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# Application Validation Methods in EHR Evaluation Models: A Systematic Literature Review

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## Abstract

**Background:** Over the last few decades, several theoretical frameworks have been proposed to evaluate electronic health records (EHRs). These frameworks provide a theoretical basis for assessing the impact and outcomes of technology adoption in healthcare settings. This can help identify areas for improvement and ensure that EHRs effectively support healthcare delivery and patient care.
**Objectives:** The purpose of this study is to present a comprehensive review of the use of validation methods in Electronic health records.
**Methods:** Out of a total of 62 EHR evaluation frameworks in our previous literature review, at the final stage, 34 relevant articles were included for analysis. Variables such as participants and study setting, analysis software, data gathering methods, missing data, and outlier handling, theoretical basis models to develop the EHR evaluation model, the relationship between variables of the EHR evaluation models with evaluation items, sampling technique and sample size reliability assessment methods and values, and statistical validation methods and criteria values were extracted.
**Results:** Among the 34 papers that disclosed the validation methods utilized, the most widely used technique was Structural Equation Modeling (SEM), employed in 26.5% of the studies. Other methods utilized were Confirmatory Factor Analysis (CFA), and Exploratory Factor Analysis (EFA). A reliability assessment was performed in 82% of the articles. Cronbach's alpha and composite reliability (CR) were popular reliability (internal validation) methods on identified papers.
**Conclusion:** It is our belief that the results of this study can assist researchers in examining and modifying EHR evaluation frameworks to suit their specific needs. Additionally, we believe that our findings serve as a solid foundation for the creation of new EHR evaluation frameworks. Furthermore, we recommend that researchers utilize the findings presented in this article to enhance the implementation and utilization of SEM, CFA, and EFA methods in EHR evaluation models.

*Keywords:* Electronic medical records, Electronic health records, Evaluation frameworks, Evaluation models, Evaluation theory

## 1. Background

In recent years, the use of electronic health records (EHRs) has dramatically increased among healthcare organizations across the globe. Although the assessment of the quality and performance of the systems is a significant concern (1), there is a need for an evaluation framework for EHRs. This framework can be adopted or developed to ensure that standard evaluation methods are followed (2). Over the last three decades, various theoretical frameworks have been suggested to evaluate and clarify the adoption and behaviors related to introducing Information and Communication Technology (ICT). Some measures have been developed to evaluate how effectively a technology aligns with the tasks of its users, and these instruments have been validated to assess the task-technology fit (3).

Electronic health records are implemented in complex healthcare settings, and their success depends on a wide array of interacting factors. Multiple studies have evaluated the success and failure factors of electronic health records and found that all influential variables do not have equal effects on system success and can interact with each other. Therefore, it is crucial to address all these factors to ensure the successful implementation and adoption of electronic health records in healthcare centers. The EHR evaluation methods have assessed the factors influencing system success and failure. The accuracy of these models is a significant issue.

## 2. Objectives

The main aim of this study was to address two crucial questions: "What is the validation method used for evaluation models?" and "What are the various variables present in the cause-and-effect models of EHR evaluation?" The primary objective of this paper is to conduct a comprehensive review of validation methods used in EHR evaluation models. Previous studies have demonstrated that review articles are useful resources for researchers seeking quick and easy access to relevant information.

## 3. Methods

A systematic search of English literature from January 2007 to August 2017 was conducted in PubMed, Scopus, ScienceDirect, and Cochrane databases to identify evaluation frameworks for electronic health records (4).

***Criteria for considering studies***

A total of 8,276 records were retrieved, and 62 studies met the inclusion criteria (4). In this study, we used the results of our previous systematic review. In the current review, among 62 articles, studies that propose an EHR evaluation model were included in the analysis. On the other hand, the exclusion criteria were as follows: 1. The use of existing evaluation framework for EHR evaluation without changes, 2. Investigating the relationship between contributed factors based on the existing evaluation framework, and 3. No reporting valuation methods and values or validity assessment.

***Eligibility screening and data extraction***

Data were extracted by the first author (ZE) and supervised by a second author (HT) using a spreadsheet file. A random sample of seven included papers (one-third of the total included papers) that used Structural equation modeling (SEM), Exploratory Factor Analysis (EFA), Confirmatory Factor Analysis (CFA), and other validation methods were selected for piloting the data extraction using a separate spreadsheet file.

***Data synthesis***

The extraction checklist was modified as necessary during the study. Data extraction included for the paper included:

- Participants and study setting
- Analysis software
- Data gathering methods, missing data, and outlier handling
- Theoretical basis models to develop the EHR evaluation model
- Relationship between variables of the EHR evaluation models with evaluation items (independent, moderating, dependent items)
- Sampling technique and sample size
- Reliability assessment methods and values

To assess the reliability and validity of the measurement scales used in the studies, Cronbach's' alpha and Composite Reliability (CR) were extracted from the papers. The mean and standard variation for these variables were calculated.

- Statistical validation methods and criteria values

***Structural equation modeling approach***

The articles that used the SEM approach for validation methods following statistical criteria were extracted. A list of Fit indices was prepared based on previous studies as follows:

Chi-square ($\chi2$), P-value, Degree of freedom (df), $\chi2$/df, Delta Chi-square, Comparative Fit Index (CFI), Differences in CFI, Incremental Fit Index (IFI), Non-Normed Fit Index (NNFI), Normed Fit Index (NFI), Parsimony Comparative Fit Index (PCFI), Parsimony Normed Fit Index (PNFI), Tucker-Lewis Index (TLI), Relative Fit Index (RFI), Goodness-of-Fit Index (GFI), Adjusted Goodness-of-Fit Index (AGFI), Parsimony Goodness-of-Fit Index (PGFI), Full Information Maximum Likelihood with Missing Data (FIMIN), Noncentrality parameter (NCP), Root Mean Square Residual (RMR), Standardized Root Mean Square Residual (SRMR), Root Mean Square Error of Approximation (RMSEA), RMSEA with a confidence interval, P-value for Test of Close Fit (PCLOSE), Akaike Information Criterion (AIC), Consistent Akaike Information Criterion (CAIC), Browne-Cudeck Criterion (BCC), Bayesian Information Criterion (BIC), Expected Cross Validation Index (ECVI), and Modified Expected Cross Validation Index (MECVI) (5-7). The mean and standard deviation were not calculated for the criteria that were affected by sample size, and only the frequency and range (minimum and maximum values) were reported in the studies.

***Exploratory Factor Analysis and Confirmatory Factor Analysis***

KMO (Kaiser-Meyer-Olkin) value and Barllet test p-value were reported in the EFA approach, and Average Variance Extracted (AVE) values were extracted for the CFA approach.

***Regression and correlation approach***

Since the current study did not specifically investigate the relationship between variables, coefficients, and p-values were not extracted in studies that used correlation and regression for evaluating EHR models. Moreover, articles that did not report Cronbach's alpha and only conducted correlation or regression analysis were excluded from the current study.

## 4. Result

According to our previous study, a total of 64 full-text papers were included in the current study. Nonetheless, during the first screening, 21 articles were excluded since they did not propose an EHR evaluation model and instead adopted an existing evaluation framework without modification (Figure 1). Among the remaining 43 articles, three papers developed an EHR evaluation model; nonetheless, the validation method was not performed. In addition, four articles did not report the values of the validation method used. The study findings are summarized in Tables 1 and Table 2.

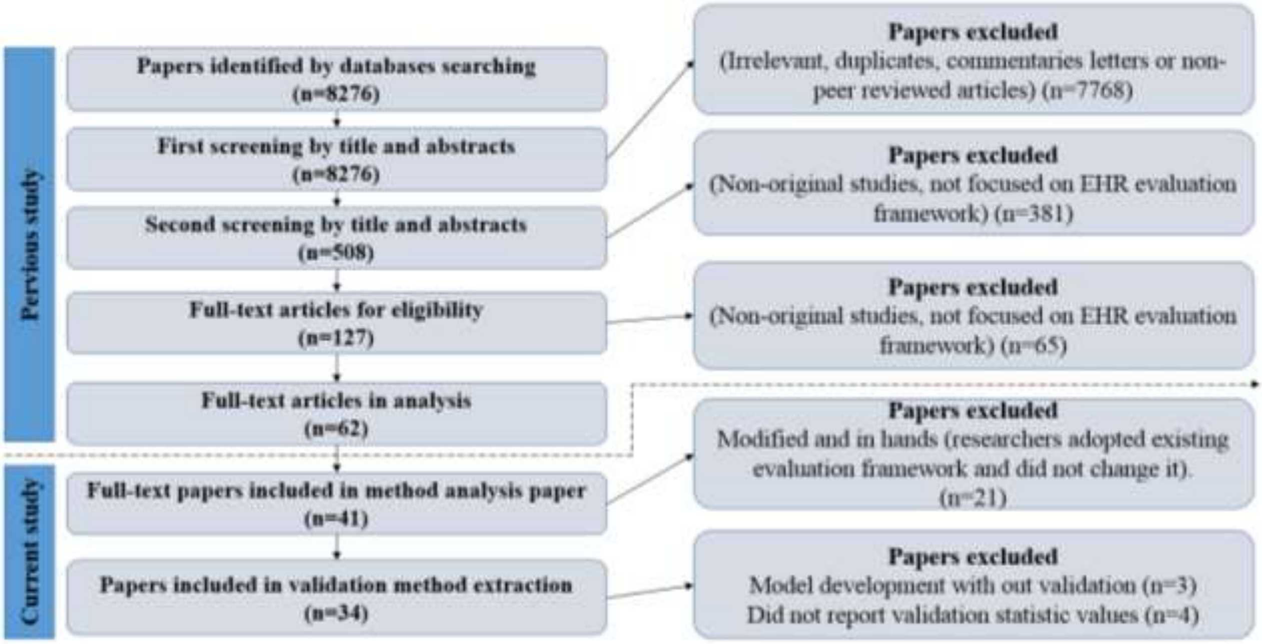


**Figure 1. Flow chart of the study selection process**

**Table 1. Evaluation items in EHR evaluation models**

| Row | Authors | Basis for evaluation framework development | Evaluation items: Independent | Evaluation items: Moderating | Evaluation items: Dependent | Diagram of EHR Evaluation Model | Data gathering methods | Analysis software | Sampling technique | Missing data | Outliers |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 505 | Lambooij et al. (8) | Literature review. | Authentic leadership\ support of administrative department\ Support of IT department\ support of HR department\ Bottom up communication in the hospital\ open culture in hospital \ Innovative culture in hospital | Ease of use\ alignment of EMR with daily routine\ perceived added value\ timeliness of use | Perceived quality of patient data | Yes | In-person | Not reported | Convenience sampling | No | No |
| 601 | Mohd Salleh et al. (9) | ISSM, EHR System Effectiveness Model. | Adequate infrastructure\ system interoperability\ perceived security control\ system compatibility\ | Did not have | Provider performance | Yes | In-person | Smart PLS | Convenience sampling | No | No |
| 504 | Kim et al. (End-User Acceptance Model) (10) | TAM, UTAUT. | Performance expectancy \effort expectancy \social influence \facilitating conditions \ | Attitude | Behavior intention to use | Yes | Online | SAS-AMOS | not report | No | No |
| 2 | Liu et al. (11) | TAM, DFM. | perceived mobility | Perceived usefulness\ perceived ease of use\ perceived threat | Behavior intention | Yes | In-person | Not reported | Convenience sampling | No | No |
| 507 | Sintonen et al. (12) | TAM, TBP. | Complexity\ reliability | Perceived usefulness \behavioral control\ usage intention | Actual use | Yes | Email | Smart PLS | Convenience sampling | No | No |
| 512 | Gan et al. (13) | TTF, SCT. | Organizational perceived task technology fit | Organizational valence to EHR\ social contagion | Intention to adopt EHR | Yes | In-person | not reported | Convenience sampling | Yes | No |
| 63 | Kralj et al. (Initial Framework Model) (14) | Literature review. | Business functionality\ privacy and data security\ domain (health) functionality\ data exchange with patient\ ergonomic functionality \additional services | * | * | Yes | Online | SPSS | not report | No | No |
| 68 | Wang et al. (User Acceptance Model of EPR) (15) | TAM | Personal characteristics: type of user, gender, age, education, occupation, number of outpatient visit\ work characteristics: job seniority, level of position, title of physician, level of hospital\ human aspects: reason to use EMR, level concerns\ technology | Did not have | Behavioral intention of use: attitude to privacy attitude to hospital information support | Yes | Online | SAS | Convenience sampling | No | No |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | aspects: usefulness, major information source | | | | | | | | |
| 40 | Michel-Verkerke et al. (16) | IT-Used model | Task support satisfaction\ interface satisfaction\ compatibility\ collaboration\ learnability\ ease of use\ support of use | * | * | No | Online | Not reported | not report | No | No |
| 519 | Hysong et al. (17) | UTAUT, Job JDRM. | Monitoring and feedback\ provider\ supportive norm\ provider perceptions of value\ training | Physician satisfaction\ intention to quit | Voluntary turn over | Yes | Online | SPSS-AMOS | Convenience sampling | No | No |
| 48 | Gagnon et al. (18) | TAM, TIB, DFM. | Perceived consequences\ facilitating conditions\ computer self-efficacy\ demonstrability of results\ personal identity\ social norm\ professional norm\ resistance to change | Perceived usefulness\ perceived ease of use | Behavioral intention to use | Yes | Online | AMOS | Convenience sampling | Yes | No |
| 545 | Iqbal et al. (19) | TAM, UTAUT, TPB. | Computer Self-efficacy\ Subjective Norm\ Security\ Privacy\ | Perceived usefulness\ Perceived ease to use | Intention to use | Yes | Online | SPSS | Convenience sampling | No | No |
| 548 | Kuo et al. (20) | TAM, TRI. | Optimism\ innovativeness\ insecurity\ discomfort | Perceived Ease Of Use\ Perceived Usefulness | Behavioral intention to use | No | Unclear | Smart PLS | bootstrapping resampling | No | No |
| 14 | Lu et al. (21) | TAM, ISSM. | System quality\ information quality\ service quality | Perceived ease of use\ perceived usefulness | Hospital information acceptance | Yes | In-person | LISREL-SPSS-STATA | simple random sampling | No | No |
| 21 | Aggelidis et al. (22) | ISSM, Bailey and Pearson's model, Doll and Torkzadeh. | Information quality\ system quality | Insourcing support\ outsourcing support | Overall satisfaction | Yes | In-person | AMOS | Convenience sampling | No | No |
| 20 | Chen and Hsiao (23) | TAM, HOT-FIT. | Human characteristic: self-efficacy, compatibility\ organizational characteristic: top management support, project team competency \ technology characteristic: system quality, information quality | Perceived usefulness\ perceived ease of use | Hospital information system acceptance | No | In-person | AMOS | not report | No | No |
| 521 | Lin et al. (24) | TAM, Lin et al., Bhattacherjee and Hikmet's. | Perceived threat | Perceived usefulness\ perceived inequity | Behavior intention | Yes | In-person | SPSS-AMOS | Convenience sampling | No | No |
| 122 | Carayon et al. (Model of electronic health records (EHR) acceptance) (25) | Chin et al., Carayon et al., Hoonakker et al. | Usefulness\ Usability | * | HIS acceptance | No | In-person | Not reported | Convenience sampling | Yes | No |
| 109 | Tilahun et al. (26) | ISSM | System quality\ information quality\ service quality\ computer literacy\ | User satisfaction\ system use | Perceived net-benefit | Yes | In-person | SPSS-AMOS | simple random sampling | No | No |
| 506 | Steininger et al. (27) | TAM | Privacy concerns\ social influence\ HIT experience\ cost saving\ stakeholder benefit\ improvement | Perceived usefulness | Intention to use | Yes | In-person or online | Not reported | not report | No | No |
| 32 | Kowitlawakul et al. (28) | TAM | Self-efficacy | Perceived ease of use\ behavioral intension\ attitude toward using | Intention to use | No | Online | SPSS-AMOS | Convenience sampling | Yes | Yes |
| 511 | Hsieh et al. (29) | TBP | Perceived usefulness\ perceived ease of use\ compatibility\ interpersonal influence\ governmental influence\ self-efficacy\ facilitating conditions\ situational normality\ structural assurance | Attitude \ subjective norm\ perceived behavior control\ institutional trust\ perceived risk | Usage intention | No | Unclear | Not reported | not report | No | No |
| 537 | Abdekhoda et al. (30) | TAM | Management support \adequate training \physicians' involvement \physicians' autonomy \doctor–patient relationship | Perceived usefulness\ perceived ease of use | System usage | Yes | In-person | AMOS | Convenience sampling | No | No |
| 7 | Messeri et al. (31) | ISSM | System Quality\ IT support | User Satisfaction: ease of use\satisfaction | Individual Impact: productivity\ prevention\ decision making, workflow\ | Yes | In-person | STAT | Convenience sampling | Yes | No |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | documentation | | | | | | |
| 56 | Hsu et al. (32) | DOI | Relative advantage\ Compatibility\ Complexity\ Trialability\ Observability\ Unit\ Seniority | Did not have | Behavior intention | Yes | Online | Not reported | Convenience sampling | No | No |
| 53 | Leblanc et al. (33) | TPB | External variables: age, gender, education, prior use of EHR, type of organization | Behavioral beliefs\ Normative beliefs\ facilitating conditions\ Attitude\ subjective norm\ perception of behavioral control | Intention | Yes | In-person | Not reported | Convenience sampling | No | No |
| 50 | Chen and Hsiao (34) | TAM | System quality\ Information quality\ Service quality | Perceived usefulness\ Perceived ease of use\ | HIS acceptance | Yes | In-person | Not reported | Convenience sampling | No | No |
| 26 | Hsiao et al. (35) | TAM | IS construct\ personal construct\ organizational construct\ Perceived ease of use\ | Did not have | Hospital information system acceptance | Yes | In-person or online | SPSS | Convenience sampling | No | No |
| 33 | Sicotte et al. (36) | ISSM | Qualities of PACS\ data quality\ quality of technical support | Overall satisfaction\ Use | Future intention | Yes | In-person or online | Not reported | Convenience sampling | No | No |
| 602 | Erlirianto et al. (37) | HOT-Fit | Technology:(system quality \information quality\ service quality) | Human: system use, user satisfaction\ Organization: structure, environment | Net benefit | Yes | Unclear | GeSCA | Convenience sampling | No | No |
| 11 | Ho et al. (38) | IPA | Installation and Maintenance \ Product Effectiveness \ System Function \ Customer Service\ Personal Information\ | * | * | Yes | Unclear | Not reported | Convenience sampling | Yes | No |
| 52 | Devine et al. (39) | ITAM | Finesse | Perceived ease of use\ Perceived usefulness | Intent to use | Yes | In-person or online | STAT | Convenience sampling | No | No |
| 64 | Otieno et al. (40) | ISSM | EMR use\ Quality of EMR systems\ User satisfaction | * | * | Yes | Online | SPSS | Convenience sampling | No | No |
| 66 | Otieno et al. (41) | ISSM | EMR use\ Quality of EMR systems\ User satisfaction | * | * | Yes | Online | SPSS | Convenience sampling | Yes | No |

Star sings (*) shows unclear causal relationship between variables

Ammenwerth and Dekeizer (ADK), Computer Anxiety Model (CAM), Diffusion of innovation (DOI), Composite Index (CI)Dual Factor Model (DFM), Fit Between Individuals, Task and Technology framework (FITT), Human, Organization And Technology-Fit Factors (HOT-Fit), Information Success Model (ISSM), Job Demands Resource Model (JDRM), Theory of Planned Behavior (TPB), Technology Acceptance Model (TAM), Task and Technology and Fit (TTF),Technology Readiness Index (TRI), Unified Theory of Acceptance and Use of Technology (UTAUT).

*Participants and study setting*

The majority of the studies (n=23; 67.64%) were conducted in hospitals, followed by primary care clinics (n=7; 20.58%). Other locations included physician offices, specialty associations, and universities. In 64% of the studies (n=22), physicians participated in the evaluation of EHR, while in 56% of the studies (n=19), nurses were involved.

**Table 2. The validation models and values with study characteristics of EHR evaluation models**

| | Authors | | Validation methods | SEM, CFA, EFA values | Reliability methods and values | Sample Size | Participants | Study setting |
|---|---|---|---|---|---|---|---|---|
| 1 | Lambooij et al. (8) | 505 | SEM | χ2chi2= 3852.62, CFI = 0.93, TLI = 0.93, RMSEA = 0.046 | Cronbach's alpha: 0.70 to 0.92 | 914 | Physicians\nurse | Hospital |
| 2 | Mohd Salleh et al. (9) | 601 | CFA | AVE= 0.583-0.823 | CR: 0.807-0.926 | 367 | Nurses\resident\medical officer | Hospital |
| | Kim et al. (End-User Acceptance Model) (10) | 504 | SEM | χ2=449.217, df=108, P-value=0.000, TLI=0.910, CFI=0.936, and RMSEA=0.84 | Cronbach's alpha: 0.844 to 0.979 | 942 | Physicians and nurses | Hospital |
| 3 | Liu et al. (11) | 2 | CFA | AVE= 0.81-0.88 | Cronbach's alpha: 0.89 to 0.96\ CR: 0.93-0.97 | 158 | Physicians | Hospital |
| 4 | Sintonen et al. (12) | 507 | CFA | AVE= 0.762-1.000 | CR: 0.862 to 1.000 | 187 | Physicians and head nurses | Primary Care Clinic |
| 5 | Gan et al. (13) | 512 | CFA | AVE= 0.511-0.886 | CR: 0.733 to 0.955 | 51 | Health organization management students | University |
| 6 | Kralj et al. (Initial Framework Model) (14) | 63 | EFA | KMO= 0.857 -0.962, Bartlett's test: P-value < 0.001, factor loading:**** | Cronbach's alpha: 0.637 to 0.973 | 384 | Physicians and other non-clinical participants | A Medical Association |
| 7 | Wang et al. (User Acceptance Model of EPR) (15) | 68 | EFA | KMO=0.46, 0.63, and 0.48 physicians, for MRS, and patients, respectively | Cronbach's alpha: 0.72 to 0.85 | 379 | Physicians, non-clinical participants, and patient | Hospital |
| 8 | Michel-Verkerke et al. (16) | 40 | EFA | KMO=0.910, Bartlett's test: (P-value < .001) ) | Cronbach's alpha: 0.896, 0.903, and 0.907 | 222 | Physicians, nurses, and other clinicians | Hospital |
| 9 | Hysong et al. (17) | 519 | SEM | RMSEA= 0.04, PCLOSE = 0.47 | not reported | 2590 | Physicians | Medical Facilities |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 10 | Gagnon et al. (18) | 48 | SEM | CFI=0.94, IFI=0.94, TLI= 0.92 | Cronbach's alpha: 0.66 to .91 | 157 | Physicians | A Medical Association |
| 11 | Iqbal et al. (19) | 545 | Correlation analysis | ***** | Cronbach's alpha: > 0.90 | 1097 | Primary care clinic, physicians | Hospital |
| 12 | Kuo et al. (20) | 548 | CFA | AVE=0.69-0.87 | Cronbach's alpha: =0.77 to 0.95 CR= 0.87 to 0.96 | 878 | Nurses | Hospital |
| 13 | Lu et al. (21) | 14 | CFA-SEM | AVE 0.80-0.90, χ2 =3294.48, GFI=0.68, PGFI = 0.62, NFI= 0.98, NNFI= 0.98, CFI=0.98, RMSEA=0.08, RMR=0.035, SRMR=0.048. | Cronbach's alpha: 0.90 to 0.98, CR= 0.74 to 0.87 | 297 | Nurses | Hospital |
| 14 | Aggelidis et al. [22] | 21 | SEM | χ2/Df= 1.82, CFI=0.015, GFI=0.958, NFI=0.928, RMR=0.928, 0.980, RMSEA= 0.064 | Did not reported | 341 | Physicians, nurses, other clinicians, and other non-clinical participants | Hospital |
| 15 | Chen and Hsiao [23] | 20 | CFA-SEM | AVE=0.756 to 0.933, , X2 =1124.56, d.f.=466.00, X2/d.f.=2.41, GFI=0.85, NFI=0.90, NNFI=0.91, IFI=0.93, CFI=0.90, RMSEA)=0.08 | Cronbach's alpha: 0.701 to 0.908, CR:0.857 to 0.967 | 202 | Physicians | Hospital |
| 16 | Lin et al. [24] | 521 | CFA-SEM | AVE=0.76 to 0.84, , X2 =1124.56, d.f.=466.00, χ2/d.f.=1.13, GFI=0.93, NFI)=0.97, IFI)=0.99, CFI=0.99, RMSEA=0.03, AGFI=0.93 | Cronbach's alpha: 0.93 to 0.95, CR=0.91 to0.94 | 115 | Physicians | Hospital |
| 17 | Carayon et al. (Model of electronic health records (EHR) acceptance) (25) | 122 | MRA | - | Cronbach's alpha: 0.90-0.98 | 282 | Nurses | Medical Center |
| 19 | Tilahun et al. (26) | 109 | CFA-SEM | AVE=0.68 to 0.81, CR=0.84 to 0.96, χ2/d.f. = 2.39, GFI =0 .92, AGFI =0 .87, NFI = 0.92, RMSR = 0.056 | Cronbach's alpha:0.84 to 0.91 | 384 | Physicians, nurses, and other clinicians | Hospital |
| 20 | Steininger et al. (27) | 506 | SEM | χ2= 38.76, df=13, AIC=100.7, CFI=60.97, TLI=0.91, RMSEA=0.10 | Cronbach's alpha: 0.76 to 0.92 | 204 | Physicians | Physician Office |
| 21 | Kowitlawakulet al. (28) | 32 | SEM | χ2/d.f.=1.757, GFI=0.90, NFI=0.97, IIFI=0.931, CFI=0.969, RMSEA=0.06, AGFI=0.863 | Cronbach's alpha: 0.76 to 0.92 | 212 | Nurses | Primary Care Clinic |
| 22 | Hsieh et al. (29) | 511 | CFA | AVE=0.766 to 0.961, CR=0.908 to 0.967 | not reported | 191 | Physicians | Hospital |
| 23 | Abdekhoda et al. (30) | 537 | SEM | Relative χ2= 1.9, df=13, NFI =0.93, CFI=0.93, TLI=0.92, RMSEA=0.02 | not reported | 234 | Physicians | Hospital |
| 24 | Messeri et al. (31) | 7 | MRA | - | Cronbach's alpha: 0.64 to 0.74 | 460 | Physicians and nurses | Primary Care Clinic |
| 25 | Hsu et al. (32) | 56 | MRA | - | Cronbach's alpha: 0.622 to 0.930, CR: 0.650 to 0.930 | 720 | Nurses | Hospital |
| 26 | Leblanc et al. (33) | 53 | MRA | - | Cronbach's alpha: 0.62 to 0.89 | 99 | Nurses | Hospital |
| 27 | Chen and Hsiao (34) | 50 | CFA, MRA | AVE: > 0.51 | CR: > 0.87 | 81 | Physicians | Hospital |
| 28 | Hsiao et al. (35) | 26 | MRA | - | Cronbach's alpha: 0.97 | 545 | Nurses | Hospital |
| 29 | Sicotte et al. (36) | 33 | Linear regression analysis | - | Cronbach's alpha: 0.73 and 0.97 | 125 | Physicians | Hospital |
| 30 | Erlirianto et al. (37) | 602 | SEM | FIT: 0.386, AFIT=0.370, GFI = 0.943 | not reported | 67 | Nurses, other clinicians, and other non-clinical participants | Hospital |
| 31 | Ho et al. (38) | 11 | Pearson correlations | - | Cronbach's alpha: > 0.87 | 581 | Physicians | Primary Care Clinic |
| 32 | Devine et al. (39) | 52 | Linear regression analysis | - | Cronbach's alpha: 0.90 to 0.92 | 117 | Physicians and nurses | Primary Care Clinic |
| 33 | Otieno et al. (composite index (CI)) (40) | 64 | Correlation analysis | - | Cronbach's alpha: 0.475 to 0.843 | 1892 | Physicians, nurses, and other non-clinical participants | Hospital |
| 34 | Otieno et al. [41] | 66 | EFA | KMO >0.80 (Field 2005) and Bartlett's tests P-value >0.00 | Cronbach's alpha total:0.88, range: 0.36 to 0.94 | 1666 | Physicians, nurses, and other non-clinical participants | Hospital |

EFA
correlation analysis CA
Multiple Regression Analysis MRA

***Data gathering methods, missing data, and outlier handling***

Data were collected using various methods, including in-person (n=14), online (n=11), in-person or online (n=4), email (n=3), and nuclear (n=6). Handling missing cases was discussed in 20.6% of papers (n=7). Therefore, only one of the selected papers explained outlier handling.

***Analysis software***

The most commonly used software was SPSS, used in 14.7% of the papers. AMOS and Smart PLS were used in 11.8% and 8.8% of the papers, respectively, followed by GeSCA, LISREL, SAS, and STAT, each used in less than 6% of papers. It is worth noting that used software not reported was used in 35.3% (n=12) of papers.

***Theoretical Basis models***

A number of 16 studies (47%) used the Technology Acceptance Model (TAM) to develop the EHR evaluation model, while the Information System Success Model (ISSM) was used in 7 papers (20%). Other models used to develop the EHR evaluation model included the Ammenwerth and Dekeizer (ADK) model, Computer Anxiety Model (CAM), Diffusion of Innovation (DOI), Composite Index (CI), Dual Factor Model (DFM), Fit Between Individuals, Task, and Technology framework (FITT), Human, Organization, and Technology-Fit Factors (HOT-Fit), Job Demands Resource Model (JDRM), Theory of Planned Behavior (TPB), Task and Technology and Fit (TTF), Technology Readiness Index (TRI), as well as Unified Theory of Acceptance and Use of Technology (UTAUT).

***Relationship between variables of the EHR evaluation models***

Among 34 papers, 29 articles (85.29%) developed a causal model that included independent, moderating, and dependent variables. Four causal models did not include moderating variables, while five papers proposed a non-causal model for evaluating Electronic Health Records (EHR). The EHR evaluation model diagram was included in most articles (n=27). The moderating variables that were most commonly observed in the analyzed articles were perceived usefulness (n=12) and perceived ease of use (n=9). The dependent variables that received the most attention were behavior intention to use/system use (n=16) and system adoption (n=6). The independent variables that were most frequently studied were system quality (n=11), information quality (n=7), and service quality (n=6).

***Statistical validation methods***

Among the 34 papers that disclosed the validation methods utilized, the most widely used technique was SEM, which was employed in 26.5% (n=9) of the studies. Other methods utilized were Confirmatory Factor Analysis (CFA) (17.6%; n=6), Exploratory Factor Analysis (EFA) (11.8%; n=4), Multiple Regression Analysis (MRA) (14.7%; n=5), Correlation (5.9%; n=2), Linear Regression (5.9%; n=2), and Pearson (2.9%; n=1). Furthermore, it is worth noting that in addition to the methods listed in the articles, four studies used both CFA-SEM (11.8%) and CFA, while one study (2.9%) utilized both CFA and MRA.

***Sampling technique and sample size***

Convenience sampling was the most frequently used method of sampling, reported in 73.5% of papers, followed by random sampling (5.9%) and bootstrapping resampling (2.9%). Six papers (17.6%) did not provide information on the sampling technique used. The mean sample size used in the papers was 504.14 (SD= ±570.99, range = 51 to 2590). Among the 34 papers, the majority (n=25; 73.5%) used convenience sampling as their sampling technique, which was the most frequently used method. Random sampling was used in only 2 (5.9%) papers, while bootstrapping resampling was used in only 1 (2.9%) paper. Meanwhile, 6 (17.6%) papers did not provide information on the sampling technique used. The means and 95% confidence intervals for each of the different validation methods were in ascending order as follows: Linear regression: Mean = 121(SD=±4), CFA and SEM: Mean = 249.5 (SD=±58.23), CFA: Mean = 305.33 (SD=±121.82), EFA: Mean = 662.75 (SD=±336.52), MRA: Mean = 421.2 (SD=±107.7), SEM: Mean = 629 (SD=±267.62), and Correlation: Mean = 1494.5, (SD=±397.5).

***Reliability assessment methods and values***

A reliability assessment was performed in 28 (82%) articles. Cronbach's alpha and composite reliability (CR) were popular reliability (internal validation) methods on identified papers. Reliability was not reported in six articles. Cronbach's alpha and composite reliability (CR) were calculated together in seven articles, while Cronbach's alpha was calculated in 2 5(73.5%) papers. The CR was calculated in 9 (26%) articles. The mean of CR was 0.94 (SD=±0.03), with values ranging from 0.87-1.00 in identified studies. As for Cronbach's alpha, the mean was 0.92 (SD=±0.058), varying from 0.74-1.00.

***Statistics criteria in the SEM approach***

The most commonly used criteria in the SEM approach included the Comparative Fit Index (CFI), Root Mean Square Error of Approximation (RMSEA), Chi-square ($\chi 2$), and Normed Fit Index (NFI). After analyzing eleven articles, it was found that the mean CFI was 6.30845, with a range of 0.015-60.97 and a standard deviation of 18.13. The mean RMSEA was 0.172 (SD=±0.29) across nine papers. The Chi-square ($\chi 2$) was reported in eight articles, with values ranging from 1.90-3852.620. The NFI in seven papers was 0.94 (SD=±0.3). The Degree of Freedom (df) was calculated in six articles, ranging from 1.82-466.00. The Goodness-of-Fit Index (GFI) had a mean of 0.85 (SD=±0.14) across five papers. The $\chi 2$/df was reported in four articles, with values ranging from -2.72-2.41. The TLI was measured in five articles, with values ranging from 0.91-0.93 and a mean of 0.918 (SD=±0.008). The Incremental Fit Index (IFI) in four papers ranged from 0.931-0.990.

The Non-Normed Fit Index (NNFI) was calculated in two papers, with values of 0.91 and 0.98. Differences in CFI were reported in one article, with a value of 0.9900. The range of the Adjusted Goodness-of-Fit Index (AGFI) in three papers was 0.86-0.93. The Root Mean Square Residual (RMR) was reported in three papers, ranging from 0.035-0.928. The Standardized Root Mean Square Residual (SRMR) ranged from 0.048-0.056 in two articles. The value of the Parsimony Goodness-of-Fit Index (PGFI) in one paper was 0.68. The Akaike Information Criterion (AIC) was reported in one article, with a value of 100.700. None of the identified studies reported criteria, such as PCFI, PNFI, RFI, P Ratio, NCP, FIMIN, RMSEA with a confidence interval, PCLOSE, CAIC, BCC, BIC, ECVI, and MECVI.

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None of the identified studies reported such criteria as PCFI, PNFI, RFI, P Ratio, NCP, FIMIN, RMSEA with a confidence interval, PCLOSE, CAIC, BCC, BIC, ECVI, and MECVI. A reliability assessment was performed in 28 (82%) articles. Cronbach's alpha and composite reliability (CR) were popular reliability (internal validation) methods on identified papers. Reliability was not reported in six articles. Cronbach's alpha and composite reliability (CR) were calculated together in seven articles, while Cronbach's alpha was calculated in 25 (73.5%) articles. The CR was calculated in 9 (26%) articles. The mean of CR was 0.94 (SD=±0.03), with values ranging from 0.87-1.00 in identified studies. As for Cronbach's alpha, the mean was 0.92 (SD=±0.058), varying from 0.74-1.00. A reliability assessment was performed in 28 (82%) articles. Cronbach's alpha and composite reliability (CR) were popular reliability (internal validation) methods on identified papers. Reliability was not reported in six articles.

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***Statistics criteria in CFA and EFA approach***

The AVE in 10 papers was calculated. The articles analyzed had a mean of 0.71 (SD=±0.97) for lower AVE with a minimum value of 0.51 and a maximum value of 0.81. The mean for upper AVE was 0.8863 (SD=±0.97), with a range of 0.80-1.00. KMO was measured in three papers. Bartlett's test was significant in all these studies.

## 5. Discussion

The present study aimed to conduct an overview of reliability and validity evaluation methods in EHR evaluation models. The obtained results revealed that EHR evaluation models were created using various validation methods, each with different levels of accuracy. In addition, the effectiveness of these methods depended on the sample size used in the study. Researchers can perform more reliable validation methods in studies with larger sample sizes. Our research revealed that the most common validation methods applied in EHR evaluation models are SEM and CFA. Factor analysis and structural analysis are the two fundamental methods used for evaluating models, with high power to identify the model structure and variable relationships (7).

The SEM is a crucial tool for analyzing and comprehending causal relationships among direct and indirect variables in EHR evaluation studies (6, 42). It has been applied to evaluate EHR implementation and its impact on users in previous studies (43). The SEM can provide a new perspective on analyzing data and the potential for advancing research in medical and health sciences (44). In agreement with our findings, Dash and Paul pointed out that SEM can overcome the limitations of mediation analysis, CFA, and regression methods (5) and has widespread use in social and human studies (45). The SEM has been used in various healthcare studies, such as those on COVID-19 (46), nursing research (47) and psychological research (48).

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Based on the results of the current study, a number of identified studies used both CFA and SEM as validation methods. These findings are supported by previous research, such as the model proposed by Dash and Paul, which outlines a five-step process for utilizing SEM. This process includes individual construct identification, preparation for CFA, running CFA, structural modeling, and finally, interpreting findings (5). In a similar vein, Dragan and Topolsek have outlined the basic steps often used in SEM modeling, which include EFA, CFA, and calculating model indices (50). The CFA is a crucial component of the measurement model, which assesses the relationships between a construct and its indicator variables (7). This process helps explain how the data fits into the structure model (11). Once the measurement model is validated using CFA, pathway analysis is conducted to examine the relationships among the latent variables (5). Path modeling involves estimating multiple regression models simultaneously and can demonstrate mediation, moderation, and interaction relationships among variables (5).

Our review revealed that some of the identified studies used EFA to develop an EHR validation model. In the study by Dragan and Topolsek, EFA was used as a preliminary step in structural modeling when the researchers were interested in data reduction. It is essential to note that the selection of analysis methods may vary depending on the research question and goals of the study (50). Furthermore, our findings demonstrated that the goodness of fit index (GFI), adjusted goodness of fit index (AGFI), and root mean square error of approximation (RMSEA) criteria were prominent in all the included criteria for SEM approaches. This is in line with previous studies, where GFI, AGFI, and RMSEA measures were commonly used in the SEM literature to assess the goodness of fit of the model (48).

TAM, TPB, and UTAUT are all human and social-based theories that focus on understanding individuals' attitudes toward technology adoption (51). These theories were used frequently in our identified papers. In healthcare research, Technology Acceptance Model (TAM), as well as its extensions and modifications, are at the forefront. Modified and extended TAM models were developed to improve the explanatory power of the original TAM model. In addition, the Unified Theory of Acceptance and Use of Technology (UTAUT) is considered one of the other most pertinent and actively used models in technology acceptance studies in healthcare (52).

The obtained results pointed to several ways to develop an EHR evaluation framework. A framework can be developed based on a literature review or a combination of existing frameworks. For instance, measuring end-user computing satisfaction (EUCS) was developed based on UTAUT, Doll and Torkzadeh (1988), and Bailey and Pearson's model (1983) (22). End-User Acceptance Model (EUAM) is a hybrid framework of TAM and UTAUT (10). Lambooij et al. carried out a literature review and developed an original evaluation framework, which was not based on any existing evaluation framework (8). Michel-Verkerke et al. combined observations of the developments in the EHR market and healthcare together with a literature search to propose the "Six P-model of EPR-use" (16).

Another method to develop an EHR evaluation framework is to modify an existing EHR evaluation framework which refers to adding or removing dimensions to an existing evaluation framework. For example, Sicotte et al. added two variables to ISSM that had been used in another study on the benefits of PACS (36). Messeri et al. conducted a literature search and prepared a modified ISSM (31). Chen and Hsiao extended TAM to take quality aspects into account (34). Tilahun and Fritz added computer literacy to ISSM (26). Steininger and Stiglbauer presented a modified TAM and included social influence, health information technology experience, and privacy concern factors as external variables to the TAM [27].

## 6.Conclusion

It is believed that the results of this study can assist researchers in examining and modifying EHR evaluation frameworks to suit their specific needs. Furthermore, our findings serve as a solid foundation for the development of new EHR evaluation frameworks. The present review study can assist researchers in understanding the viability of validation methods, such as SEM techniques, correlation models, and hierarchical regression models in the context of electronic health records. Moreover, it is recommended that researchers utilize the findings presented in this article to enhance the implementation and utilization of SEM, CFA, and EFA methods in EHR evaluation models.

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## Conflicts of interest

The authors declare that they have no conflict of interest.

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