SINAVE

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The implementation of technological solutions in the health area has been providing better results for patients and boosting the efficiency of the health system. This article arose from the need to show the importance of an application of the health system in Portugal, the SINAVE - *Sistema Nacional de Vigilância Epidemiológica* - which allows the health professional to notify in real-time the occurrence of a communicable disease, for the implementation of prevention and control measures, limiting the spread of the disease. It also works as an instrument for real-time epidemiological surveillance of the occurrence of communicable diseases that must be declared by the Health Authorities at local, regional and national levels. It is extremely important to mention the existence of interoperability of this application with other applications in the health system.

Keywords: Health systems; SINAVE; Interoperability; Epidemiological surveillance.

1. Introduction

The population is increasingly aware of the impact that health and care received in this area can have on their lives.

The reappearance of communicable diseases already under control, the emergence of new diseases and the evolution of antimicrobial resistance mean that communicable diseases in a country, today, represent a global concern. The World Health Organization (WHO) has identified the development of effective surveillance systems as one of the main means of responding to global and national concerns about communicable diseases and the identification of public health emergencies, both in industrialized and developing countries.

Thus, the National Epidemiological Surveillance System emerged, which dematerializes the mandatory notification of communicable diseases and other public health risks, allowing the physician to notify in real-time the occurrence of a communicable disease to the local health authority for implementation. prevention and control measures, limiting the spread of the disease and the occurrence of additional cases. It also functions as an instrument for the continuous monitoring of

the occurrence of communicable diseases with mandatory reporting in Portugal. SINAVE has been an extremely important element in the fight against COVID-19, as it allows us to monitor this epidemic and to take measures over time. Epidemiological surveillance is a central pillar of the practice of epidemiology.

This article is divided into 5 primary sections, according to the structure of a scientific article. In the first section, the state of the art of this application is discussed, which refers to what it is, the company that developed it, and discusses the types of interoperability that exist. Then, in sections 2 and 3, an analysis is made of the functional architecture and how the application works. Section 4 shows the importance of interoperability and how it is used with this software. Finally, in section 5, customer satisfaction with the product is mentioned.

2. State of the art

The State of the Art is one of the most important parts of all scientific work since it refers to what has already been discovered on the researched subject, avoiding wasting time on unnecessary investigations.

2.1 Health Information Systems

Health Information Systems are data processing systems. These allow cooperation, the sharing of knowledge and information, as well as the development of service provision activities in the areas of information systems and technologies. They play an important role in improving health quality, with the main objectives of improving accessibility, efficiency and safety [1].

In health institutions, professionals have their work increasingly dependent on the use of computer systems. These systems have shown a great capacity to improve clinical processes and the quality and continuity of care, which leads to more effective care leading to greater patient satisfaction. In addition, they help to reduce the occurrence of errors and safeguard the protection of patient data.

SPMS, *Serviços Partilhados do Ministério da Saúde* - figure 1, is a Public Business Entity that ensures the provision of shared services in the areas of purchasing and logistics, financial management and human resources, for the entities that are part of the National Health Service. SPMS is also responsible for ensuring the operationality and security of the technological infrastructures and information systems of the Ministry of Health, promoting the definition and use of standards, methodologies and requirements that guarantee the interoperability and interconnection of health information systems between itself, aiming to develop and protecting the health of citizens [2],[1].

Figure 1: *Serviços Partilhados do Ministério da Saúde* [2]

2.2 SINAVE

Surveillance systems based on mandatory reporting of communicable diseases are well-established systems in most industrialized countries. The International Health Convention of 1926, which took place in Paris, is a milestone in this context.

Subsequently, in 2000, Portugal created a single information medium used to carry out notifications within the scope of the mandatory reporting system for communicable diseases. This form of communication presented limitations for epidemiological surveillance since the information from the notification in paper form had to be complemented by telephone contact so that the preventive measures provided for the programs for the control of diseases could be instituted in due time. various infectious diseases, measures that generally have demonstrated efficacy in the appearance of additional cases of disease, if implemented in the first hours.

Currently, Portugal, as a Member State of the European Union, has to report cases of illness to the European Commission through the European Center for Disease Prevention and Control, as well as to the World Health Organization. The communication by States, at the European and Global levels, of cases of these diseases, is what allows the establishment of an international surveillance network with the necessary characteristics to respond adequately to the need to monitor and implement preventive and control measures worldwide [3].

SINAVE (figure 2), approved by Law No. 81/2009 and developed by SPMS, responded to these needs through the establishment of a public health surveillance system that allows the identification of risk situations, collecting, updating, analyzing and disseminating data on communicable diseases and other public health risks, as well as preparing contingency plans, in the face of emergencies or as serious as a public calamity [4].

Figure 2: *Sistema Nacional de Vigilância Epidemiológica* [4]

Thus, real-time electronic communication/notification was established between doctors from public, private and social health institutions and the Public Health Units and Health Authorities, allowing interaction through an available computer platform. on the world wide web, which ensures the speed and confidentiality necessary for the intervention of Health Authorities and their services in the prevention and control of communicable diseases [3].

In Portugal, there is a list of diseases (figure 3) that, upon learning that the patient is a carrier, the doctor is obliged, by law, to communicate their existence, whether they are possible, probable or confirmed cases. The main objectives are the control of the spread of the disease, the study, alteration and implementation of preventive measures. This list appears in Order No. 1150/2021, of the Ministry of Health.

Anthrax	West Nile virus infection
Botulism	E. coli Infection
Brucellosis	Visceral leishmaniasis
Campylobacteriosis	Leptospirosis
Chikungunya	Listeriosis
Chlamydia trachomatis	Malaria
Cholera	Lyme Neuroborreliosis
Cryptospororidiasis	Acute Flaccid Paralysis
Dengue	Mumps
Diphtheria	Plague
Creutzfeldt-Jakob disease	Acute poliomyelitis
Hansen's disease (Leprosy)	Rabies
Legionnaire's disease	Congenital rubella
Pneumococcal Invasive Disease	Rubella, excluding Congenital Rubella
Haemophilus influenzae invasive disease	Salmonellosis not Typhi and not Paratyphi
Meningococcal disease	Measles
Ebola	Shigellosis
Echinococcosis/ Hidatidosis	Congenital syphilis
Tick-borne viral encephalitis	Syphilis, excluding congenital syphilis
Yellow Fever	Severe Acute Respiratory Syndrome (SARS)
Nodular Scarlet Fever (Rickettsiosis)	Tetanus
Viral Hemorrhagic Fevers	Whooping cough
Q fever	Congenital toxoplasmosis
Typhoid Fever and Paratyphoid Fever	Trichinelliasis
Giardiasis	Tuberculosis
Gonorrhea	Tularaemia
Flu	Smallpox
Influenza A or other influenza viruses of animal origin	HIV (Human immunodeficiency virus)/AIDS (acquired immunodeficiency syndrome)
Hepatitis A, B, C, E	Yersiniosis
Infection by MERS-Cov	Zika (Virus infection)
Infection by SARS-Cov -2 /COVID -19	Congenital Zika (Virus infection)

Figure 3: List of mandatory reporting transmittable diseases [5]

This system is operationalized through a computer platform, which allows the notification of communicable diseases, integrating clinical and laboratory surveillance, through:

- SINAVE*med*, which allows the clinical notification of communicable diseases, by health professionals (mandatory from 1 January 2015);
- SINAVE*lab*, which allows laboratory notification of communicable diseases, (mandatory from 1 January 2017).

As a system that only collects information, it has no way of presenting and visualizing data. Only internally, at the *Direção-Geral da Saúde* (DGS), it is possible to extract the data directly from the database, obtaining a file in excel format with the desired results. This leads to a slower analysis of the data and it is difficult to detect, at first glance, outbreaks and specific information such as which age group with the highest incidence with a certain disease or the vaccination status of patients [6]. The data from SINAVE, med and lab, are centralized in a database hosted by the SPMS - figure 4.

Figure 4: Notifications at SINAVE*med* and SINAVE*lab* (adapted from [6])

Notification is the basis on which the system of epidemiological surveillance of communicable diseases with mandatory notification is based. The electronic notification form allows the notifier to communicate all information specific to the disease that he notifies and that can only be provided by him, so the type of information collected in the epidemiological survey varies with the disease in question. The notification gives rise to an alert to the Health Authorities.

The severity of the disease and the form of transmission are generally the factors that condition the urgency of the course of the epidemiological investigation and the implementation of control measures [5].

2.3 Interoperability in Health Systems

The filling in of the notification forms, by the health professionals, can be done in two ways. They can do this directly on the SINAVE portal or through automatic interoperability mechanisms (in the institutions/laboratories own systems).

Thus, interoperability is an important requirement. The concept of interoperability is defined as the ability of a system or product to work with other systems or products without any additional effort by the user. From another point of view, and more fully, it can be defined as the ability of an independent system to exchange meaningful information and initiate actions with other systems to work together to achieve mutual benefit. To guarantee interoperability in a health sector is a difficult task mainly due to the complexity and specificity of medical information and also due to socio-political and ethical problems [7].

In the health area, there is a great heterogeneity of information systems that cohabit and, inevitably, have to interoperate (figure 5).

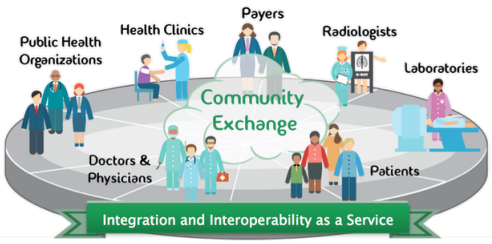

Figure 5: Interoperability in Health Systems [8]

Thus, to facilitate interoperability, all information transferred between different systems is standardized, avoiding different structures and misinterpretation. For this, there must be standards to ensure better communication between health professionals, users and technological systems. These guarantee the safety of products, equipment and systems, reduce errors and allow professionals to comply with current legislation [9].

Health Level Seven (HL7) is a not-for-profit organization that provides standards for the transmission of messages from medical equipment, administrative systems and medical databases, allowing its interoperability [10].

Ensuring interoperability between systems requires great responsibility at 3 levels: a stable and well-defined organizational environment, semantic interoperability in agreement with the data to be exchanged and a technical level capable of protecting it and enabling its transfer.

The Organizational level deals directly with the processes, objectives and standardization of functionalities. Organizational interoperability

occurs when two organizations, even with different working methods, can adapt to each other's reality.

The Semantic level addresses data integration and consistency. It is a standardization of information meanings, promoting understanding between the parties involved. It involves aspects such as communication context, taxonomy, meanings, languages used, texts, images, sounds, etc. Semantic interoperability occurs when data from one system is correctly interpreted by the other.

The Technical level involves aspects such as devices, interfaces, data formats, communication, transport, storage, etc. It refers to the coding of data for the development of systems, that is, the infrastructure of the systems and their ability to exchange information with each other, with technological compatibility between them. Technical interoperability occurs when the systems involved use compatible technological standards for the presentation, processing, collection and exchange of data [9].

In Portugal, HL7 is present, at the level of technical interoperability, with three brokers: LIGHT, PNB and NCP (figure 6).

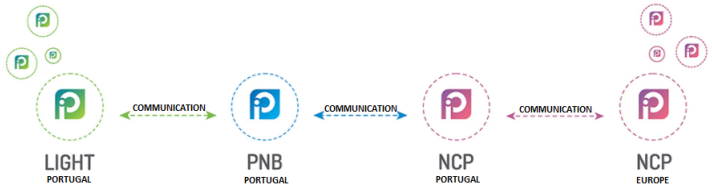

Figure 6: Technical interoperability [9]

LIGHT (Local Interoperability Gateway for Healthcare) is SPMS's Local Integration Platform. With this product, SPMS intends to promote the adoption of standards in messages exchanged at the local level of the institutions systems, unifying them at a national level so that everyone speaks the same language and in a standardized way. This way, it facilitates future international integrations.

PNB (Portuguese National Broker) is used to centralize and consolidate the transfer of health data between the NHS systems. In this way, it contributes to the promotion of technical interoperability.

Finally, the NCP (National Contact Point) aims to support all communication between the national infrastructure of the Ministry of Health and abroad (other European countries).

By allowing communication between different systems, interoperability creates an environment in which information circulates continuously and between any device, making communication between systems more agile and effective, ensuring the establishment of objectives and strategies and the achievement of good results [9].

3. Functional Architecture of SINAVE

The flow of information in the computer application to support SINAVE follows the process of notification and epidemiological investigation (figure 7).

Each user, involved in the surveillance process, accesses the computer application to support SINAVE according to their profile, having only access to information strictly necessary for the exercise of their functions [3]. User profiles have different functionalities, according to the users' roles in the surveillance process, including:

- Registration of mandatory notification of communicable diseases;
- Search for patient identification by consulting the *Registo Nacional de Utentes* (RNU);
- Record of the epidemiological survey for the notified disease and contact list, if applicable;
- Printing of epidemiological notification and inquiry forms;
- Creation of outbreaks;
- Search by disease, notification's status, dates and geographic area;
- Export of an anonymized database for epidemiological surveillance;
- Management of the functionalities of the computer application.

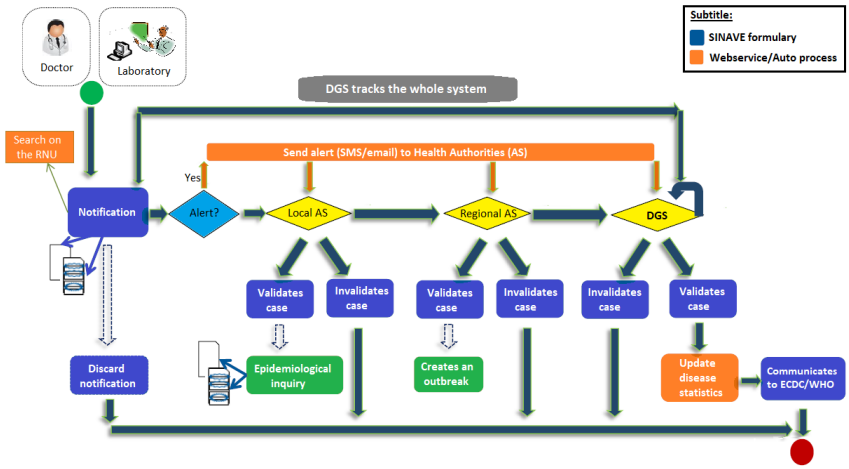

Figure 7: Functional architecture of the SINAVE, Portugal (adapted from [3])

The notification form is filled out by the notifying physician or by the laboratory, using the number of the National Registry of Users to automatically fill in the individual's identification, or by manually entering the identification data, whenever that number is not available.

After submitting the notification, it goes electronically to the Local Health Authority. Upon receiving the notification, whether it is a possible, probable or confirmed case, it starts the epidemiological investigation of the case. It is, therefore, responsible for filling in the electronic form related to the respective epidemiological inquiry and for rectifying the notification, whenever necessary, ensuring the collection of relevant information for epidemiological surveillance and classification of the case. The lack of information regarding the surveys results in the issuing of automatic alerts to the Local and Regional Health Authorities.

After the case has been validated by the Local Health Authority, it goes to the Regional Health Authority, awaiting validation. Once validated by the regional level, the case is awaiting validation by the DGS. DGS is always responsible for the final classification of the case, notifying the European Center for Disease Prevention and Control, the World Health Organization and other international institutions.

For a specific set of communicable diseases, for which immediate intervention by the Health Authorities is essential, the computer application to support SINAVE sends an alert via email and/or SMS to the Local, Regional and National Health Authority, as soon as it is notification has been submitted. These alerts are defined according to the epidemiological situation, and for this reason, they can be changed at any time.

All information available to users has been approved by the National Data Protection Commission and all information exported from the computer application supporting SINAVE is anonymized [3],[11].

4. SINAVE's Support Computer Application

The computer application to support SINAVE was developed by DGS for the notification of communicable diseases with mandatory notification and other risks to public health, registration of epidemiological research and collection of data on the characteristics and distribution of these diseases. Access is done through the Sinave's website: *https://sinave.min-saude.pt* (figure 8). Maintenance and development are ensured by the SPMS [3].

Figure 8: Home screen [6]

This application technologically supports the electronic communication, in real-time, of notifications of communicable diseases made by doctors/laboratories, to the Local Health Authorities, Regional Health Authorities and the National Health Authority in all the national territory, in a fast way, secure and confidential.

The registration of information on each case of illness is carried out in two forms:

- The notification form, which presents a set of variables that include demographic information about the patient, clinical information and laboratory information. Each disease notification form has questions adapted to the selected disease, with relevance for epidemiological surveillance.
- The epidemiological survey form includes variables obtained through the epidemiological investigation carried out, which complement the variables collected in the notification form. For each disease, questions adapted to the reported disease are presented.

The variables included in the notification and the epidemiological survey are based on international standards for the collection of information for the surveillance of the diseases concerned, namely the ECDC and the WHO and correspond to the essential information for characterizing the case of the disease and the incidence of the disease (measured through reported cases) in the population over time, to generate useful information for planning. The variables contained in these forms are updated in line with the evolution of metadataset (set of variables to be collected and the respective categories), for international reporting and with the review of disease case definitions for epidemiological surveillance [3].

The entity responsible for data processing of the computer application supporting SINAVE is the Director-General of Health.

The doctor's use of SINAVE*med* is described below.

After logging in by the doctor, the creation of notification is available on the home page on the button marked in figure 9.

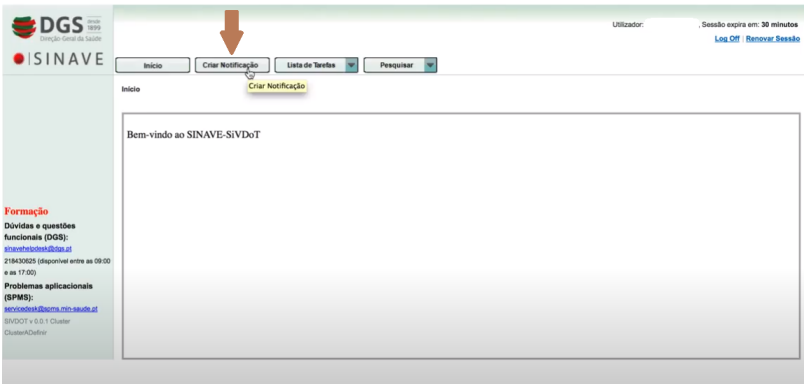

Figure 9: Home screen after Login [12]

Before creating the notification, the notifying physician must identify the patient, as shown in figure 10.

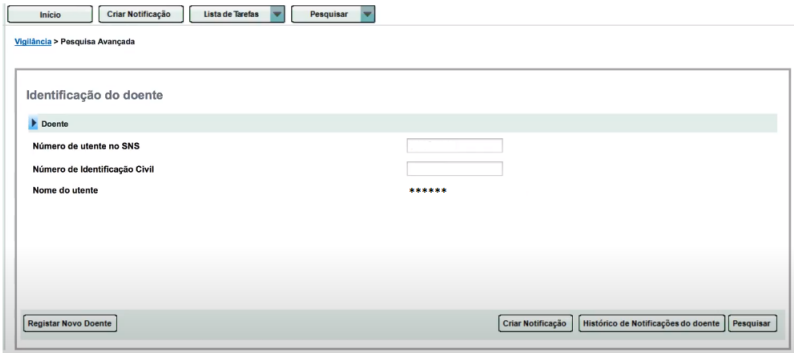

Figure 10: Patient's identification [12]

The user can search for 2 alternative fields:

- The search by patient's SNS number - is the priority form of research at SINAVE. This method allows data to be obtained from the National Registry of Patients (RNU) and rarely requires the insertion of additional identification data.
- The search by civil identification number - is carried out within SINAVE so that only if the patient has already had any notification is it registered in the application and is found through this search.

After the patient has been successfully researched, press the Create notification button. Whenever a search for a user does not return results, it is possible to register a new patient in SINAVE through the button "Register New Patient". The patient registration page is shown in image 11 .

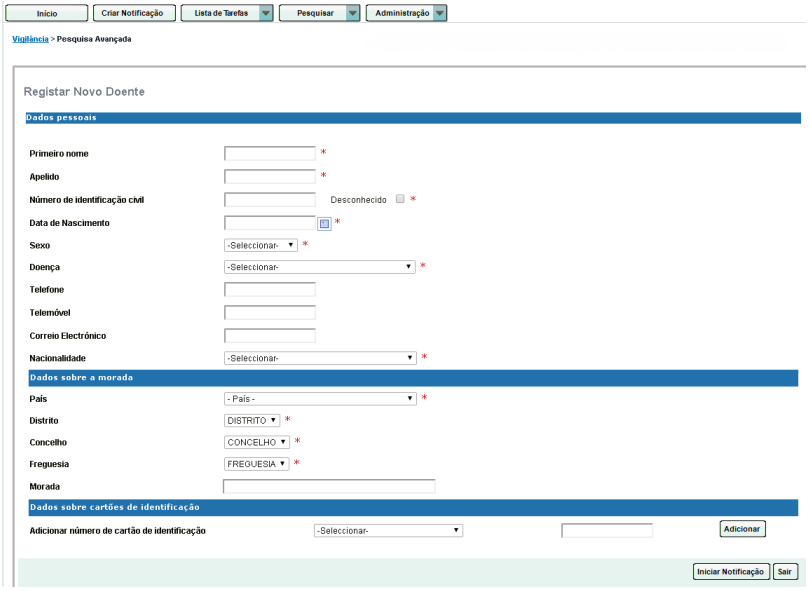

Figure 11: New patient registration page [12]

On this page, the doctor must fill in the personal data (including the disease to be notified) and the data on the patient's address. Mandatory fields are marked with a red asterisk. It is important to insert whenever the "Civil Identification Number" is known for further research at SINAVE. In the last field, other patient numbers can be inserted, such as ADSE, tax number, social security number, driving license number, etc. To do this, simply enter the type of number, the number itself and press the Add button.

After entering the patient's data, press the Start Notification button, as a way to start the notification creation process for the new patient identified in SINAVE.

Then, in figure 12, the patient's data (name, contact, age, etc.) appear. You can also see the notifications already made for the patient in question. You must choose the disease to be notified and click on the Create Notification button.

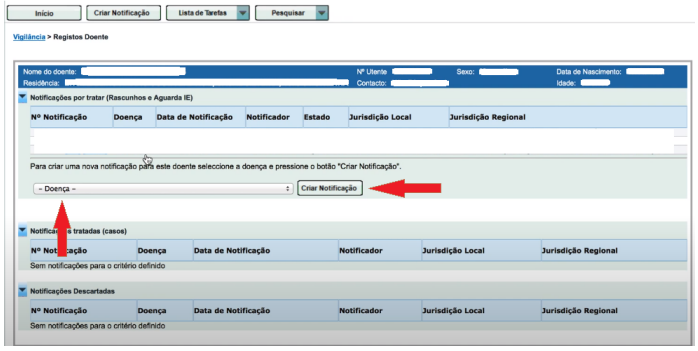

Figure 12: Notification process I [12]

Following the notification process, will be directed to the notification page (figure 13), where the previously chosen disease notification form must be filled out. The image shows a notification page for Gonorrhea disease (as an example).

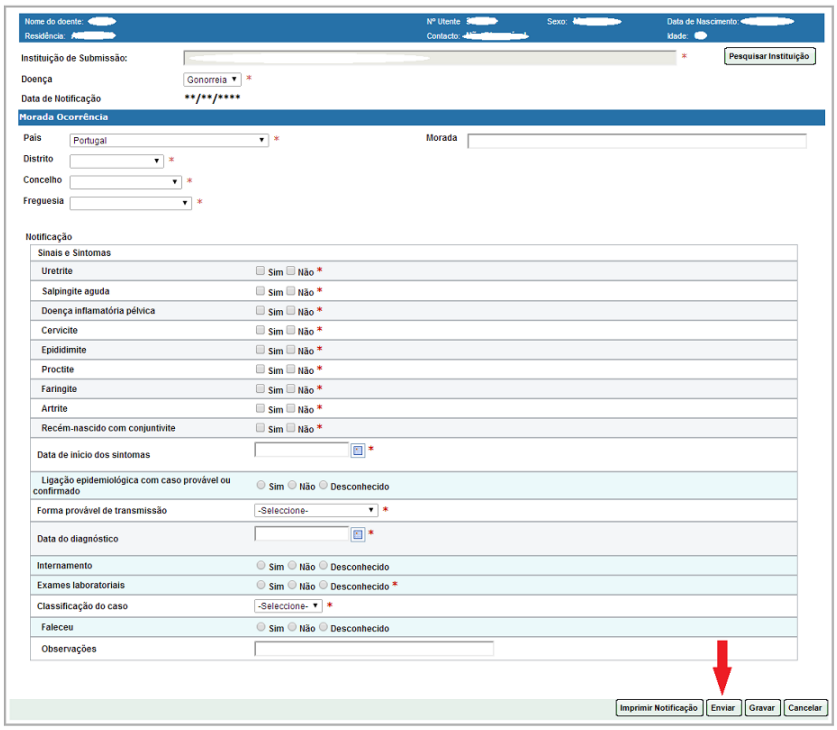

Figure 13: Notification process II [12]

This form is divided into the following items:

1. Patient information (initial bar not editable) - Information about the patient is displayed.
2. Submission Institution - This is the notifying physician's workplace.
3. Disease - check if the disease is the one you want to report;
4. Address of occurrence - corresponds to the patient's place of infection.
5. Notification - Fill out the notification questionnaire. This questionnaire varies with the disease;

After filling in the fields, the features available on this page are: Print Notification, Send, Save and Cancel.

Notification must be sent to the Public Health Unit (USP), for investigation, whenever it is duly completed and no subsequent changes are foreseen. To proceed with the electronic sending of a notification to USP, the physician must select the Send button, which is at the bottom of the notification page. Before sending, you must record and, if necessary, print, or save to a PDF file, the notification already filled out with the respective questionnaire for the disease in question.

The notification is sent and is waiting for the local health delegate to review it. It is important, therefore, that it regularly searches for notifications waiting for the Epidemiological Survey (IE) [12]. An example of an IE is shown in figure 14.

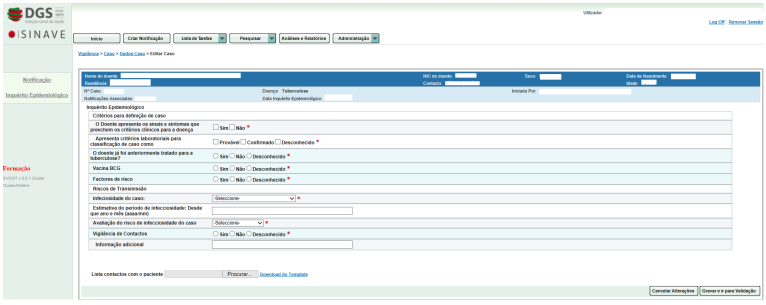

Figure 14: Epidemiological Survey [12]

In addition to filling out the forms and their respective consultations, this platform allows you to generate and view reports of diseases/outbreaks over a certain period (monthly, yearly, etc.) or even by region (districts, counties, etc.).

5. Interoperability in SINAVE's service

Computer applications to support the clinical process have been progressively adopted at different levels in health care, initially through independent systems, planned to manage the activity and support some of the functions of health service and later integrated into information systems essentially aimed at for the communication of clinical data. More recently, the electronic clinical process provides healthcare professionals with organized and contextualized access to patient information, representing an extremely important work tool.

To promote automatic notification from the patient's clinical process, integrating the notification process with clinical practice, an interoperability mechanism was developed between the computer application to support SINAVE and the computer applications to support the clinical process.

Furthermore, as an example, the following 2 applications interoperate with SINAVE's support application:

- *SClínico dos cuidados de saúde primários* (CSP) / *SClínico dos cuidados de saúde hospitalares* (CSH) - figure 15. *SClínico* is part of the strategy defined by the Ministry of Health for the area of clinical computerization of the *SNS*, which provides for the standardization of procedures clinical records, to guarantee the normalization of information. In this case, just select the SINAVE button, in the upper right corner. After clicking this button, the user will be redirected directly to the SINAVE support computer application [13].

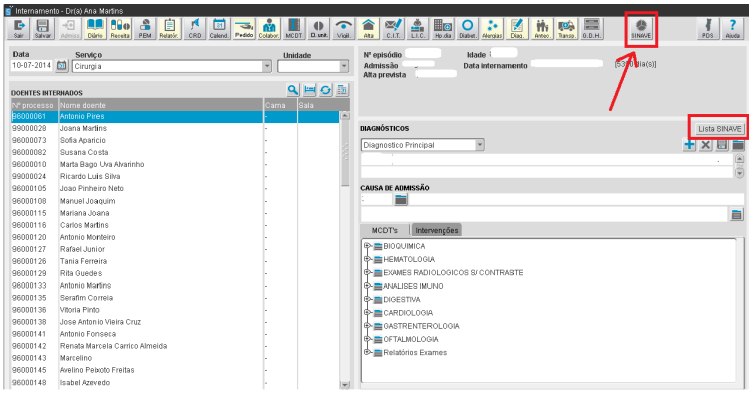

Figure 15: *SClínico* application, with SINAVE button identification [3]

- MedtrixEPR - figure 16. The "Medtrix EPR", implemented by *Hospital São Sebastião*, in Santa Maria de Feira, is a platform that provides doctors with an integrated perspective of all clinical information related to patients, since their admission to the hospital. In this case, the SINAVE button is available on the top button bar. After clicking this button, the user will directly access the SINAVE website [14].

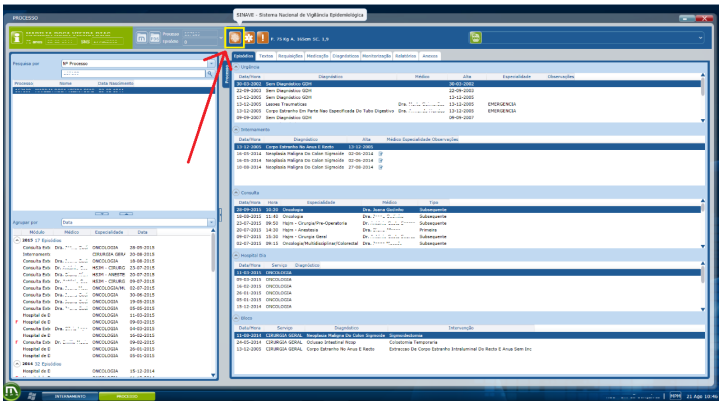

Figure 16: *MedtrixEPR* application, with SINAVE button [3]

In the various computer applications to support the clinical process with interoperability with SINAVE, an alert system was created for some communicable diseases that must be notified. This allows that, when diagnoses corresponding to those diseases are selected, a pop-up appears that alerts the doctor to notify the disease [3]. At the same time, the functionality to consult the list of mandatory transmittable diseases was included (figure 17).

Figure 17: List of mandatory reporting transmittable diseases [3]

With the interoperability between the computer application to support SINAVE and clinical applications, the doctor does not need to authenticate with SINAVE, identify the institution where he is located, or register the information about the patient. In the context of medical consultation or hospitalization and after pressing the SINAVE button, you only have to select the disease to be notified, fill out the form and press the send button, immediately returning to the patient's clinical file. This is one of the main advantages of the existence of interoperability.

6. SWOT Analysis

Customer satisfaction is a fundamental part of the development and implementation of an application in the market. For this, it is essential to adopt the SWOT analysis - figure 18 - to understand how the business will expand and the importance it will have in the user's life in the future.

According to Philip Kotler, "The global assessment of strengths, weaknesses, opportunities and threats is called a SWOT analysis" [15].

Figure 18: SWOT Analysis [16]

Thus, SWOT analysis is a strategic tool to help an organization identify its strengths, weaknesses, opportunities and threats.

It can be divided into two parts [15]:

- Internal factors, where the strengths and weaknesses of an organization will be identified;
- External factors, where threats and opportunities lie.

Regarding SINAVE:

Strong points	▪ Quick response to a possible outbreak, after notification; ▪ Better quality of assistance and support for new users; ▪ Provides statistics for the Directorate-General for Health (DGS), for reporting to ECDC; ▪ Enables the recording of antibiotic resistance; ▪ Ensures the privacy of patient information, since there is no longer a need for paper handling by employees that are not part of the information system.
Weaknesses	▪ Computer equipment with Internet access is required for the use of SINAVE's application; ▪ It requires a greater need for human resources, either due to the volume of reported cases or due to the requirement in terms of recording and analyzing information.
Opportunities	▪ Competence for emergency responses; ▪ Availability of multiple information systems solutions through cooperation with the Ministry of Health; ▪ There is interoperability between SINAVE and the clinical process computer applications, in most SNS' health institutions.
Threats	▪ Failures in accessing the platform in major health events (pandemics, etc.); ▪ Great dependence on SPMS in the resolution of internal system errors.

Figure 19: Sinave's SWOT Analysis

In the first six months of mandatory use of the computer application to support SINAVE, which took place between January 1 and June 30, 2015, 3926 cases of mandatory notification diseases were notified at a national level. The comparison with the same period in the previous two years (1642 cases in 2013 and 1293 cases in 2014) showed a large increase in notifications in this period. Among the factors that may have contributed to this result include the carrying out of training actions on SINAVE in health institutions, the reinforcement of the dissemination for the system through the media, driven by the alteration of the surveillance system and probably the most important, the computer "alerts" and the increased ease of the notification process achieved through the development of interoperability with the computer applications supporting the clinical process [3].

7. Conclusion

The restructuring of the mandatory notification system for communicable diseases surveillance in Portugal that created SINAVE and regulated a surveillance network whose participants are linked electronically constitutes an opportunity to improve the quality of epidemiological surveillance. The existence of interoperability with other applications makes the notification process even easier.

The identification of a larger number of cases has improved the quality of public health interventions, namely in the timely implementation and execution of prevention and control measures for additional cases. In the medium and long term, the computerized collection of information at the national level on cases of illness should allow improving the quality of the information available for the identification of needs and health planning.

SINAVE is one of the most important systems, in Portugal, for data processing and viewing information related to the Covid-19 pandemic. Due to intense epidemic activity, DGS, together with SPMS, had to improve information systems. Then came the BI SINAVE, a system that allows collecting and analyzing, through automatisms, an increasing volume of data and communicating information more quickly and with greater quality and greater detail for the citizen, local intervention teams, the academy and policy makers [17]. This new platform also has a greater capacity to handle constant information in the databases, allowing maximization of the usefulness of information from several complementary sources.

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