

# Development and evaluation of digital software tool for collecting clinical-epidemiological data in patients with post-COVID-19 conditions\*

Desenvolvimento e avaliação de *software* digital para coleta de dados clínicoepidemiológicos de pacientes em condições pós-COVID-19

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#### **ABSTRACT**

**Objective:** to develop and evaluate a digital software tool for collecting clinical-epidemiological data from patients with post-COVID-19 conditions. Methods: technology development and evaluation study conducted in three phases: content validation by health experts; software development; and assessment of technical quality and functional performance. Content was validated by nine health-care specialists. The software was evaluated by these professionals and by nine computer science experts. Results: the software includes modules for sociodemographic information, social determinants of health, clinical conditions, and quality of life. Overall content validity coefficients were: clarity of language, 0.92; practical pertinence, 0.94; and theoretical relevance, 0.94. Expert assessments indicated satisfactory levels for functional suitability, reliability, usability, performance efficiency, compatibility, security, maintainability, and portability. Conclusion: the software demonstrated evidence of content validity and was deemed functional, with potential for use in research to monitor individuals with post-COVID-19 conditions. Contributions to practice: the tool represents a methodological innovation for data collection, promoting standardized, secure, and high-quality information in public health research.

**Descriptors:** Software; Coronavirus Infections; Data Collection; Public Health Nursing; Biomedical Technology.

## RESUMO

Objetivo: desenvolver e avaliar um software digital para coleta de dados clínico-epidemiológicos de pacientes em condições pós-COVID-19. Métodos: estudo de desenvolvimento e avaliação de tecnologia, realizado em três fases: análise de validade de conteúdo por especialistas em saúde; desenvolvimento do software; e avaliação da qualidade técnica e do desempenho funcional. O conteúdo foi validado por nove especialistas em saúde, e o software avaliado por esses profissionais e por nove especialistas em informática. Resultados: o software contempla módulos de dados sociodemográficos, determinantes sociais da saúde, condições clínicas e qualidade de vida. Os coeficientes de validade de conteúdo total foram: clareza de linguagem - 0,92, pertinência prática - 0,94 e relevância teórica - 0,94. As avaliações dos especialistas indicaram níveis satisfatórios para a adequação funcional, confiabilidade, usabilidade, eficiência de desempenho, compatibilidade, segurança, manutenibilidade e portabilidade. **Conclusão**: o *software* apresenta evidências de validade de conteúdo e foi considerado funcional, com potencial de uso em estudos científicos para o monitoramento de pessoas em condições pós-COVID-19. Contribuições para a prática: o software é uma inovação metodológica para a coleta de dados, promovendo a padronização, segurança e qualidade das informações em pesquisas de saúde pública.

**Descritores:** Software; Infecções por Coronavírus; Coleta de Dados; Enfermagem em Saúde Pública; Tecnologia Biomédica.

# Introduction

Over recent decades, advances in computing technology have transformed social, political, economic, and cultural dynamics worldwide, directly affecting work processes and the circulation of information<sup>(1)</sup>. In health care, this transformation has been particularly rapid, accelerating technological innovation and the adoption of health information systems as essential tools for planning, monitoring, and evaluating health actions. The collection, organization, and analysis of clinical-epidemiological data — enabled by specialized software and hardware — have strengthened the responsiveness of health services, supporting problem identification, public policy development, and the implementation of evidence-based interventions<sup>(2-3)</sup>.

With the onset of the COVID-19 pandemic, there was an urgent need for digital solutions capable of enabling secure, rapid, and remote data collection amid restrictions imposed by physical distancing and mobility limitations. In this context, custom software and applications emerged as viable tools for remote data management, facilitating the continuity of scientific investigations under adverse conditions<sup>(4-5)</sup>.

Among the technological initiatives introduced during the pandemic were tools for symptom screening, contact tracing, and patient follow-up, such as telemedicine/mHealth platforms, the Buoy Health symptom checker<sup>(6)</sup>, and the Lark Health digital platform for prevention and disease management<sup>(7)</sup>. As diagnostic support, smartphones were employed to aid interpretation of COVID-19 test results and to monitor and trace contacts and patients during the disease course. In addition, wearable sensors were used to track physiological signals in real time, expanding the possibilities for continuous remote surveillance<sup>(8)</sup>.

Despite these advances, there remains a gap in technologies specifically designed to collect clinical-epidemiological data for scientific studies, particularly for monitoring the medium- and long-term repercussions of COVID-19. The lack of solutions tailored to contexts of social isolation or prolonged surveillance

limits the production of robust evidence on COVID-19's impact at individual and population levels<sup>(9)</sup>.

Accordingly, the aim of this study was to develop and evaluate a digital software tool for collecting clinical-epidemiological data from patients with post-COVID-19 conditions.

#### **Methods**

## Study design and phases

This technology development and evaluation study focused on a digital software tool designed to support the collection of clinical-epidemiological data in scientific studies involving patients diagnosed with post-COVID-19 and/or other respiratory syndromes. The work proceeded in three phases: i) development and content validation of the material to be incorporated into the software; ii) software development; and iii) technical quality and functional performance evaluation by subject-matter experts in health and in informatics.

## Phase 1: Content development and validation

The content to be embedded in the software comprised patient identification, pre-COVID-19 clinical conditions, clinical data related to COVID-19, and Social Determinants of Health (SDOH). As references, we used the coronavirus guidance manual<sup>(10)</sup>, clinical care guidelines for patients with coronavirus in the Americas<sup>(11)</sup>, the national forms for investigating suspected COVID-19 cases and for reporting severe acute respiratory syndrome cases<sup>(10)</sup>. The theoretical framework was the SDOH model<sup>(12)</sup>, organized into five concentric layers to enable a broader appraisal of health conditions.

Integrating SDOH into the software was intended to improve the assessment of health inequities and to support investigation of how social and environmental factors influence health outcomes<sup>(13)</sup>. Content validity evidence was then examined by a

committee of nine health experts recruited via snow-ball sampling<sup>(14)</sup>, according to predefined criteria<sup>(15)</sup>, including experience in public health, emerging diseases, COVID-19, respiratory syndromes, and/or epidemiology. The first expert — a physician working in COVID-19 care units and linked to a public-university research group in Ceará — identified subsequent participants. Experts rated each item for clarity of language, theoretical relevance, and practical pertinence<sup>(16)</sup>.

The multidisciplinary committee — composed by nurses, physicians, and pharmacists — received an invitation letter, the informed consent form, and the content-evaluation instrument via email. All experts returned the completed materials within the specified 15-day period. Content validation occurred in October 2020 and followed the three criteria above<sup>(16)</sup>. Data analysis used descriptive statistics (frequencies) and the content validity coefficient (CVC); items with CVC > 0.80 on all three dimensions were considered valid<sup>(17)</sup>.

## Phase 2: Software development

Software development spanned 4 months, from October 2020 to January 2021, and followed software-engineering principles of definition, development, and maintenance<sup>(18)</sup>. A computer-science professional with programming experience led the development in partnership with the research team. An incremental development model was adopted, encompassing model construction, model analysis, and model repair<sup>(18)</sup>, the same methodological approach successfully used in prior health-software research<sup>(19)</sup>.

Two main feedback cycles were conducted during incremental development. Each cycle deployed a functional prototype for testing by researchers involved in the project. After each testing round, participants discussed software functionality; suggestions were reviewed and led to technical adjustments and user-interface improvements.

The software was designed for web-browser access with no local installation to facilitate field and remote use by researchers. Its structure comprises

modules covering pre-infection clinical data, current clinical conditions, SDOH, and quality-of-life information. In addition to bespoke content, two instruments validated in Brazil were integrated: the 36-Item Short Form Survey (SF-36) for quality-of-life assessment<sup>(20)</sup> and the St George's Respiratory Questionnaire (SGRQ) specific to obstructive respiratory diseases<sup>(21)</sup>. Both are available under the "Platform Tasks" tab and can be sent to patients.

#### Phase 3: Technical and functional evaluation

Technical and functional evaluation applied the System and Software Quality Requirements and Evaluation (SQuaRE) framework, which encompasses eight quality characteristics: functional suitability, reliability, usability, performance efficiency, compatibility, security, maintainability, and portability<sup>(22)</sup>. Evaluations took place in January–February 2021 and involved two groups: nine health experts (the same who participated in content validation) and nine informatics experts, also recruited via snowball sampling. The first informatics expert was indicated by one of the study researchers and selected using predefined criteria<sup>(15)</sup>.

Health experts assessed six characteristics — functional suitability, reliability, usability, performance efficiency, compatibility, and security — while informatics experts evaluated these same six plus maintainability and portability, which are specific to their domain. All assessments were conducted online using Google Forms and included an informed consent form; an expert-characterization questionnaire; the technical-quality instrument (health area); and the functional-performance instrument (informatics area). Both groups received a software access link with predefined login credentials.

## Measures and rating criteria

Experts rated characteristics and sub-characteristics on a five-point Likert scale from 1 ("not at all appropriate") to 5 ("completely appropriate"). To do-

cument modules and judgments, we used a methodology that provides guidance for reporting evaluation modules<sup>(23)</sup>, as adapted previously<sup>(19)</sup>. An item was deemed adequate if at least 70% of ratings were "very appropriate" or "completely appropriate." Items not reaching this threshold were classified as inadequate, indicating the need for refinement and/or correction.

#### **Ethical considerations**

The study followed the recommendations of National Health Council Resolution 466/2012 and was approved by the Research Ethics Committee at Universidade Federal do Ceará (decision no. 4,278,495/2020; Certificate of Submission for Ethical Appraisal No. 36193820.1.0000.5054).

#### Results

The expert-validated content comprised 36 items mapped to the five concentric layers of the SDOH model. Layer 1 (individual determinants; items 1-5) covered patient identification, age, sex, genetic background, and clinical conditions. Layer 2 (proximal/ micro-determinants; item 6) addressed individual behaviors and lifestyle. Layer 3 (social and community networks; items 7-15) included variables such as religion and educational attainment. Layer 4 (intermediate determinants; items 16-34) encompassed health status, living conditions, environment, and work — diet, housing, sanitation, pollution, workplace environment, access to information, and access to health services. Layer 5 (structural determinants; items 35-36) addressed societal economic, cultural, and environmental conditions that shape the other layers.

Content evaluation by health experts indicated high validity: total CVC values (CVCt) were 0.92 for language clarity and 0.94 for both practical pertinence and theoretical relevance. In addition to these quantitative results, experts proposed wording refinements to selected items (Table 1).

**Table 1** – CVC for software items by language clarity, practical pertinence, and theoretical relevance. Fortaleza, CE, Brazil, 2021

Ib (1-b	Content validity coefficient			
Item (1st	Language Practical Theoretical		Action	
version)	clarity	pertinence	relevance	
1	0.89	0.96	0.98	Modified
2	0.98	0.98	0.93	Modified
3	0.96	0.96	0.98	Kept
4	0.91	0.96	0.89	Modified
5	0.93	0.98	0.96	Modified
6	0.84	0.96	0.91	Modified
7	0.91	0.93	0.91	Modified
8	0.89	0.91	0.91	Modified
9	0.98	0.89	0.96	Modified
10	0.93	0.93	0.93	Modified
11	0.93	0.93	0.91	Modified
12	0.93	0.89	0.87	Modified
13	0.96	0.91	0.91	Modified
14	0.82	0.96	0.98	Modified
15	0.91	0.98	0.98	Kept
16	0.82	0.91	0.96	Modified
17	0.91	0.93	0.93	Modified
18	0.91	0.96	0.96	Modified
19	0.93	0.96	0.96	Modified
20	0.98	0.98	0.93	Modified
21	0.89	0.96	0.96	Modified
22	0.91	0.98	0.98	Modified
23	0.96	0.98	0.98	Kept
2.4	0.00	0.00	0.98	Modified and
24	0.98	0.98		reallocated
25	0.96	0.91	0.91	Modified
26	0.96	0.96	0.96	Kept
27	0.84	0.87	0.93	Modified
28	0.78	0.96	0.96	Modified
29	0.91	0.91	0.93	Modified
30	0.89	0.91	0.91	Modified
31	0.93	0.93	0.93	Modified
32	0.96	0.96	0.96	Kept
33	0.96	0.96	0.96	Kept
34	0.91	0.96	0.96	Kept
35	0.91	0.91	0.93	Modified
36	0.93	0.87	0.96	Modified
CVCt	0.92	0.94	0.94	

CVCt: Content validity coefficient total

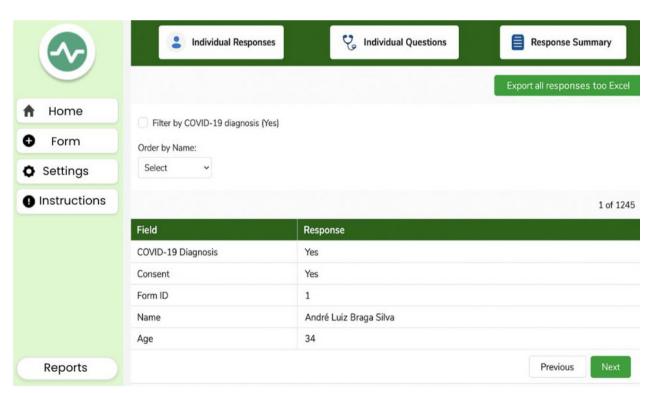
Among the suggestions not incorporated, one requested adding options for "high-risk pregnancy" or "usual-risk pregnancy." This recommendation was declined because, since March 2020, the Ministry of Health of Brazil has classified all pregnant women as a COVID-19 risk group regardless of gestational con-

dition, given the physiological changes inherent to pregnancy. Another expert suggested specifying test results by immunologic markers (IgG and IgM). This change was also not adopted, as some assays report results only as "reactive" or "non-reactive," which could create confusion for system users.

During software development, data structuring and the projected architecture were defined first. This included selecting programming technologies and architectural properties — operating environment and model, data modeling and database, programming language, interfaces with other software, and hardware/connectivity resources. The stack comprised PHP for the backend, JavaScript for the frontend, and MySQL 5 as the database. The initial interface implemented restricted access via username and password, allowing entry only to users pre-registered by the system administrator. Access was role-based — programmer (software developer), administrator (research team),

and interviewer (nursing staff and students responsible for patient data collection) — to ensure security, confidentiality, and data integrity.

After login, the home screen provides access to patient information and serves as the area for viewing individual responses collected through the forms in an organized, intuitive manner. At the top, users can navigate three tabs — Individual Responses, Individual Questions, and Response Summary — and may export all responses to Excel to facilitate analysis and archiving (Figure 1). In the main panel, data can be filtered by COVID-19 diagnosis and records can be sorted by name to optimize retrieval of specific information. Each completed form displays key fields such as COVID-19 diagnosis, consent, name, age, and other relevant variables. Navigation controls ("Previous" and "Next") allow sequential access across all collected forms. This interface was designed to streamline data management and analysis in public health studies.



**Figure 1** – Patient-information access screen in the post–COVID-19 monitoring software. Fortaleza, CE, Brazil, 2021

The forms menu is the entry point for data collection and begins with the presentation of the informed consent form. This document obtains a participant's authorization to take part in studies conducted by third parties, as the software was designed as a data-collection tool for different investigations on COVID-19 and/or other respiratory diseases. The consent form outlines the study objectives, potential benefits, guarantees of confidentiality and data privacy, and the participant's right to accept or refuse participation without any penalty. After reading, the participant must indicate agreement. If consent is given and the participant has a confirmed COVID-19 diagnosis, the system automatically unlocks access to subsequent forms. This structure enables longitudinal follow-up and supports continuous, systematic updates of participant information over time, fully integrated with the study workflow. In the Reports tab, users can generate files and charts using predefined filters to optimize analysis of collected data. The Settings tab offers the "Create User" module, which allows registration of new users with different access levels, and the "Questionnaires Fields" module, which provides access to the SF-36 and SGRQ instruments for quality-of-life assessment. The Instructions tab contains a detailed user guide to support researchers during system operation.

The technical quality and functional performance of the system were evaluated by health and informatics specialists with diverse profiles and relevant experience. Among the health experts, seven (78%) were women, ages ranged from 29 to 58 years (mean 37.1 years), and the group comprised five nurses, three physicians, and one pharmacist-biochemist. Regarding academic credentials, three held doctorates, four held master's degrees, and two had completed multiprofessional residencies. Among the informatics specialists, all were men (n = 9), with a mean age of 30 years; five were from Ceará, three from Maranhão, and one from Paraná. Two held master's degrees, one had a specialization, and six held undergraduate degrees without additional formal training, although all had prior experience developing software. This multidisciplinary evaluator set concluded that the software met adequacy criteria across all characteristics assessed by both health and informatics experts, as presented in Table 2.

**Table 2** – Evaluation by health and informatics experts of the technical and functional quality of the post–COVID-19 patient-monitoring software. Fortaleza, CE, Brazil, 2021

Quality attribute	Health experts		Final
	(%)	experts (%)	mean (%)
Functional suitability	70.4	77.8	74.1
Reliability	83.3	72.3	77.8
Usability	76.9	70.7	73.8
Performance efficiency	88.9	96.3	92.6
Compatibility	100.0	100.0	100.0
Security	96.3	93.4	94.4
Maintainability	_	91.1	91.1
Portability		100.0	100.0

To facilitate access and use across settings, the software was hosted on a dedicated server and is accessible from any internet-connected device, extending its applicability to both field and remote studies. It features a responsive design that adapts to different screen types, including computers, tablets, and smartphones. An additional strength is the automated delivery of questionnaires via e-mail or messaging applications. Delivery status is indicated by a color bar - green (not yet sent), orange (link sent, no response), and blue (completed) — allowing the research team to track data-collection progress and intervene strategically to reduce sample loss. Overall, the results indicate that the software meets technical quality, functionality, and security criteria expected of digital tools for clinical-epidemiological data collection and has potential for replication in other scientific studies.

### Discussion

The findings indicate that the software was judged valid in terms of content and functional performance, meeting expected standards. These results align with established methodological criteria<sup>(16)</sup> and

international software quality guidelines<sup>(22)</sup>. Similar evidence has been reported in the validation of an audiovisual script for people living with HIV, in which experts obtained a total content validity coefficient of 0.96, indicating that the items adequately represented the construct<sup>(24)</sup>. This is consistent with the high content validity indices observed here. However, validation goes beyond numerical indicators: incorporating expert suggestions is essential to enhance applicability and tailor the technology to user needs.

Digital health tools must satisfy a set of quality attributes to ensure effectiveness for their target audiences. Integrating such technologies into public health systems can expand access, improve care, and generate positive population-level effects, even if these effects are gradual<sup>(25)</sup>. In the present evaluation, most functional characteristics achieved satisfactory levels. These results are consistent with prior evidence of strong performance in usability, efficiency, maintainability, and security<sup>(19)</sup>, reinforcing the robustness of the findings and the technical feasibility of deploying this tool in research settings.

Some limitations were identified, notably accessibility, which did not reach the desired thresholds. Accessibility is a well-recognized challenge in health technology development(3,19). Based on expert feedback, adjustments were made, particularly to automate certain responses and improve the configuration of data-entry fields. Beyond technical aspects, the subjective and behavioral impacts of digital technologies on users should also be considered. Tools such as the software developed here may foster patient empowerment and shared responsibility in care, supporting paradigm shifts in health services<sup>(26)</sup>. In nursing, there is a growing trend toward the development of technological solutions — especially in academic environments — to improve professional training and strengthen educational practices<sup>(27)</sup>.

Innovation in nursing informatics requires an integrated approach that considers the sociopolitical contexts in which devices will be used. Looking ahead, the field is likely to move beyond software creation to

emphasize active user participation in self-care as well as the need for usability and interoperability across platforms and devices<sup>(28)</sup>. Taken together, the results suggest that the software is suitable for multicenter studies and can be adapted to diverse public health contexts. The high ratings for maintainability and portability further support its capacity to accommodate new demands, as seen in emergency scenarios such as the COVID-19 pandemic.

The COVID-19 pandemic context underscored the need for digital tools that enable remote monitoring and continuity of health research amid social-isolation measures, which hindered follow-up of people with chronic conditions in health services<sup>(2,29)</sup>. In this scenario, digital technologies became essential not only for screening or contact tracing, but also for enabling the structured collection of clinical-epidemiological data, as proposed by this software.

As a methodological distinction, this software integrates clinical variables, quality-of-life indicators, and the SDOH<sup>(12)</sup>. This approach supports a broader assessment of patients' health status and helps identify structural and social factors that influence health outcomes. Understanding these determinants goes beyond epidemiologic risk factors and includes political and social decisions that affect the equity and sustainability of health actions<sup>(30)</sup>.

Accordingly, the development of this study and the availability of the proposed technology represent a contribution to symptom monitoring, patient prognosis, and prevention of new COVID-19 infections. In addition, use of the software can streamline researchers' work, support decision-making in public health, and help address the challenges posed by the current epidemiological context.

In a post-pandemic scenario marked by pronounced inequalities and new demands in health surveillance, technological solutions such as the software developed here play a strategic role — not only by enabling data collection and organization, but also by promoting more equitable, sustainable, and user--centered practices. In this context, partnerships with public-health institutions are important to enable testing, adaptation, and potential incorporation of the tool into Brazil's Unified Health System (SUS), especially for epidemiological surveillance and for monitoring patients with chronic conditions. Dissemination of this type of solution can strengthen digital health as an ally of scientific production and public management.

# **Study limitations**

This study has some limitations. First, the software was designed specifically to support data collection in scientific research and has not yet been tested in real-world care settings, which restricts its immediate applicability in SUS services. In addition, the sample used for content-validity evidence was non-probabilistic and obtained by convenience, limiting the generalizability of the results. Data collection was conducted online, which may have constrained participation by specialists less familiar with digital tools.

The software is not yet adapted for people with disabilities, which compromises accessibility in contexts involving functional diversity among researchers or participants. Future studies are recommended to assess software use in health-care units and to validate the user guide with end users, with the aim of verifying its effectiveness in orienting professionals, minimizing entry errors, and reducing bias in future research.

# **Contributions to practice**

This study resulted in a digital technology for collecting clinical-epidemiological data from patients diagnosed post-COVID-19 and it has already been used in several studies. The software also supports efficient, standardized fieldwork by researchers, particularly in adverse contexts such as the pandemic. It is currently being used in a multicenter study across Brazil's five regions.

The tool showed technical and functional adequacy according to evaluations by health and informatics specialists and stands out as a promising resource

for data systematization, optimization of collection processes, and assurance of information security. These features are especially relevant when physical contact must be limited, as during pandemics, but they are also adaptable to other public-health and epidemiological-surveillance contexts.

#### Conclusion

This study enabled the development of software for collecting clinical-epidemiological data from patients diagnosed post-COVID-19 or with severe acute respiratory syndrome, intended for use in scientific research. The technology allows tracking of clinical evolution, assessment of quality of life, mapping of the disease's impact on families' socioeconomic conditions, evaluation of access to health services, and identification of possible complications associated with COVID-19. Expert evaluation confirmed that the assessment instrument was adequate in terms of content and could be incorporated into the software. The software, in turn, met technical and functional criteria, reinforcing its potential for use in future studies focused on public health, epidemiological surveillance, and population monitoring, in both routine and emergency settings.

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#### Authors' contributions

Conception and design or analysis and interpretation of data; drafting of the manuscript or critical revision for important intellectual content; final approval of the version to be published; and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part are appropriately investigated and resolved: Fontenele MGM, Lima FET. Final approval of the version to be published and agreement to be accountable for all aspects of the work in ensuring accuracy or integrity are appropriately investigated and resolved: Florencio SSG, Lima GA, Pascoal LM, Barbosa LP.

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