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# Fuzzy Optimization and Modelling Journal

Journal homepage: https://sanad.iau.ir/journal/fomj/

Fuzzy Optimization and Modeling Journal

Paper Type: Research Paper

# Novel Fuzzy-based Framework for Ethical Innovation in COVID-19 Vaccine Production: Integrating Individual Organizational and Social Ethics

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### ARTICLE INFO

Article history: Received 4 October 2024 Revised 20 December 2024 Accepted 25 December 2024 Available online 29 December 2024 *Keywords:* Organizational and Individual Ethics Supervisory and Legal Ethics Social Ethics Infrastructures Ethical Innovation COVID-19 Vaccine Production

#### ABSTRACT

While several studies have addressed technical aspects of vaccine production, a comprehensive ethical framework that integrates individual, organizational, and social dimensions is still missing. This study presents a novel integrated ethical innovation model for human vaccines production, combining fuzzy-based methodology with structural equation modeling to capture both expert knowledge and empirical validation. This research is applied in terms of its purpose and quantitative-qualitative [mixed] in terms of its method. The statistical population consisted of the Razi Vaccine and Serum Research Institute and Pasteur Institute of Iran, both active in the vaccine production domain. The participants in the qualitative phase involved the vaccine production researchers and experts selected by snowball sampling till theoretical saturation was reached. The statistical sample in the quantitative phase included the managers and experts of the vaccine production domain and was selected by purposive and convenient sampling. The Fuzzy Delphi method run in the EXCEL software was used for extracting the variables and presenting the theoretical model, while the structural equations modeling run in the SMART PLS software was employed for factor analysis. The analysis gave rise to 60 initial indices, which were reduced to 53 after screening and Fuzzy Delphi analysis. Then, they were framed into five dimensions, including individual ethics, organizational ethics, supervisory and legal ethics, social ethics, and infrastructures. All identified factors significantly impact ethical innovation in the production of COVID-19 vaccine in the following order: Organizational ethics, supervisory and legal ethics, infrastructures, individual ethics, and social ethics.

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DOI: 10.71808/fomj.2024.1185909

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# 1. Introduction

The strategic significance of vaccine production has become even more pronounced given the effect of direct and indirect costs of diseases on nations' economies, alongside security and defense concerns like bioterrorism and passive defense. This strategic privilege has justified Iran's investment in achieving vaccine production capacity as an industry with a low profit margin but pioneering in developing biotechnology [21]. The COVID-19 pandemic has dramatically transformed the landscape of vaccine development and production.

In November 2019, the first diagnosed cases of COVID-19 were identified in Wuhan, China [32]. Following the release of genetic information on January 10th, 2020, the first doses of human vaccines were tested by March 13th, 2020 - just 63 days after the outbreak of the SARS-CoV-2 sequence [28]. This unprecedented rapid development of vaccines, while demonstrating remarkable scientific achievement, has raised significant ethical concerns and challenges [11].

The ethical dimensions of vaccine development and distribution have become increasingly complex in the COVID-19 era. As Boschiero [7] argues, the current legal proprietary regime applied to vaccines has transformed an intrinsically non-excludable common/public good into something excludable and rival in consumption. This transformation has led to significant disparities in vaccine access globally, with richest countries collectively preordering 8.8 billion doses of vaccine, far exceeding their needs and forcing billions in the Global South to wait years for vaccination [7].

The concept of ethical innovation has emerged as a critical framework for addressing these challenges. Ethical innovation encompasses not only the technical aspects of vaccine development but also considers the broader societal implications and responsibilities [31]. This approach requires balancing rapid development and deployment of vaccines with ethical considerations such as safety, efficacy, and equitable access [24]. Recent studies have highlighted the need for integrating individual, organizational, and social ethics in vaccine development processes [10].

However, modern mechanisms have created new challenges that must be addressed, particularly as COVID-19 has introduced special priorities and conditions for vaccine production. While many specialists agree that safe, potent, cost-effective, and widely available vaccines are the sole way to end the epidemic medically and socially, repeated promises on fast vaccine production can interrogate ethics, reinforce the anti-vaccination movement, and potentially extend the epidemic period [15]. The ethical challenges extend beyond development to distribution, with studies showing significant disparities in vaccine access between developed and developing nations [10].

Innovation in vaccine production develops not merely through creative ideas but within a process that originates from idea selection, application, and ultimately yields commercial profits [3]. What makes ethical innovation particularly crucial in vaccine production is its potential impact on both individual and societal levels. As Marciano [22] demonstrates, vaccines are socially shaped by socio-economic, political, and organizational factors, with property rights, value capture strategies, and public innovation policies guiding research teams in their biochemical design [22].

The challenges faced by Iran's vaccine production industry, particularly the contrast between its prosperous first half-century [manufacturing 10 vaccine types] and the limited production through technology transfer in the second half, despite better knowledge and infrastructure availability, underscore the need for a comprehensive examination of ethical innovation in vaccine production [21]. This analysis becomes even more critical given the strategic importance of vaccine production for national health security and industrial self-reliance.

Therefore, this study aims to present a model of ethical innovation in the production of human vaccines, with a particular focus on COVID-19 vaccines. Specifically, it seeks to address why some people in society hesitate in accepting and utilizing vaccines and what ethical principles vaccine-producing companies should observe in offering innovations. This research enriches the domestic literature associated with ethical innovation and can help organizations to employ ethics in innovation-related discussions, while assisting society members in accepting produced vaccines [4, 19].

The research is particularly timely as studies have shown that ethical considerations in vaccine development

and distribution have far-reaching implications beyond immediate health outcomes. As Scholz et al. [27] demonstrate through their analysis of COVAX engagement, pharmaceutical companies' adherence to ethical principles in vaccine production and distribution significantly impacts global health equity [27]. Moreover, recent research by Rhodes and Parry [26] emphasizes that pandemic management requires societal coordination, global orchestration, respect for human rights, and defense of ethical principles [26].

Addressing these issues is significant for several reasons. First, it contributes to the growing body of literature on ethical innovation in healthcare, particularly in vaccine production. Second, it provides practical insights for organizations active in vaccine production to implement ethics in innovation-related discussions. Third, it helps bridge the gap between technical vaccine development and societal acceptance, which has become increasingly important in the context of COVID-19 [23].

The responsiveness to ethical considerations in vaccine development has become crucial not only for public health but also for maintaining public trust and ensuring widespread vaccine acceptance. As Agampodi et al. [2024] note, the COVID-19 pandemic has catalyzed unprecedented vaccine innovation while revealing critical shortcomings in achieving equitable vaccine access [1]. These challenges underscore the need for a comprehensive ethical framework that can guide future vaccine development and distribution efforts.

This research specifically investigates the pattern of ethical innovation in vaccine production through a mixed-methods approach, employing both qualitative and quantitative methodologies to develop a comprehensive understanding of the ethical dimensions involved. By examining various stakeholders' perspectives and analyzing multiple aspects of ethical innovation, this study aims to contribute to both theoretical understanding and practical implementation of ethical principles in vaccine production.

The novelty of this research lies in three key contributions: First, it develops a comprehensive ethical innovation framework that integrates multiple dimensions [individual, organizational, social, and legal] specifically for vaccine production - an approach not previously attempted in the literature. Second, it employs a unique methodological combination of Fuzzy Delphi and structural equation modeling to validate the framework empirically. Third, it provides practical guidelines for implementing ethical innovation in vaccine production facilities, addressing a critical gap between theoretical frameworks and operational requirements. These contributions are particularly significant given the urgent need for ethical frameworks in vaccine production highlighted by the COVID-19 pandemic. To better illustrate the research gap and position our study within the existing literature, Table 1 summarizes key previous studies and identifies areas that require further investigation.

As shown in Table 1, while previous studies have addressed various aspects of ethical considerations in vaccine development and distribution, there remains a significant gap in developing an integrated framework that combines individual, organizational, and social dimensions of ethical innovation specifically in vaccine production processes. Most studies have focused on either distribution ethics, access issues, or specific technical aspects, leaving a notable gap in comprehensive ethical production frameworks that consider multiple stakeholder perspectives and organizational dynamics.

The core research question driving this study is: How can an ethical innovation model be effectively implemented in producing human vaccines? This question encompasses several sub-questions:

- 1. What are the key dimensions of ethical innovation in vaccine production?
- 2. How do organizational and individual ethics interact in the vaccine production process?
- 3. What role do supervisory and legal ethics play in ensuring ethical vaccine production?
- 4. How can social ethics be integrated into the vaccine production framework?

Through addressing these questions, this study aims to develop a comprehensive model that can guide future vaccine production efforts while maintaining high ethical standards. The findings will be particularly relevant for vaccine producers, healthcare policymakers, and regulatory bodies seeking to balance rapid vaccine development with ethical considerations.

The remainder of this paper is organized as follows: First, we present our research methodology, including both qualitative and quantitative approaches. Then, we discuss our findings regarding the dimensions of ethical

innovation in vaccine production. Finally, we conclude with implications for practice and recommendations for future research in this critical area.

<b>D</b> (	Table 1. Research gaps in ethical innovation studies related to vaccine production				
References	Focus Area	Key Findings	Research Gap		
[7]	Global vaccine access and intellectual property rights	Identified issues in proprietary regime and vaccine nationalism	Limited focus on ethical production processes and organizational ethics		
[30]	Knowledge management in vaccine production	Developed serendipity- mindsponge-3D framework for vaccine production	Lack of ethical considerations in knowledge management		
[31]	Patent rights and business ethics	Analyzed patent pledges during COVID-19	Missing integration with broader ethical innovation framework		
[11]	One Health approach to pandemic prevention	Emphasized need for balanced human-animal-environment approach	Insufficient attention to production ethics and industry practices		
[10]	Vaccine equity and research ethics	Examined vaccine apartheid and ethical challenges in Africa	Gap in practical implementation guidelines		
[4]	AI and ethical challenges in COVID-19	Explored ethical implications of AI in pandemic response	Limited focus on production processes		
[24]	Vaccine access and justice	Analyzed global vaccination equity issues	Insufficient attention to production ethics		
[22]	Social shaping of biotechnology	Analyzed institutional factors in vaccine development	Missing integrated ethical model for production		
[26]	Gene-based vaccine development	Examined ethical concerns in rapid vaccine deployment	Gap in comprehensive ethical framework		
[27]	Corporate social responsibility	Analyzed pharmaceutical companies' COVAX engagement	Limited focus on internal production ethics		
[23]	Innovation policies for COVID-19	Developed innovation biosphere framework	Lack of specific ethical guidelines		
[1]	Global pandemic preparedness	Identified challenges in vaccine development and distribution	Gap in ethical production framework		

 Table 1. Research gaps in ethical innovation studies related to vaccine production

# 2. Method

The present study is applied in terms of its purpose since its results can be used in research and vaccine production centers. Also, it is methodologically qualitative since the researchers have employed the Fuzzy Delphi method with experts' perspectives to extract the theoretical model of the research. Alternately, it can also be recognized as a quantitative study due to using factor analysis for confirming the extracted components of the qualitative model. Therefore, this study is mixed-methods research since both quantitative and qualitative methods are employed. The statistical population in the qualitative phase consisted of vaccine production experts and researchers who entered the study based on the following criteria: Possessing Ph.D. degrees and work experiences of over ten years in human vaccines production and vaccine technology transfer. These individuals were selected by snowball sampling until the theoretical saturation was reached. Concerning the information obtained from the managers of Razi Vaccine and Serum Research Institute and Pasteur Institute of Iran, the researchers could identify ten experts who introduced other their expert colleagues in this domain. Totally, 15 vaccine production experts were identified, and the researchers benefitted from their perspectives to identify factors impacting ethical innovation in vaccine production.

The statistical population of the quantitative phase comprised the respective managers and experts selected according to the following criteria: Possessing Ph.D. and M.A. degrees and work experiences of over five years. These participants were selected by convenient and purposive sampling. The questionnaires were distributed among 67 managers and experts, and 61 questionnaires were finally returned and analyzed. Likewise, the library method was used for recognizing the literature and topical backgrounds of ethical innovation [referring to

internet bases, documents, and domestic and foreign scientific papers]. Also, interviews and questionnaires were the most significant instruments employed by the researchers in their field study. The validity of the qualitative data was examined and confirmed by Maxwell's descriptive and theoretical validities, and the validity of the members was probed by Newman's validation method. Reliability was tested and confirmed by the test-retest method. The validity of the quantitative data was examined and confirmed by face and content validities, and its reliability was tested and confirmed by Cronbach alpha [Table 2]. The Fuzzy Delphi method run in the EXCEL software was used for extracting the variables and presenting the theoretical model, while the structural equations modeling run in the SMART PLS software was employed for factor analysis.

# 3. Results

Sixty initial indices Table 2 were derived from investigating the theoretical literature, respective research background, and expert interviews.

Factors	Index	Code	Reference
In dissident	Ethical values	IE1	[11], [20]
Individual — ethics-IE —	Personal ethics	IE3	Experts, [25
eunics-ie —	Professional ethics	IE4	Experts
	Researchers' knowledge and technical capacity	OE1	Experts
Organizational	Social responsibility	OE2	[25]
ethics	Non-ethical pricing	OE4	[6]
	Selecting a suitable site for vaccine testing		[8]
	Sufficient and suitable medical care for the tested society	OE5 OE6	Experts
	Observing ethical principles	OE7	Experts
—	Training the ethical system	OE8	Experts
	Observing professional standards and ethics	OE9	Experts
	Observing biological ethics	OE10	Expert
	Presence of an ethical prism	OE11	Experts
_	Examining the safety and efficacy of the vaccine in different target populations	OE12	[29]
	Building relationships with national and international legal institutions	OE13	Expert
	Ethical decisions in production phases	OE14	Expert
	Management based on ethical principles	OE15	Expert
	Transparency in performance	OE16	Expert
	Being honest and attracting the trust of patients and employers	OE17	Expert
	Preserving patient privacy	OE18	Expert
	Respecting human dignity and patient autonomy	OE19	Expert
	Ethical interactions with stakeholders	OE20	Expert
	Ethics-oriented and responsible innovation and research	OE22	Expert
	Interaction with other members of the health society for better observing ethical principles	OE23	Expert
	Presence of ethical orientations	OE24	Experts
	Acquiring license according to exact standards	OE25	[8]
	Employing teams of researchers with different specializations	OE26	Expert
T 1 1	Observing international standards	LE1	Expert
Legal and	Observing intellectual property rights	LE2	Expert
supervisory — ethics-LE —	Presence of supervisory systems	LE3	[29]
culles-LE —	Preserving child safety in testing vaccines	LE4	[29]
	Preserving the vulnerable society in testing vaccines [like individuals with underlying diseases and elderlies]	LE5	[29]
	Ethically selecting control groups for vaccine testing [especially in less-developed societies]	LE6	[29]

Table 2. Dimensions and components of ethical innovation in human vaccines production: Focusing on COVID-19 vaccines

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	Attention to psychological risks of the tests on the target population [like HIV vaccine] Fairness in vaccine distributions and other health resources		[8], [17]
—			[17]
—	Presence of ethical evaluation systems	LE9	Experts
_	Perceiving the impact, safety, and effectiveness of vaccines in different societies, especially less developed countries [like the screening method]	LE10	Experts
_	Observing ethical principles in using vulnerable groups in clinical tests	LE11	[6]
_	Observing global assignment criteria	LE12	[17]
	Selecting suitable groups for effective vaccine testing	LE14	[8]
_	Employing proper pharmaceutical companies for producing vaccines	LE15	[17]
_	Presence of advanced laboratories	IN1	Experts
	Time limitations for vaccine production	IN3	Experts
Infrastructures- —	Presence of vaccine-producing systems	IN4	Experts
IN IN	Capacities for cooperating, networking, and employing the open innovation systems	IN5	Experts
	Presence of advanced technologies	IN6	Experts
	Access to technological knowledge	IN7	Experts
	Educational system	SE1	Experts
Social thics-SE	Alignment of the priorities and motives of vaccine-producing companies with public benefits of society	SE3	[17]
-	Attention to communicating with the target population and acquiring its consent according to social cultures	SE4	[30]
	Attention to health differences [individual differences in terms of hygiene, health, age, treatment costs, diseases]	SE5	[17]
	Institutionalizing value-centered culture	SE7	Experts
	Recognizing social impacts	SE8	Experts

The proposed methodological approach offers several advantages over traditional methods. First, the combination of Fuzzy Delphi and structural equation modeling provides both qualitative depth and quantitative validation. While traditional Delphi methods might suffer from ambiguity in experts' opinions, the fuzzy approach better captures the uncertainty in expert judgments. Additionally, our two-phase approach allows for both exploratory identification of factors and confirmatory validation of their relationships. This hybrid methodology has proven particularly suitable for studying complex phenomena like ethical innovation, where both expert knowledge and empirical validation are crucial.

# • Results of Fuzzy Delphi

The Delphi technique is a robust process based on a group communication structure. This method is used for attaining group consensus among experts when incomplete and uncertain knowledge is at hand [18]. Experts' perspectives are numerically presented in the classic Delphi method. However, experts employ their mental competencies to express their ideas. This indicates the governance of probability and uncertainty in these conditions, being compatible with fuzzy sets. Therefore, it was suggested that the conventional Delphi method be integrated with the fuzzy theory and called the fuzzy Delphi method. With the application of the fuzzy theory in the Delphi method, the integrated fuzzy Delphi algorithm was developed [16]. The present study employed the fuzzy Delphi method in three phases with the following steps in every phase:

**Phase 1**: After the identification of experts and preparation of the Delphi questionnaire according to the previous results of the research, the participants, including 15 vaccine production experts and researchers, filled out the questionnaires, and the table of the results of the first fuzzy round, consisting of 60 variables, was obtained. Then, value variables were used for specifying the significance of every index. That is, the experts

were asked to determine the significance of every identified variable in every index's dimensions using the verbal variables of strongly low, low, moderate, high, strongly high.

**Phase 2**: In this phase, verbal variables were defined as triangular fuzzy numbers. That is, triangular fuzzy numbers were allocated to the perspectives of every expert, and a set of triangular fuzzy numbers were obtained for every expert. Then, the difference between the expert's perspectives and the mean perspectives of the expert panel was determined. Since the absolute value of the mean difference of the expert's perspectives is still >0.2 in 11 indices in the second round, the third-round Delphi survey was run only for indices whose differences in the first and second phases were >0.2.

**Phase 3**: The indices were screened by the comparison of the acquired value of every index with the threshold value. Researchers have introduced 0.7 as the threshold value, i.e., the criterion for the index acceptance. Therefore, if the non-fuzzy value of an index is  $\geq 0.7$ , it is accepted; otherwise, the index is omitted. In this phase, the difference between the experts' perspectives and the absolute value of the mean difference of the perspectives collected in the first and second rounds, and the final table was prepared.

Since the mean difference of the experts' perspectives is <0.2 in all indices, we can conclude that the survey has reached a consensus. Furthermore, since the non-fuzzy values of  $\ge 0.7$  were only accepted, seven indices [out of 60], including contextual personal factors, contextual organizational factors, balanced and ethical pharmaceutical policies, defining the roles of supervisory institutions, implementing innovation programs, ethical challenges, and the risk of virus transmission, had below-threshold values and were thus omitted. Finally, 53 indices in five dimensions were confirmed at the end of the fuzzy Delphi method, and the theoretical model was developed in Figure 1.

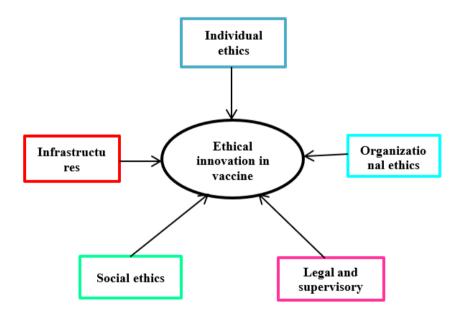


Figure 1. Qualitative theoretical model

### • Confirmatory factor analysis results

This study applied Partial Least Squares Structural Equation Modeling, a multivariate technique widely employed for examining structural relations. This method enables multiple variables to be analyzed simultaneously in an integrated model, provides useful insights on conceptualizing the constructs and theories tested by empirical data, and manifests the complexities of causal modeling [14]. This method enables us to estimate a model using a small sample with numerous latent variables [21]. In this regard, the SMART PLS 3.2.8 software was used for analyzing the measurement and structural models, and the results are reported.

The construct validity was examined by the convergent and divergent validities in the SMART PLS software. Convergent validity reflects the degree of the indices' dependence on their respective variable, while divergent validity compares the degree of a factor's correlation with its indices against its correlation with other factors. On the other hand, the Cronbach alpha coefficient, with a criterion of >0.7 for all factors, was used for measuring the reliability of the questionnaire [13]. Our questionnaire enjoyed the necessary reliability since the estimated Cronbach alpha was above 0.7 for all factors. Furthermore, composite and communality reliabilities in the PLS method were employed.

Factor loadings with coefficients of >0.7 are accepted in the Partial Least Squares method. According to Figure 2, four of 53 indices, i.e., perceiving the impact, safety, and effectiveness of vaccines in different societies, especially less developed countries [like the screening method], interaction with other members of the health society for better observing ethical principles, alignment of the priorities and motives of vaccine-producing companies with public benefits of society, and recognizing social impacts, were omitted due to having factor coefficients of below 0.7, and the fitness and homogeneity of the measurement model were confirmed. According to the results of Table 3, the validation tests of the measurement model have been presented in the following, all falling into the permitted and confirmed range.

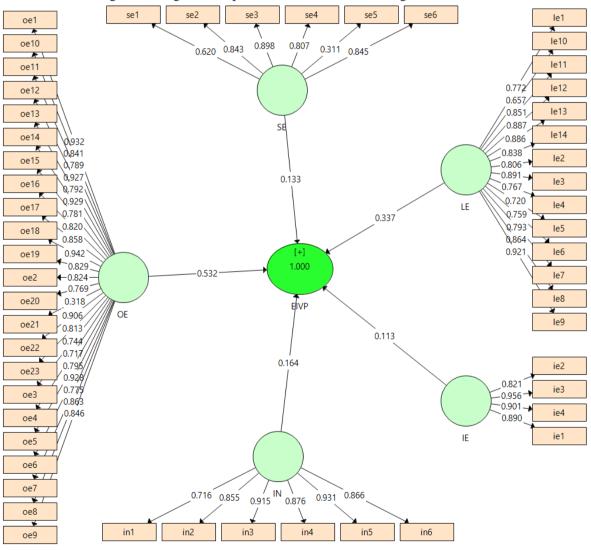


Figure 2. Initial measurement model when estimating standard coefficients [factor loading]

	Table 5. Reliability, convergent validity, and quarky of measurement model					
Latent variables	Reliability			Convergent valid	Convergent validity	
	Cronbach alpha	Communality reliability	Composite reliability	AVE	CR>AVE	
Individual ethics	0.915	0.798	0.940	0.798	OK	
Infrastructures	0.930	0.744	0.946	0.744	ОК	
Legal ethics	0.962	0.692	0.907	0.692	ОК	
Organizational ethics	0.980	0.706	0.911	0.706	ОК	
Social ethics	0.896	0.764	0.928	0.764	ОК	

Table 3. Reliability, convergent validity, and quality of measurement model

Figure 3 and Figure 4 illustrate structural models. Three criteria were used for evaluating these models, and the Z coefficients were applied for the model fit. These coefficients should be >1.96 so that their significance is confirmed at the 95% confidence level [13]. According to Figure , all coefficients are larger than 1.96, and  $R^2$ , which reflects the path coefficient, indicates the effect of an exogenous variable on an endogenous one. Three values of 0.19, 0.33, and 0.67 have been considered as weak, moderate, and strong values for  $R^2$ . In this research,  $R^2 = 0.898$ , which is suitable. On the other hand, the Q<sup>2</sup> criterion specifies the predictive power of a model. If it acquires three values of 0.02, 0.15, and 0.35 concerning an endogenous variable, it can weakly, moderately, and strongly predict its related exogenous constructs, respectively [12]. The Q<sup>2</sup> value obtained for the study's model equals 0.359, which indicates the high prediction power of the model.

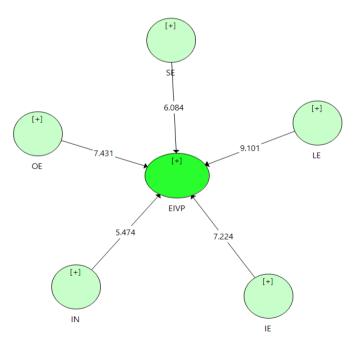


Figure 3. Structural model with significant path coefficients.

Finally, the GOF index was used for examining the quality of the structural model. Values of 0.01, 0.25, and 0.36 indicate if this index is weak, moderate, or strong. The quality of the qualitative model was confirmed in this study since the GOF index equaled 0.814.

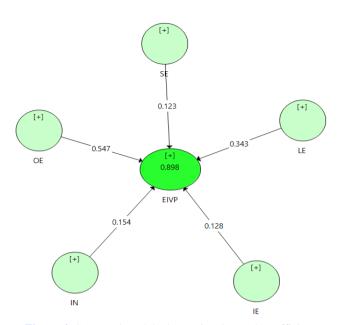


Figure 4. Structural model when estimating path coefficients

### • Validation and Reliability Assessment

To ensure the robustness of our findings, several validation procedures were implemented. The construct validity was examined through both convergent and divergent validities. The reliability was confirmed through multiple indicators including Cronbach's alpha [>0.7], composite reliability, and communality measures [Table 2]. Additionally, the model's predictive power was assessed through Q<sup>2</sup> criterion [0.359], indicating strong predictive capability. The GOF index of 0.814 further confirmed the overall quality of the structural model. These multiple validation measures provide strong support for the reliability and validity of our findings.

#### 4. Conclusion

The analysis of ethical innovation in vaccine production through our mixed-methods approach revealed several significant findings that contribute to both theoretical understanding and practical implementation. Our results demonstrate that ethical innovation in vaccine production is influenced by five key dimensions: organizational ethics, supervisory and legal ethics, infrastructures, individual ethics, and social ethics. The factor analysis confirmed these dimensions' significant impact on ethical innovation in COVID-19 vaccine production, with organizational ethics showing the strongest influence [path coefficient = 0.547], followed by legal and supervisory ethics [0.343], infrastructures [0.154], individual ethics [0.128], and social ethics [0.123].

These findings align with but also extend recent research in the field. For instance, our emphasis on organizational ethics corresponds with Scholz et al.'s [27] findings regarding pharmaceutical companies' engagement with COVAX, but our study provides a more comprehensive framework by quantifying the relative importance of different ethical dimensions. Similarly, while Dhai [10] highlighted the importance of ethical leadership and governance in vaccine production, our research demonstrates specifically how these factors interact within organizational contexts.

The strong influence of organizational ethics [54.7%] on ethical innovation aligns with Marciano's [22] findings about the institutional shaping of biotechnological innovation. This suggests that organizational structures and policies play a crucial role in ensuring ethical vaccine production. The high impact of legal and supervisory ethics [34.3%] supports Boschiero's [7] arguments about the need for reformed legal governance in vaccine production, while also providing empirical validation for these theoretical propositions.

Our methodological approach offers unique insights when compared to previous studies. While other

researchers have employed either purely qualitative [11] or quantitative methods [4], our hybrid approach combining Fuzzy Delphi and structural equation modeling provides both depth of understanding and statistical validation. This combination has enabled us to not only identify relevant factors but also quantify their relationships and relative importance.

The findings have several important theoretical and managerial implications. From a theoretical perspective, our study extends the understanding of ethical innovation by providing an integrated framework that encompasses multiple dimensions. This addresses the gap identified by Yuan and Li [31] regarding the need for comprehensive ethical frameworks in healthcare innovation. The empirical validation of these dimensions contributes to the growing literature on ethical considerations in vaccine production and distribution.

From a managerial perspective, our findings suggest several actionable recommendations. Organizations should prioritize developing robust ethical frameworks within their organizational structure, given the strong influence of organizational ethics. This could include establishing clear ethical guidelines, implementing training programs, and creating accountability mechanisms. The significant impact of legal and supervisory ethics suggests that organizations should invest in compliance systems and maintain transparent relationships with regulatory bodies.

The influence of infrastructures [15.4%] indicates that organizations need to maintain and upgrade their technological capabilities while ensuring ethical considerations guide their implementation. This aligns with Agampodi et al.'s [1] emphasis on building robust systems for future pandemic preparedness. The role of individual ethics [12.8%] suggests the importance of personal value systems and professional ethics in vaccine production, supporting the need for ethical training and development programs.

The social ethics dimension, while showing the lowest direct influence [12.3%], remains crucial for sustainable vaccine production and distribution. This finding resonates with Privor-Dumm et al.'s [24] emphasis on social justice in vaccine access and distribution. Organizations should therefore consider social impact assessments and community engagement strategies as integral parts of their ethical innovation framework.

However, this study has several limitations that should be acknowledged. First, our research focused on vaccine production facilities in Iran, which may limit the generalizability of findings to other contexts. Future research could extend this study to different geographical and cultural contexts. Second, the study was conducted during the COVID-19 pandemic, when organizations were operating under unprecedented pressure. This unique context might have influenced participants' responses and should be considered when interpreting the results. Third, while our methodology provided robust results, the complexity of ethical considerations in vaccine production might benefit from longitudinal studies that can capture changes over time. Additionally, future research could employ different methodological approaches, such as case studies or experimental designs, to validate and extend our findings.

For future research, we recommend investigating how ethical innovation frameworks evolve in postpandemic contexts, exploring the role of emerging technologies in ethical vaccine production, and examining how different cultural contexts might influence the implementation of ethical innovation frameworks. Researchers might also consider studying the interaction between different dimensional factors and their combined effects on ethical innovation outcomes.

**Conflict of interest:** The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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