not be verified. Thus, such an indicator can be interpreted as a ratio of the costs and benefits of using a certain test in the first place. The lower this ratio, the more likely it is that such a test will be used first.

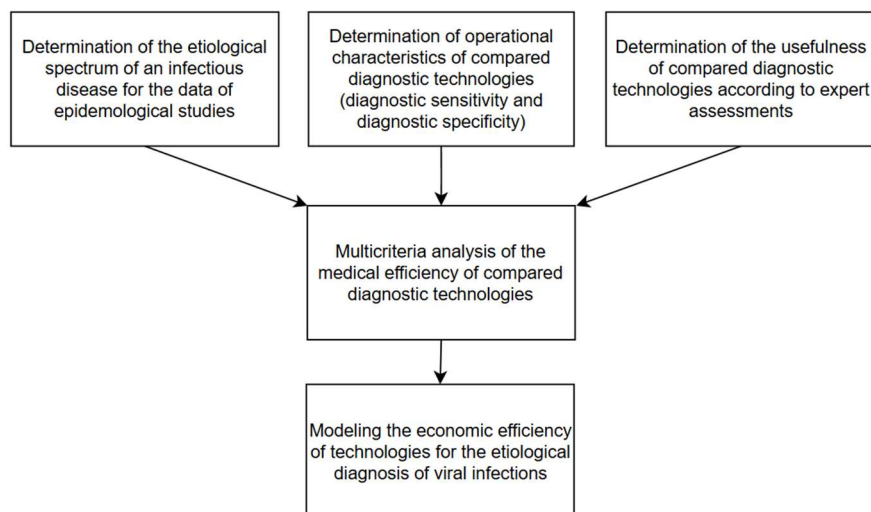


Figure 3: Algorithm for modelling the economic utility of technologies for the etiological diagnosis of viral infections

The basis of pharmacoeconomic analysis helps to solve the inverse problem, namely it answers the question of which cost ratio is the limit when choosing one diagnostic technology over another. The *i*th diagnostic technology is more acceptable than the *j*th provided that (7, 8):

$$CUR_i < CUR_j \quad (7)$$

$$\frac{Cost_i}{EU_i} < \frac{Cost_j}{EU_j} \quad (8)$$

and it is possible to formulate a model of economic utility and diagnostic technology based on known values of expected utility for both compared technologies (9):

$$\frac{Cost_i}{Cost_j} < \frac{EU_i}{EU_j} \quad (9)$$

where $Cost_i$ and $Cost_j$ are the costs of the relevant diagnostic technologies (*i*) and (*j*); EU_i , EU_j – the overall utility of the respective analytical strategies (1) and (2) is determined.

3. Value of information analysis

Value of information analysis is a methodology that allows quantifying the expected benefit of minimizing the uncertainty during the decision-making process through additional research, improved data collection, or more precise parameter estimation. Such an evaluation identifies the parameters that contribute the most to the decision uncertainty, highlights possible areas of improvement, further research directions, or otherwise confirms that the current decision is optimal and that subsequent attempts at reducing the uncertainty will not yield any substantial benefit

The objective is to evaluate the worth of resolving uncertainty in choosing between PCR and rapid immunochromatographic diagnostic tests, taking into account variability in diagnostic test sensitivity and specificity, diagnostic spectrum, costs, and utility values. This approach provides a more comprehensive understanding of decision uncertainty and potential benefits from further research.

The stochastic simulation model was used to simulate 10000 individual-level iterations. The simulated population was considered symptomatic individuals presenting for diagnostic testing during a respiratory infection season. Empirical data on diagnostic test costs and diagnostic spectrum were used to parameterize the model with realistic and context-specific inputs.

Based on data gathered from the Public Health Center of Ukraine [20], diagnostic spectrum estimates were calculated, summarizing diagnostic outcomes across different pathogens and time periods. The pro-

portion of positive samples was calculated for all pathogens for each test. The data were restricted to span from week 40 to week 20 for each year from 2019 to 2023. This timeframe is consistent with the typical seasonal period for the analysed illness. The diagnostic spectrum was averaged across these five years.

Diagnostic accuracy parameters were integrated into the model to reflect the reliability of each test in distinguishing between infected and uninfected individuals. Estimates for sensitivity and specificity were obtained from peer-reviewed studies on the clinical performance of PCR and rapid antigen tests in diverse healthcare settings [21, 22].

To capture the variability and uncertainty in these parameters, beta distributions were applied, which are appropriate for proportions derived from binary outcomes. The distribution parameters were derived using the mean and standard deviation values, allowing for the modeling of the expected range of diagnostic outcomes.

Estimates of diagnostic utility, reflecting the perceived value of correct test-based decision-making, were obtained through expert elicitation. Laboratory specialists provided their judgments on the relative utility of accurate diagnoses for each testing modality, and these values were used to define beta distribution parameters for probabilistic analysis.

The expected utility of each diagnostic strategy was calculated by combining the sampled sensitivity, diagnostic spectrum (as prevalence), and utility values in each iteration taking into account only the positive test results (10):

$$EU = P \cdot Se \cdot U_{TP} \quad (10)$$

where EU is the expected utility of *i* technology; P is the diagnostic spectrum of *i* technology; Se is the sensitivity of *i* technology; U_{TP} is the utility of a true-positive diagnostic result.

The usefulness of U_{FP} and U_{FN} outcomes was considered to be zero, that reflects the assumption that the absence of the direct therapeutic benefit from incorrect diagnostic outcomes. This assumption reflects a laboratory-centered analytical framework, where the primary value of diagnostics lies in pathogen detection rather than in downstream clinical decision-making, which is beyond the scope of the present model. The simulated population consists of symptomatic individuals, which underlines that the primary clinical value lies in confirming the presence of the pathogen rather than excluding it. Thus, the U_{TN} was set to zero and the main analytical focus was centered on the true positive outcomes.

In order to apply the VOI evaluation, both the economic value and the technology efficiency must be accounted for in the unified metric. The introduction of NMB enables direct comparison of both

technologies in the same units. This method allows interpreting health outcomes in terms of monetary worth and provides a direct comparison of cost-effectiveness across interventions. For each simulation, the following formula was used to evaluate NMB (11):

$$NMB = \frac{EU_i}{EU_j} \cdot Cost_j - Cost_i \quad (11)$$

where is EU_i , EU_j are the expected utilities of i and j technology respectively; $Cost_i$, $Cost_j$ are the costs of i and j technology respectively.

This approach simplifies decision-making under uncertainty by evaluating the relative efficiency of two diagnostic technologies. It estimates whether the relative effectiveness per unit cost of strategy i exceeds that of strategy j . A positive NMB value indicates that PCR-based diagnostics (technology i) offer a more favorable cost-utility profile compared to rapid tests (technology j).

To quantify the value of eliminating decision uncertainty, EVPI was calculated (12). EVPI represents the maximum amount a decision-maker should be willing to pay for additional information that would perfectly resolve current uncertainties in model parameters. It reflects the potential benefit of further research or improved data quality before committing to a specific intervention.

The EVPI was computed by comparing the expected NMB under current uncertainty with the NMB that could be achieved if all uncertainties were resolved. Mathematically, this is expressed as (12):

$$EVPI = E[(NMB_{PCR}, NMB_{Rapid})] - (E[NMB_{PCR}], E[NMB_{Rapid}]) \quad (12)$$

A higher EVPI indicates greater decision uncertainty and a stronger justification for further data collection. It can be interpreted as the current expected opportunity loss associated with making the decision under uncertainty. In other words, it is the monetary value of the potential harm that is caused by the selection of a suboptimal diagnostic technology. Taking into account the assumptions of the current model, this value represents the maximum expected benefit that could theoretically be gained by resolving all parameter uncertainty simultaneously. Accordingly, EVPI provides a practical reference point for evaluating whether further data collection can improve the decision-making quality. If the anticipated cost of a proposed study approach or exceeds this value, additional research may offer limited economic benefits.

The value of EVPI is also dependent upon the probability of an incorrect current decision, considering existing evidence. If the distribution of NMB is mostly concentrated in positive areas, suggesting that

the preferred technology is outperforming the alternative in all scenarios, then it implies that the expected opportunity loss of the current decision is low, and therefore EVPI is also low. On the other hand, an NMB distribution with significant overlap with zero suggests uncertainty in the current decision and, therefore, a potentially higher value of additional information. This relationship between the distribution of NMB and EVPI offers an intuitive rationale for understanding VOI results in conjunction with simulation-based results.

To assess the value of resolving uncertainty in specific parameters prior to making a diagnostic decision EVPPI was calculated. EVPPI quantifies the expected gain in decision quality that would result from knowing the true value of a subset of uncertain parameters, while keeping all other parameters uncertain. In contrast to EVPI, which assumes full resolution of uncertainty, EVPPI focuses on the impact of learning only a specific part of the model.

EVPPI provides a monetary estimate of how much value would be generated if selected model inputs were known with certainty. This allows identification of the most influential parameters and supports prioritization of targeted future research. The EVPPI is calculated as (13):

$$EVPPI(\varphi) = (E[\varphi]) - (E[NMB]) \quad (13)$$

where is φ represents a subset of the uncertainty parameters for which we aim to obtain additional information

To assess the potential benefit of conducting additional research prior to implementing a diagnostic strategy EVSI was calculated. EVSI quantifies the expected improvement in decision-making that would result from obtaining new, but imperfect, information — such as the outcomes of a proposed study with finite sample size. Unlike the EVPI, which assumes complete resolution of all uncertainty, EVSI models the effect of partial uncertainty reduction through additional data. EVSI provides a monetary estimate of how much value a specific future study could bring by refining parameter estimates and improving the expected NMB of the decision.

In practice, EVSI is approximated using simulation. For each simulation a new dataset is generated, a posterior distribution is formed, and the corresponding updated NMB is computed. The EVSI is calculated as (14):

$$EVSI(n) = \frac{1}{S} \sum_{s=1}^S (NMB_{(s, posterior)}) - (E[NMB]) \quad (14)$$

where is n is the proposed sample of the future study; S is the number of simulations; $NMB_{(s, posterior)}$ is the

NMB in simulation s using posterior parameter estimates.

This formulation allows decision-makers to estimate the monetary value of a study of size n , enabling prioritization of research efforts and assessment of the return on investment in further evidence generation.

In general, VOI analysis follows the sequential decision process: if the current average NMB is positive, the chosen technology should be implemented in consideration of the current evidence. The evaluation of the necessity to conduct further studies is made separately by comparing the expected value of the information against the cost of the information. In the scenario when the degree of uncertainty in the values of the model parameters is low enough that no possible study will be able to provide decision value greater than the study costs, the current evidence is deemed adequate for decision-making.

Results

The proposed information and analytical models for evaluating the economic effectiveness of diagnostic technologies were implemented as part of the cycle of thematic improvement “Laboratory diagnosis of HIV infection, viral hepatitis B, C, D, herpes virus infections” at Shupyk National Healthcare University of Ukraine. The experts in the cycle were the heads of diagnostic laboratories and virologists who were asked to evaluate the diagnostic effectiveness of immunochromatographic rapid tests and molecular genetic technologies based on PCR, which are used in the diagnosis of acute viral infections.

Five randomly selected experts were asked to determine the main indicators of diagnostic technologies. These were the possibility of automation, time spent, accessibility and the reproducibility of the method. Each expert independently determined the weight of each indicator from 0 to 1, evaluated each diagnostic technology according to these indicators, and calculated the diagnostic utility of rapid tests and the PCR method for diagnosing acute viral infections (Tab. 2).

The convergence of the experts’ opinions was evaluated on the basis of the variance and root-mean-square deviation of the calculated values of diagnostic utility (Tab. 3).

The dispersion of the values of expert opinions regarding rapid tests was determined to be ~9.8 %, and for the PCR method ~19.9 %, i.e. the experts’ opinions of the diagnostic utility of rapid tests coincided by approximately 90 %, and the expert’s opinions’ of the diagnostic efficiency of the PCR method was about 80 %. These findings show that experts’ opinions were more consistent when assessing the diagnostic utility of rapid tests than the PCR methods. This was explained by the fact that not all experts used the PCR

method during their work. The diagnostic utility assessments were used to evaluate the cost-effectiveness of selected technologies for the diagnosis of acute respiratory viral infections.

The laboratory-reported sensitivity and specificity data were incorporated into the decision-making model to further characterize diagnostic performance. The parameters were used for modeling the diagnostic accuracy and estimating the overall utility of the examined diagnostic methods. The following table presents the average metrics for sensitivity and specificity parameters for PCR and rapid tests (Tab. 4).

The probabilistic VOI analysis yielded a comprehensive picture of the economic performance of PCR and rapid diagnostic testing under uncertainty.

The data on the costs was collected by the authors in May-June 2025. The data was collected from publicly available online sources. The sources of the data were the official websites of Ukrainian private diagnostic laboratory networks such as Dila, Synevo, CSD, Biopharma, and regional diagnostic centers in various regions of Ukraine. In total, the data was collected from 10 sources for PCR-based diagnostic tests and 9 sources for rapid antigen tests. The data was initially in Ukrainian hryvnias and was converted into United States dollars at the official rate quoted by the National Bank of Ukraine. The values reported reflect the prices for PCR (Fig. 4) and rapid antigen tests (Fig. 5) as performed in real-world settings.

For this study, cost data were collected specifically from the Ukrainian healthcare market. The prices of diagnostic tests were modeled using gamma distributions to account for observed variability. For PCR tests, the price was modeled as a gamma distribution $\Gamma(\alpha_1, \beta_1)$, where the shape (α_1) and scale (β_1) parameters were calculated based on the empirical mean of 32.07 and standard deviation of 10.65. Similarly, rapid test prices were modeled as $\Gamma(\alpha_2, \beta_2)$, using the corresponding mean of 12.60 and standard deviation of 5.21.

Rapid tests were more affordable on average but had high standard deviation indicating considerable price variability. The prices of PCR tests were more expensive and showed even wider range of prices.

Variability in prices observed for both tests could be attributed to the differences in procurement channels or the number of pathogens, market fluctuations, regional pricing policies or other included services such as sample collection and result interpretation. These descriptive statistics were used as parameters to define gamma cost distributions which were used in probabilistic simulations.

The graphs were built for the diagnostic spectrum, where the weekly proportion of positive results across five epidemic seasons was displayed. In the following data, rapid tests (Fig. 6) were used only to detect adenoviruses. In contrast, PCR tests (Fig. 7)

Table 2: Determining diagnostic utility by semantic differential

Indicator	Rapid tests		PCR method	
	Indicator weight w_i	Awarded score r_i	Indicator weight w_i	Awarded score r_i
EXPERT 1				
Possibility of automation	0.1	1	0,3	5
Working time costs	0.1	1	0.3	5
Accessibility	0.4	3	0.1	5
Reproducibility	0.4	5	0.3	5
Calculated utility	0.68		1.0	
EXPERT 2				
Possibility of automation	0.1	1	0.2	5
Working time costs	0.3	3	0.4	4
Accessibility	0.3	3	0.1	1
Reproducibility	0.3	3	0.3	3
Calculated utility	0.56		0.43	
EXPERT 3				
Possibility of automation	0.1	2	0.3	5
Working time costs	0.4	5	0.2	5
Accessibility	0.3	4	0.2	3
Reproducibility	0.2	4	0.3	4
Calculated utility	0.84		0.86	
EXPERT 4				
Possibility of automation	0.1	5	0.2	4
Working time costs	0.5	5	0.2	4
Accessibility	0.2	2	0.4	2
Reproducibility	0.2	3	0.2	3
Calculated utility	0.80		0.60	
EXPERT 5				
Possibility of automation	0.1	5	0.2	5
Working time costs	0.3	5	0.2	2
Accessibility	0.2	2	0.4	3
Reproducibility	0.4	3	0.2	4
Calculated utility	0.72		0.76	

Table 3: Average value of diagnostic utility and assessment concurrence of experts' opinions

Expert	Rapid tests			PCR method		
	Diagnostic utility u_i	$u_i - \bar{u}$	$(u_i - \bar{u})^2$	Diagnostic utility u_i	$u_i - \bar{u}$	$(u_i - \bar{u})^2$
1	0.68	-0.04	0.0016	1.0	0.26	0.0676
2	0.72	0	0	0.76	0.02	0.0004
3	0.8	0.08	0.0064	0.6	-0.14	0.0196
4	0.56	-0.16	0.0256	0.48	-0.32	0.1024
5	0.84	0.12	0.0144	0.86	0.12	0.0144
Dispersion	D = 0.01			D = 0.04		
Mean standard deviation - no deviation	$\sigma = 0.098$			$\sigma = 0.199$		

Table 4: Tests sensitivity and specificity parameters

	PCR		Rapid tests	
	Sensitivity	Specificity	Sensitivity	Specificity
Mean	0.9394	0.9893	0.7193	1
Standard deviation	0.0076	0.0013	0.0622	0.0255

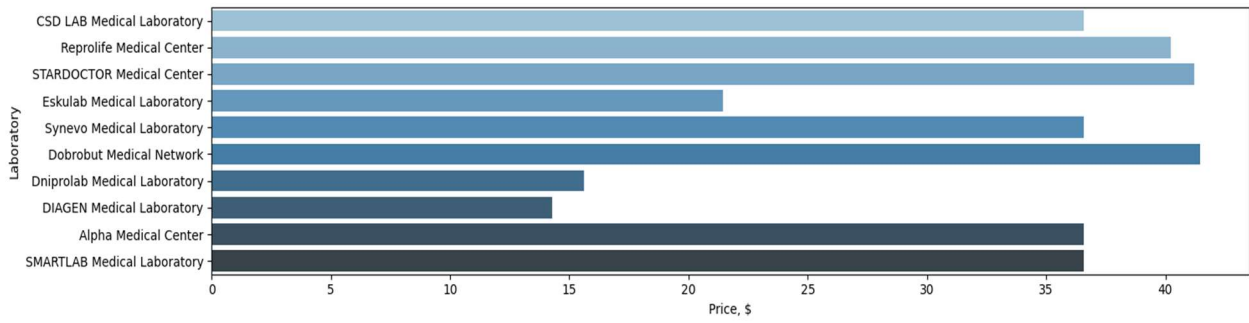


Figure 4: PCR test costs in different Ukrainian diagnostic laboratories

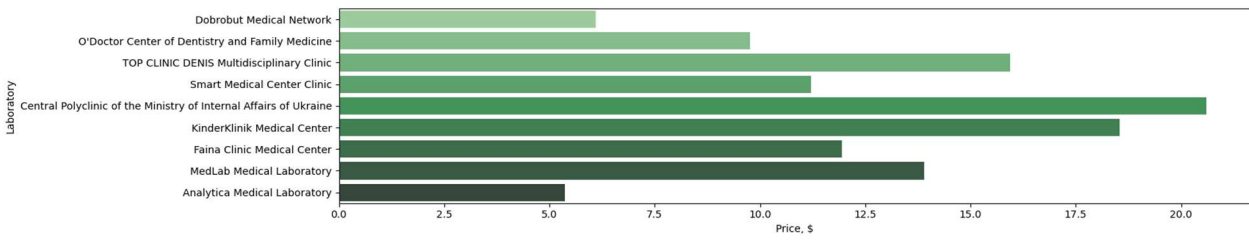


Figure 5: Rapid test costs in different Ukrainian diagnostic laboratories

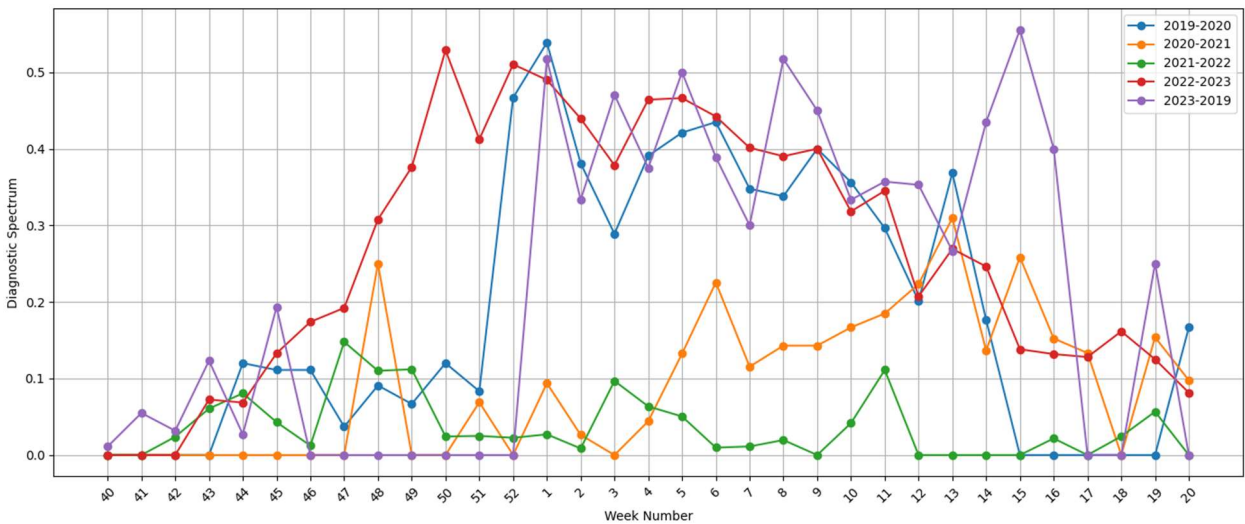


Figure 6: Rapid test weekly diagnostic spectrum

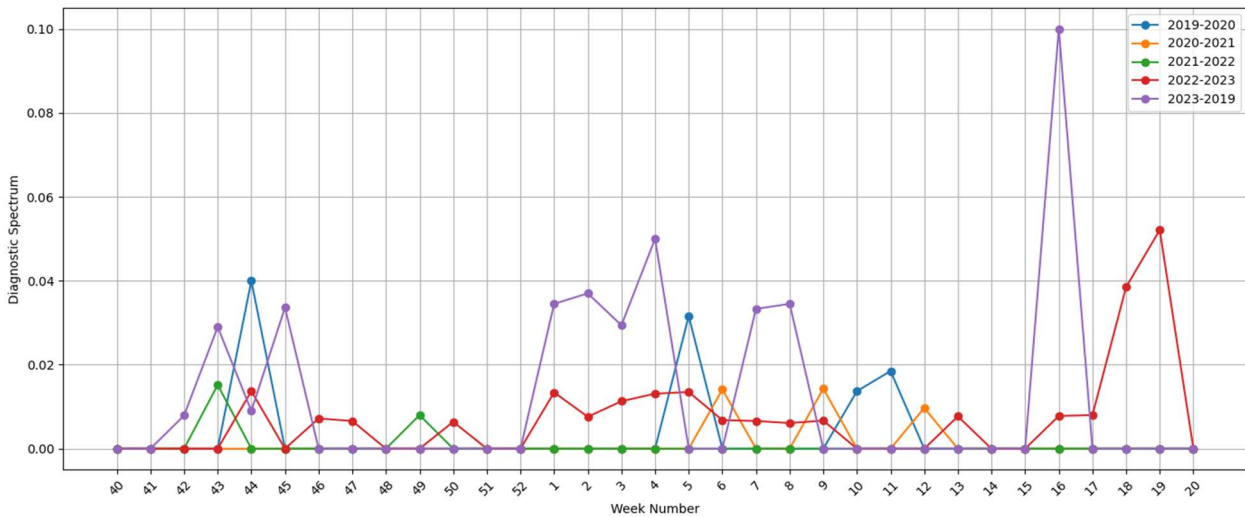


Figure 7: PCR weekly diagnostic spectrum

covered a much broader range of pathogens, including adenoviruses, metapneumoviruses, parainfluenza viruses types 1 – 3, influenza A and B viruses, respiratory syncytial viruses A and B, rhinoviruses A/B, and coronaviruses OC43/HKU1 and 229E/NL63

The average diagnostic spectrum for PCR tests was 0.161, with a standard deviation of 0.0995, indicating a moderate level of positive results and substantial variability across observations. For rapid tests, the average diagnostic spectrum was markedly lower at 0.0048, with a standard deviation of 0.0051. Despite both testing methods demonstrating low average diagnostic spectrum – particularly rapid tests – the observed standard deviations reflect significant heterogeneity in diagnostic outcomes over time or across settings. These fluctuations may be attributed to variations in infection dynamics, tested populations, or differences in testing strategies and operational conditions during the observation period.

The data showed a clear distinction in positivity rates between PCR and rapid antigen tests, indicating the fact that these methods are typically used in populations that have different pre-test probabilities. For the modeling of the test diagnostic spectrum, the beta distribution was used, fitted with mean and standard deviation as the basis for defining the distribution parameters. By basing both cost and diagnostic spectrum parameters on actual observed data from healthcare laboratory reports, the study ensures that its model inputs are directly tied to the operational context in which diagnostic decisions are made.

The performed simulation demonstrated that PCR tests had higher expected utility than rapid tests. This result logically stems from PCR tests having greater sensitivity and broader diagnostic coverage.

Thus, PCR tests were chosen to be the base technology in the following analysis. Negative NMB values would justify switching to rapid tests, whereas positive values support retaining the current practice. For each of 10,000 simulations, NMB was calculated as (15):

$$NMB = \frac{EU_{PCR}}{EU_{Rapid}} \cdot Cost_{Rapid} - Cost_{PCR} \quad (15)$$

The scatter plot was built based on the simulated data (Fig. 8). It illustrates that in the majority of scenarios, most outcomes are positive, indicating that PCR tests have a higher cost-utility value. The average NMB is estimated at approximately \$854 per patient. These results show that the PCR test is the economically favorable option under current uncertainty. In the plot are included only the simulations where the EU ratio is below its 90th percentile to reduce the impact of extreme outliers and improve the graph readability.

NMB was used to determine EVPI in accordance with the formula 12. According to the simulation results, the EVPI was estimated at \$0.25 per patient. This value reflects the monetary worth of resolving all uncertainty around test performance and disease parameters.

The estimated EVPI represents the upper bound on the economic value of further research aimed at reducing uncertainties in this model. With the average NMB favoring the PCR test was approximately \$854, the EVPI constitutes less than 0.03% of the benefit. Such a relationship indicates that the current decision is highly robust and would be unlikely to be reversed even if all model parameters were estimated with perfect precision.

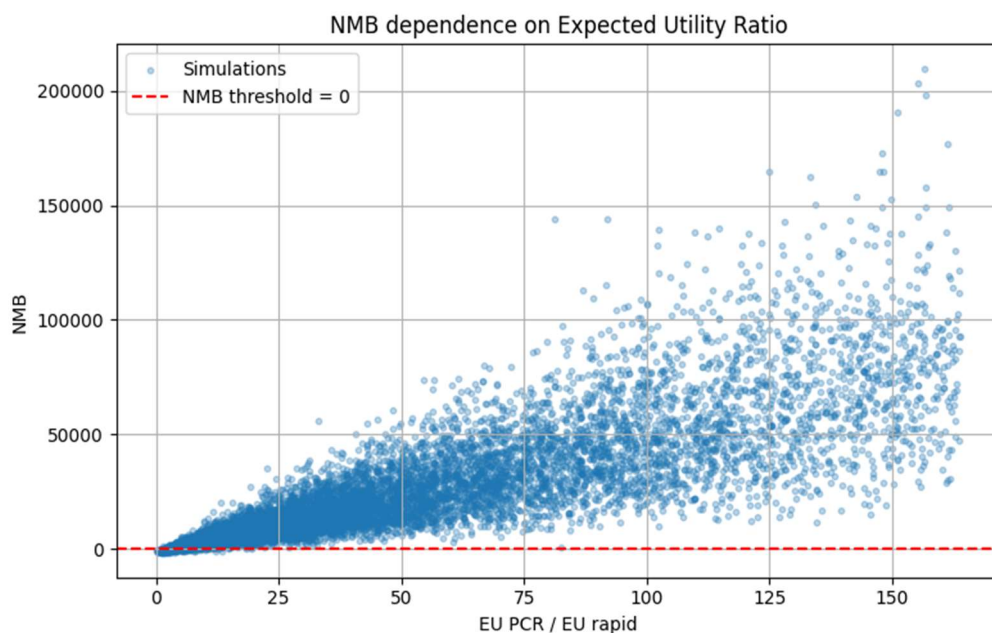


Figure 8: NMB dependence on Expected Utility Ratio

The low values of EVPI shown in the present analysis also correspond with the distribution of NMB values computed in the probabilistic simulations, as demonstrated in Fig. 8. From the scatter plot, it is clear that most of the simulated scenarios fall in the range of positive NMB values, indicating that there is a general advantage of PCR-based diagnostics over rapid tests in the entire range of the parameter space. The EVPI is influenced by the proportion of the NMB distribution that crosses the zero line, indicating scenarios in which the current decision is suboptimal. The correspondence between the results of the probabilistic simulation and the VOI analysis further strengthens the conclusion that uncertainty in the current decision is not significant.

EVPI curve (Fig. 9) shows that at an NMB threshold of \$888.89, EVPI reaches its maximum of \$344. This point represents the highest level of decision uncertainty in this simulation, indicating that further research that would target this threshold would offer the greatest potential value if the uncertainty were to be reduced. The further the NMB threshold moves from this point in either direction, the more EVPI declines. This reflects increased confidence in the preferred decision under those scenarios.

The diagnostic spectrum of PCR tests demonstrated the greatest influence on the modeling out-

comes in the preliminary sensitivity analysis. Hence, it was chosen as the best candidate for the EVPPI analysis. However, the calculated value for EVPPI yielded a near-zero value. This negligible EVPPI indicates that obtaining the perfect information about PCR diagnostic performance would not provide enough meaningful economic benefit for the current decision scenario. These results suggest that even with parameters of substantial theoretical importance to model behavior, the existing uncertainty levels are already acceptable for robust decision-making.

The EVSI has been shown to be highly volatile at small sample sizes, having substantial fluctuations. This variability indicates that the marginal value of information is not well estimated in cases where the sample size is too small to provide adequate statistical power.

EVSI reached its maximum of \$2.69 at a sample size of 40. It shows that collecting additional data beyond this threshold yields diminishing returns. The EVSI subsequently decreases for further sample sizes, indicating that the marginal cost of an additional observation exceeds the marginal benefit of the reduction in uncertainty and thus that extensive data collection is economically inefficient for this specific decision problem (Fig 10).

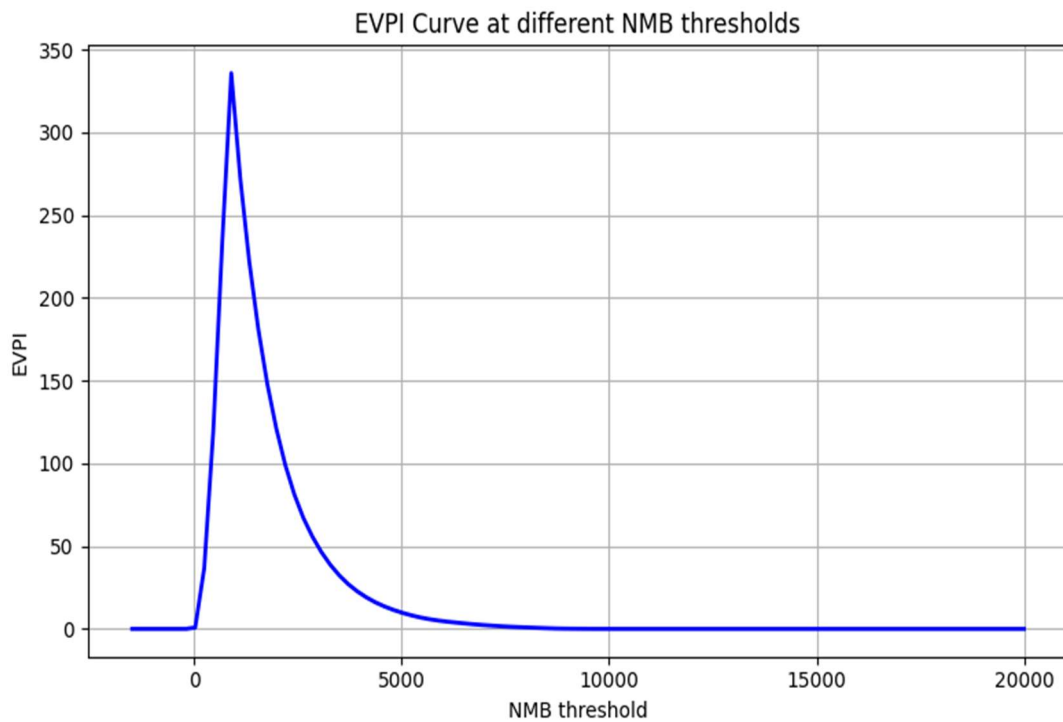


Figure 9: EVPI curve at different thresholds

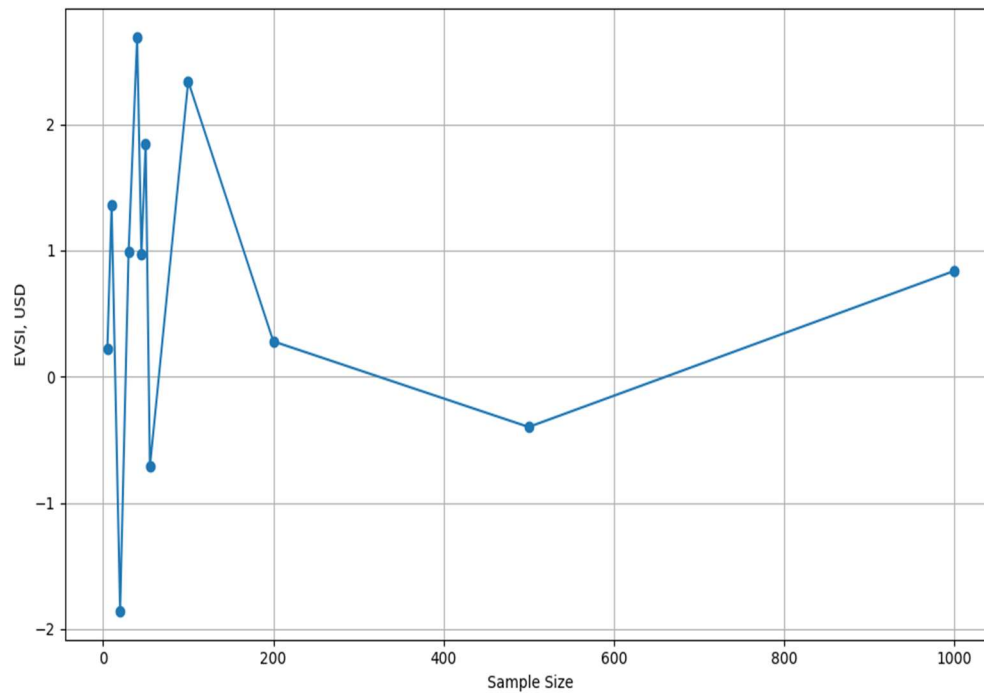


Figure 10: EVSI vs Sample Size. PCR Prevalence

Discussion

The present study contributes to the evolving field of pharmacoeconomic evaluation in laboratory medicine by proposing a multi-criteria framework for assessing the economic utility of diagnostic technologies for viral infections. Early studies in this area primarily focused on the cost-effectiveness of diagnostic interventions within clinical pathways; however, the fundamental principles of economic evaluation are also applicable to laboratory diagnostics as an independent domain of decision-making [23]. The first cost-effectiveness analyses of diagnostic technologies were based on decision-tree models and uncertainty analysis using confidence intervals of model parameters [24]. These approaches laid the foundation for integrating economic considerations into diagnostic decision-making.

Subsequent studies have explored the economic evaluation of diagnostic technologies in various contexts, including malaria screening strategies, tuberculosis diagnostics, and laboratory-based functional testing [25–28]. These studies typically incorporated the costs of diagnostic procedures, treatment interventions, and broader healthcare expenditures, while often placing less emphasis on the intrinsic utility of diagnostic technologies as analytical tools. At the same time, pharmacoeconomic analysis has increasingly been used to support decision-making regarding the implementation of new diagnostic technologies, balancing their benefits and costs within healthcare

systems [29].

One of the central methodological challenges in this field is the choice of appropriate modeling approaches. Randomized clinical trials and simulation models are often considered complementary methods for evaluating cost-effectiveness. Mathematical modeling provides a structured and quantitative framework for integrating clinical, laboratory, epidemiological, and economic data, thereby enabling the analysis of diagnostic technologies under conditions of uncertainty. The reliability of such models depends on their internal consistency, logical structure, and the appropriate representation of event probabilities and outcomes.

The present study proposes a multi-criteria cost-utility framework based on the expected utility of etiological diagnosis of viral infections. This methodology is implemented through a probabilistic decision-tree model, in which each diagnostic outcome is associated with a utility derived from expert judgment, and the probability of each outcome is determined by key analytical parameters of diagnostic technologies, including sensitivity, specificity, and diagnostic spectrum. Unlike traditional approaches, the proposed framework explicitly incorporates operational characteristics of laboratory diagnostics, making it particularly relevant for specialists working in diagnostic laboratories.

A key methodological consideration of this study is the analytical perspective adopted for comparing diagnostic technologies. In clinical practice, rapid

antigen tests and PCR-based diagnostics are often used for different purposes and are not always directly interchangeable within a single decision-making pathway. Rapid tests are typically applied for immediate decision support, particularly in the detection of influenza or SARS-CoV-2, whereas multiplex PCR is frequently used for broader etiological verification and, in some cases, epidemiological monitoring. In contrast, the present study evaluates diagnostic technologies from the perspective of laboratory medicine, where they are considered as analytical tools for etiological detection rather than as direct substitutes in specific clinical scenarios. Within this framework, the comparison focuses on diagnostic spectrum, analytical performance, operational characteristics, and costs. It should also be noted that the modeling assumptions regarding rapid tests reflect the specific dataset used in this study, in which rapid testing was limited to a narrower range of detectable pathogens. This assumption does not fully represent the diversity of rapid diagnostic technologies currently available in clinical practice and should be interpreted as a scenario-specific modeling constraint rather than a generalizable conclusion.

The probabilistic value of information (VOI) analysis provides additional insight into decision-making under uncertainty. By incorporating variability in diagnostic performance, costs, and diagnostic spectrum, the model enables a comprehensive assessment of the economic value of competing diagnostic technologies. The results indicate that PCR-based diagnostics demonstrate higher expected utility within the defined modeling framework, primarily due to their broader diagnostic coverage and higher analytical sensitivity.

At the same time, rapid tests retain important advantages, including lower costs, shorter turnaround time, and greater accessibility, which may be critical in specific laboratory workflows or resource-constrained settings. However, within the assumptions of the current model, these advantages were insufficient to compensate for the lower expected utility associated with a narrower diagnostic spectrum. The Net Monetary Benefit (NMB) analysis demonstrated that PCR-based diagnostics represent the economically favorable option under current parameter distributions, with an average incremental benefit of approximately \$854 per patient. The relatively low Expected Value of Perfect Information (EVPI) (approximately \$0.25 per patient) indicates limited decision uncertainty, suggesting that additional data collection would provide only marginal economic benefit in this context. The low EVPI and the plateau observed in EVSI values further support the conclusion that the current level of evidence is sufficient for decision-making within the defined model.

Several limitations of the study should be

acknowledged. First, the analysis is conducted from a laboratory perspective and does not explicitly incorporate downstream clinical outcomes or treatment effects. Second, the diagnostic spectrum of rapid tests was constrained by the available dataset, which may not fully reflect real-world diagnostic practice. Third, the use of expert elicitation introduces a degree of subjectivity, although consistency between expert assessments was evaluated. Finally, the utility assessment focused diagnostic value on correct positive outcomes, which represents a simplifying assumption that future iterations of the methodology should address by incorporating utility estimates across all diagnostic outcomes.

Future research should extend this framework by incorporating distinct clinical and epidemiological use cases of diagnostic technologies, including the role of rapid tests in immediate patient management and the application of multiplex PCR in surveillance systems. Expanding the range of diagnostic technologies and integrating patient-level outcomes would enhance the generalizability and practical applicability of the model. Overall, the findings demonstrate that the integration of multi-criteria cost-utility analysis with value of information methods provides a robust and flexible approach for evaluating diagnostic technologies in laboratory medicine. This framework supports evidence-based and economically justified selection of diagnostic tools while explicitly accounting for uncertainty in key parameters.

Conclusions

The growing role of etiological diagnostics of viral infections in laboratory medicine requires a robust evidence base for evaluating the economic implications of implementing diagnostic technologies. The results of such evaluations are essential for supporting informed managerial decisions in diagnostic laboratories and healthcare systems, particularly under conditions of limited resources. In this study, a multi-criteria model for assessing the economic utility of etiological diagnostic technologies was developed. The model integrates key analytical characteristics of diagnostic technologies, including sensitivity, specificity, and diagnostic spectrum, with operational and economic parameters, as well as utility values derived from expert judgement. Within this framework, a general decision rule was proposed, according to which a diagnostic technology can be considered economically justified if the ratio of its cost to a comparator does not exceed the ratio of their expected utilities.

The proposed methodology was applied to a comparative analysis of rapid diagnostic tests and PCR-based technologies used for the etiological diagnosis of viral respiratory infections. It should be emphasized that this comparison was conducted from a laboratory perspective, in which diagnostic technolo-

gies are evaluated as analytical tools for etiological detection rather than as fully interchangeable options within specific clinical decision-making pathways. Accordingly, the results reflect the assumptions and scope of the laboratory-based modeling framework. The probabilistic value of information (VOI) analysis complemented the evaluation by quantifying the economic value of reducing decision uncertainty. Within the defined model, PCR-based diagnostics demonstrated higher expected utility, primarily due to their broader diagnostic spectrum and higher analytical sensitivity. This resulted in an average positive Net Monetary Benefit of approximately \$854 per clinical sample when compared to rapid diagnostic tests.

At the same time, the results should be interpreted with caution. The representation of rapid diagnostic tests in the model was limited by the available dataset and does not fully capture the diversity of rapid testing technologies currently used in clinical practice. In addition, the model does not explicitly incorporate downstream clinical outcomes or treatment effects. Therefore, the findings should not be directly generalized to all clinical or epidemiological use cases without further context-specific analysis. The outcomes or treatment effects. Therefore, the findings should esti-

mated expected value of perfect information (EVPI) was relatively low (approximately \$0.25 per patient), indicating limited decision uncertainty within the current parameter distributions. Similarly, EVPPI and EVSI analyses suggest that additional data collection would provide only marginal economic benefit in this specific modeling context. These findings indicate that the available evidence is sufficient to support decision-making within the defined laboratory framework.

Overall, the proposed approach demonstrates that the integration of multi-criteria cost-utility modeling with value of information analysis provides a consistent and flexible methodology for evaluating diagnostic technologies in laboratory medicine. This framework enables evidence-based and economically justified selection of diagnostic tools while explicitly accounting for uncertainty and the operational characteristics of laboratory diagnostics.

Institutional Review Board Statement: The research protocol was rigorously reviewed and approved by the Institutional Review Board of Shupyk National Healthcare University of Ukraine (Kyiv, Ukraine).

Conflicts of Interest: The authors declare no conflicts of interest.

References:

- [1] GBD 2019 LRI Collaborators. Age-sex differences in the global burden of lower respiratory infections and risk factors, 1990–2019: results from the Global Burden of Disease Study 2019. *Lancet Infect Dis.* 2022;22(11):1626–1647. DOI: 10.1016/S1473-3099(22)00510-2
- [2] S van der Pol, Garcia PR, Postma MJ, Villar FA, van Asselt ADI. Economic analyses of respiratory tract infection diagnostics: a systematic review. *Pharmacoeconomics.* 2021;39(12):1411–1427. DOI: 10.1007/s40273-021-01054-1
- [3] Brigadoi G, Gastaldi A, Moi M, et al. Point-of-care and rapid tests for the etiological diagnosis of respiratory tract infections in children: a systematic review and meta-analysis. *Antibiotics (Basel).* 2022;11(9):1192. DOI: 10.3390/antibiotics11091192
- [4] Dick K, Schneider J. Economic evaluation of FebriDx®: a novel rapid, point-of-care test for differentiation of viral versus bacterial acute respiratory infection in the United States. *J Health Econ Outcomes Res.* 2021;8(2):56–62. DOI: 10.36469/001c.27753
- [5] Abbasi M, Tvakoli N, Bagheri Faradonbeh S, Bakhshayeshi A. Cost-effectiveness analysis of rapid test compared to polymerase chain reaction (PCR) in patients with acute respiratory syndrome. *Med J Islam Repub Iran.* 2022;36:36. DOI: 10.47176/mjiri.36.36
- [6] Rahmazadeh F, Malekpour N, Faramarzi A, Yusefzadeh H. Cost-effectiveness analysis of diagnostic strategies for COVID-19 in Iran. *BMC Health Serv Res.* 2023;23(1):861. DOI: 10.1186/s12913-023-09868-9
- [7] Majeed MN, Iqbal A, Murtaza N, Herrera-Zúñiga LD, Siddique S, Raza M, Hussain M, Sajid M. Designing a Multi-Epitope Vaccine Candidate to MERS-CoV: An in silico Approach. *Innov Biosyst Bioeng.* 2024;8(3):3–17. DOI: 10.20535/ibb.2024.8.3.296662
- [8] Drummond MF, Sculpher MJ, Claxton K, Stoddart GL, Torrance GW. *Methods for the Economic Evaluation of Health Care Programmes.* 4th ed. Oxford: Oxford University Press; 2015.
- [9] Briggs A, Sculpher M, Claxton K. *Decision Modelling for Health Economic Evaluation.* Oxford University Press; 2006.
- [10] Abel L, Shinkins B, Smith A, et al. Early economic evaluation of diagnostic technologies: experiences of the NIHR Diagnostic Evidence Co-operatives. *Med Decis Making.* 2019;39(7):857–866. DOI: 10.1177/0272989X19866415
- [11] Claxton KP, Sculpher MJ. Using value of information analysis to prioritise health research: some lessons from recent UK experience. *Pharmacoeconomics.* 2006;24(11):1055–1068. DOI: 10.2165/00019053-200624110-00003
- [12] Bleuler E. *Das autistisch-undisziplinierte Denken in der Medizin und seine Überwindung.* Springer, Berlin; 1919. p. 207.
- [13] Miller W, Robinson LA, Lawrence RS. *Valuing health for regulatory cost-effectiveness analysis.* Institute of Medicine. Washington, DC: The National Academies Press; 2006. DOI: 10.17226/11534
- [14] Balogh EP, Miller BT, Ball JR. Improving diagnosis in health care. In: *Technology and tools in the diagnostic process.* Washington, DC: The National Academies Press; 2015. p. 217–262. DOI: 10.17226/21794
- [15] Leeftang MM, Rutjes AW, Reitsma JB, Hooft L, Bossuyt PM. Variation of a test's sensitivity and specificity with disease prevalence. *CMAJ.* 2013;185(11):E537–E544. DOI: 10.1503/cmaj.121286

- [16] Werner M, Brooks SH, Wette R. Strategy for cost-effective laboratory testing. *Human Pathology*. 1973;4(1):17–30. DOI: 10.1016/s0046-8177(73)80043-7
- [17] Garattini L, Koleva D, Casadei G. Modeling in pharmacoeconomic studies: funding sources and outcomes. *International Journal of Technology Assessment in Health Care*. 2010;26(3):330–333. DOI: 10.1017/S0266462310000322
- [18] Roberts MS, Smith K. Decision Modeling. In: Arnold RJG, editor. *Pharmacoeconomics: From theory to practice*. Second edition. CRC Press; 2016. 2:21–43.
- [19] Caliendo AM, Gilbert DN, Ginocchio CC, Hanson KE, May L, Quinn TC, et al. Better tests, better care: Improved diagnostics for infectious diseases. *Clinical Infectious Diseases*. 2013;57(3):S139–S170. DOI: 10.1093/cid/cit578
- [20] Public Health Center of Ukraine. Incidence of influenza and acute respiratory viral infections in Ukraine [Internet]. Kyiv: PHC; [cited 2025 May 30]. Available from: <https://phc.org.ua/kontrol-zakhvoryuvan/inshi-infekciyni-zakhvoryuvannya/zakhvoryuvanist-na-grip-ta-grvi-v-ukraini>
- [21] Siemens Healthcare Diagnostics Inc. FTD Respiratory Assays: Syndromic Solutions for Respiratory Infections. Berkeley (CA): Siemens Healthcare Diagnostics Inc.; 2020. Order No. 65-20-14522-01-76.
- [22] Romero Gómez MP, Bloise Sánchez I, Gómez Arroyo B, González Donapetry P, Cendejas Bueno E, García Rodríguez J. Rapid antigen test for adenovirus in children: Age and onset of symptoms are important. *Enfermedades Infecciosas y Microbiología Clínica (English Edition)*. 2023;41(10):617–620. DOI: 10.1016/j.eimce.2022.09.015
- [23] Fryback DG, Thornbury JR. The efficacy of diagnostic imaging. *Medical Decision Making*. 1991;11(2):88–94. DOI: 10.1177/0272989X9101100203
- [24] Boelaert M, Lynen L, Desjeux P, Van der Stuyt P. Cost-effectiveness of competing diagnostic-therapeutic strategies for visceral leishmaniasis. *Bulletin of the World Health Organization*. 1999;77:667–674.
- [25] Shillcutt S, Morel C, Goodman C, Coleman P, Bell D, Whitty CJM, et al. Cost-effectiveness of malaria diagnostic methods in sub-Saharan Africa in an era of combination therapy. *Bulletin of the World Health Organization*. 2008;86(2):101–110. DOI: 10.2471/BLT.07.042259
- [26] Molicotti P, Bua A, Zanetti S. Cost-effectiveness in the diagnosis of tuberculosis: choices in developing countries. *The Journal of Infection in Developing Countries*. 2014;8(1):24–38. DOI: 10.3855/jidc.3295
- [27] Leith CP. Cost-effective flow cytometry testing strategies. *Clinics in Laboratory Medicine*. 2017;37(4):915–929. DOI: 10.1016/j.cll.2017.07.012
- [28] Komar, A., Kozerecka, O., Besarab, O., & Galkin, A. (2019). Development and Validation of a Highly Informative Immuno-Enzymatic Analysis for the Determination of Free Prostat-Specific Antigen. *Innovative Biosystems and Bioengineering*, 3(4), 220–231. DOI: 10.20535/ibb.2019.3.4.185877
- [29] Mahony JB, Blackhouse G, Babwah J, Smieja M, Buracond S, Chong S, et al. Cost analysis of multiplex PCR testing for diagnosing respiratory virus infections. *Journal of Clinical Microbiology*. 2009;47(9):2812–2817. DOI: 10.1128/JCM.00556-09

С.О. Соловйов^{1,2}, Д.С. Городецький², О.В. Ковалюк¹, В. М. Михальчук¹, Н.В. Припуга¹, Л.Ю. Бабінцева¹, М. Сідоренко³, С. Міцкявічус³, М.С. Хакім⁴

¹Національний університет охорони здоров'я України імені П. Л. Шупика, Київ, Україна

²Національний технічний університет України «Київський політехнічний інститут імені Ігоря Сікорського», Київ, Україна

³Університет Вітаутаса Великого, Науково-дослідний інститут природничих і технологічних наук, Каунас, Литва

⁴Кафедра біології та імунології, Медичний коледж, Університет Кассім, Бурайда, Саудівська Аравія

АНАЛІЗ ЦІННОСТІ ІНФОРМАЦІЇ У ФАРМАКОЕКОНОМІЧНІЙ ОЦІНЦІ ДІАГНОСТИЧНИХ ТЕХНОЛОГІЙ ДЛЯ ВІРУСНИХ РЕСПІРАТОРНИХ ІНФЕКЦІЙ

Проблематика. Респіраторні інфекції залишаються значним тягарем для світової охорони здоров'я з суттєвим економічним впливом. Різноманітність вірусних збудників та варіабельність діагностичних підходів ускладнюють етіологічну верифікацію в лабораторній практиці. З розвитком діагностичних технологій зростає потреба в економічно обґрунтованих підходах, що інтегрують аналітичні характеристики, операційні параметри та вартість. Аналіз цінності інформації (VOI) забезпечує формальну методологічну основу для оцінювання впливу невизначеності на прийняття діагностичних рішень.

Мета. Розробити та застосувати методологію оцінювання економічної ефективності та цінності інформації діагностичних технологій для вірусних респіраторних інфекцій у контексті лабораторної практики.

Методи дослідження. У дослідженні порівнювали імунохроматографічні експрес-тести та ПЛР-діагностику вірусних інфекцій. Діагностичну корисність тестів кількісно оцінювали методом експертного оцінювання за чотирма операційними критеріями: автоматизація, час виконання, відтворюваність та доступність. Побудовано багатокритеріальну модель дерева рішень з урахуванням чутливості, специфічності, діагностичного спектру та вартісних параметрів. Невизначеність моделювали за допомогою бета- та гамма-розподілів. Розроблена методологія дозволила оцінити очікувану корисність, чисту монетарну вигоду (NMB), очікувану цінність досконалої інформації (EVPI) та очікувану цінність вибіркової інформації (EVSI).

Результати. Розроблено та апробовано багатокритеріальну методологію аналізу економічної ефективності для оцінювання технологій етіологічної діагностики. У межах побудованої моделі ПЛР-діагностика продемонструвала вищу очікувану корисність завдяки ширшому діагностичному спектру та вищій аналітичній чутливості. За результатами імовірнісного моделювання

(10 000 ітерацій) середня чиста монетарна вигода ПЛР порівняно з експрес-тестами склапа близько \$854 на клінічний зразок. Аналіз VOI засвідчив низький рівень невизначеності рішення: EVPI оцінено на рівні \$0.25 на пацієнта. EVPPІ для діагностичного спектру ПЛР виявилася незначною, а EVSI досягла максимального значення \$2.69 при обсязі вибірки 40 осіб, що вказує на обмежену доцільність подальшого збору даних за поточних умов.

Висновки. Поеднання багатокритеріального моделювання економічної ефективності з аналізом VOI забезпечує послідовну методологічну основу для оцінювання діагностичних технологій у лабораторній медицині. У межах прийнятих припущень ПЛР-діагностика продемонструвала вищу економічну доцільність порівняно з експрес-тестами. Водночас результати слід інтерпретувати з урахуванням обмежень моделі, зокрема щодо діагностичного спектру експрес-тестів та відсутності даних про клінічні наслідки лікування. Запропонований підхід сприяє доказовому та економічно обґрунтованому вибору діагностичних технологій в умовах невизначеності.

Ключові слова: вірусні респіраторні інфекції; лабораторна діагностика; полімеразна ланцюгова реакція; експрес-діагностичні тести; аналіз «витрати–корисність»; дерево рішень, моделювання; цінність інформації.