DEVELOPMENT OF WEB-BASED TOOL FOR DECISION SUPPORT IN VETERINARY VACCINES DOSSIER EVALUATION TYPE

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ABSTRACT. Ensuring that only safe and effective animal vaccines are used in the industry is a mandate that must be carried out by the Department of Veterinary Services Malaysia. To ensure that vaccines are appropriately evaluated, an effective vaccine evaluation method needs to be put in place to assist top management in granting approval status to vaccine manufacturers. This study aims to develop a web-based tool that provides a vaccine dossier evaluation platform in a scalable manner and can provide complete evaluation reports that is fast, transparent and easy to understand. This system structures the dossier assessment that will make it easier for the secretariat, evaluators and top management to manage and evaluate the dossier vaccine online and the ability to store vaccine evaluation data in a more organised way and easily accessible..

Keywords: Veterinary vaccines, animal disease, vaccine dossier

INTRODUCTION

The critical goals of veterinary vaccines are to improve companion animals' safety and welfare, increase livestock productivity, and prevent zoonotic disease transmission. Vaccination is intended to prevent and control a disease's occurrence and reduce the transmission of the pathogenic agent (OIE, 2018). Although veterinary vaccines comprise only about 23% of the global market for animal health products, the sector has steadily expanded mainly due to new technological developments in the production of vaccines, the continuous growth of drug resistance by pathogens and the emergence of new diseases (Meeusen *et al*., 2007). Safe meats, eggs, and milk are essential to achieve the food security of a growing human population globally and it is not possible without healthy livestock. Animals and poultry are susceptible to many infectious diseases and some cause food-born zoonoses in human beings. The effective use of vaccines against various diseases could be essential to meet current and future food demands (Ramadevi *et al*., 2020).

As the development and availability of new veterinary vaccines for animals become increasingly important, the Department of Veterinary Services Malaysia (DVS) as the regulatory agency is strengthening their review of the newly introduced vaccines to fulfill their mandate to protect and promote animal safety and health in Malaysia. As the agency to enforce legislative requirements, DVS has set down specific procedures for registration of veterinary vaccines in Malaysia with regards to production,

importation, distribution, sale and use for diagnosis, treatment, research and control or prevention of disease which are safe for animal use (DVS, 2019).

Currently, DVS has set up a Technical Advisory Committee on Veterinary Biologics (TACB), which is responsible for setting requirements for vaccine evaluation and approval. The vaccine dossier will be evaluated manually using TACB Form 1(a) by qualified dossier readers. Assessment requirements include the vaccination regime, packaging information, vaccine development technical details and quality assurance on vaccine safety and efficacy.

The existing assessment in vaccines dossier evaluation by using TACB Form 1(a) that needs to be filled up by a dossier reader involves a lengthy process that slows down the vaccine registration procedures. The manual assessment does not have a scoring scale, complicating the vaccine dossier evaluation process. There have been numerous attempts to align the assessment requirements among dossier readers to avoid redundancy and save both resources and time for the vaccine registration. Other than that, some concerns are often raised in the evaluation of manual dossiers, such as the disparity of the dossier reader's evaluation results and the lack of the dossier reader's expertise in evaluating the dossier document.

Computer based decision tools can help to integrate information to facilitate the decision making process that directs development, acceptance, adoption and management aspects (Ellis *et al.*, 2004). This study aims to develop a web-based tool as a prerequisite for vaccine evaluation for DVS named as VACDOS (shorten form of vaccine dossier). The assessment of this vaccine dossier is critical to ensure that only vaccines that are perfectly safe to use are being used to ensure the animals' safety and health and ensure that the quality of livestock-produced food does not affect human health. Besides, ensuring that only quality vaccines are used can prevent the spread of livestock and zoonotic diseases and increase the production of animals in Malaysia.

MATERIALS AND METHOD

The mixed method approach has been used as the methodology for this dossier evaluation. Qualitative and quantitative data were collected from the evaluation scheme and analysed to obtain better study results (Allison *et al.*, 2017). The qualitative data obtained from the dossier document assessment was used quantitatively to carry out the analysis process.

For system development, agile approaches were used because agile strategies emphasise stakeholder involvement and help teams execute work more efficiently while delivering the highest quality product within budget constraints (Sriram *et al.*, 2016).

VACDOS System

System and architecture of VACDOS

The VACDOS system involves a combination of computer languages used for the frontend and backend system. The frontend uses an interactive GUI that is easy to understand. Simultaneously, the system process that

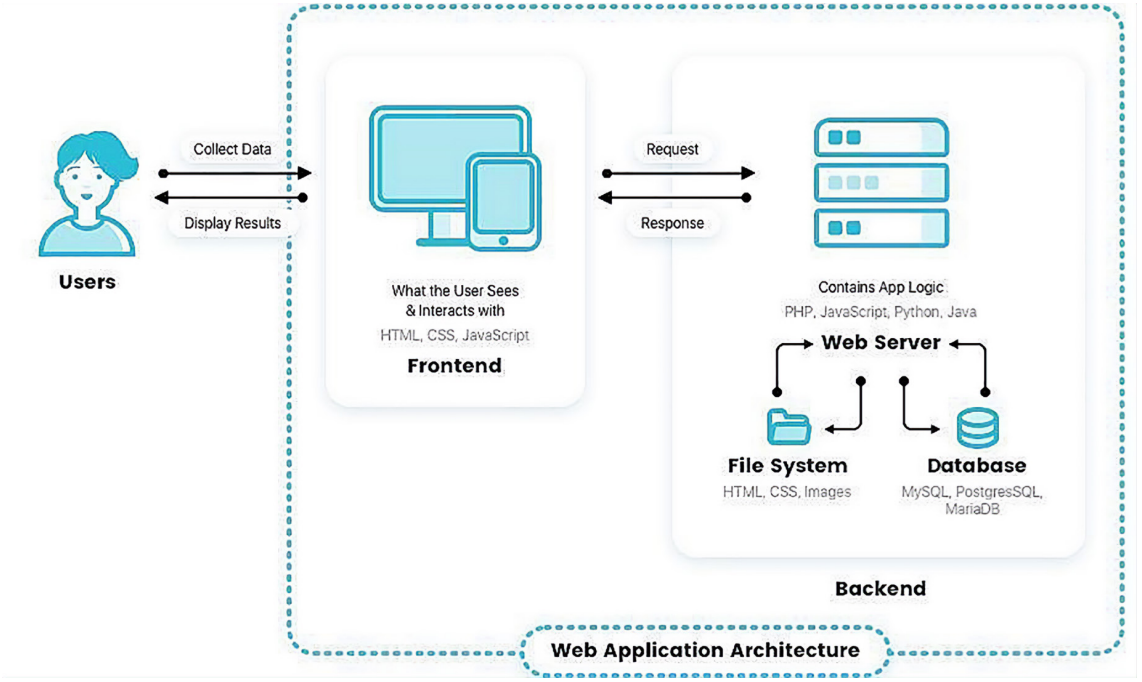

Figure 1. Architecture of VACDOS Web-based system.
(Image source: https://reinvently.com/blog/fundamentals-web-application-architecture/)

Table 1. A The vaccine evaluation category for dossier evaluation process in VACDOS.

Category		Description	No of Criteria
1.	Licenses	A certificate or letter by authority originate country on vaccine production and sale approval	3
2.	Other information and supporting documents	Valid Good Manufacturing Practices (GMP) certificate, free sale agent (local distributor) and certificate or letter approval (product registration) in any respected country	3
3.	Vaccination Regime	Route of vaccine delivery that may produce the fastest and better protection	3
4.	Dosage	Amount of vaccine needed to protect the animal against a specific disease	1
5.	Labels and Packaging	Physical appearance as same as to mention in dossier document	9
6.	Vaccine Production Capability	Quantity of vaccine can be produced in every batch annually	8
7.	Quality Control on Finished Product	The procedure with good documentation to make sure all batch can pass the stated requirement by an international standard such as 9CFR, Euro pharma	9
8.	Vaccine Efficacy	Measures direct protection (i.e. protection induced by vaccination in the vaccinated population sample).	5
	TOTAL		41

takes place in the backend involves some scripting for the data migration from/and to the database, as described by Andrew *et al.* (2012). The system uses a simple database to maintain, store, process and retrieve data that can satisfy user needs.

Architecture of VACDOS

Figure 1 shows the architecture of VACDOS. It consists of 2 tiers (frontend and backend). Frontend focused on the look and feel of the website and utilised by web users. Users will make a request through a web-based graphical user interface (GUI) developed using HTML, CSS and JavaScript. The frontend will retrieve the data from the backend and submit them to users in the frontend. In developing this system, bootstrap is used to design a responsive, interactive and user-friendly GUI. Bootstrap is the most popular open-source frontend framework for interactive web design, mobile-first web and application development (Silvio *et al.*, 2017). It mainly works on a grid structure using rows and columns to create page design and supports all browsers in multiple platforms. By using bootstrap, it enables delivering the right user experience to the suitable device. Backend focused on the file system and database that used to make the frontend possible. It consists of a server, file system and a database. To make the server, file system and database communicate, backend use server-side languages like PHP to build an application and tools like MySQL and SQL Server to find, save or manipulate data and serve it back to the user in front-end code with GUI display on the web (Hugh and David, 2002).

The system that has been developed in this study involves two main modules, namely the administrator module and evaluator module. In the administrator module, there is a submodule on user management, new dossiers set up, dossier readers set up, dossiers form generators and reporting while the evaluator module involves user management, dossier evaluation and reporting.

Application development

The application was developed using windows 10 installed with XAMMP version 5.6.38 software. XAMPP is an open-source software developed by Apache Friends. XAMPP 5.6.38 software package contains Apache distributions for Apache server, Maria DB, PHP, and Perl which is a localhost or a local server (Janet *et al.*, 2008). XAMPP uses it to test the clients or website before uploading it to the remote web server. This XAMPP server software provides a suitable environment for testing MYSQL, PHP, Apache, and Perl projects on the local computer. The application was developed using the web and database locally before being uploaded to the web server for online access.

Data Collection Process and Evaluation

The data collection process is carried out using a set of evaluation criteria by category, as in Table 1. Each category will have a list of criteria for the vaccine dossier evaluation and set to 4 scoring parameters. Each of

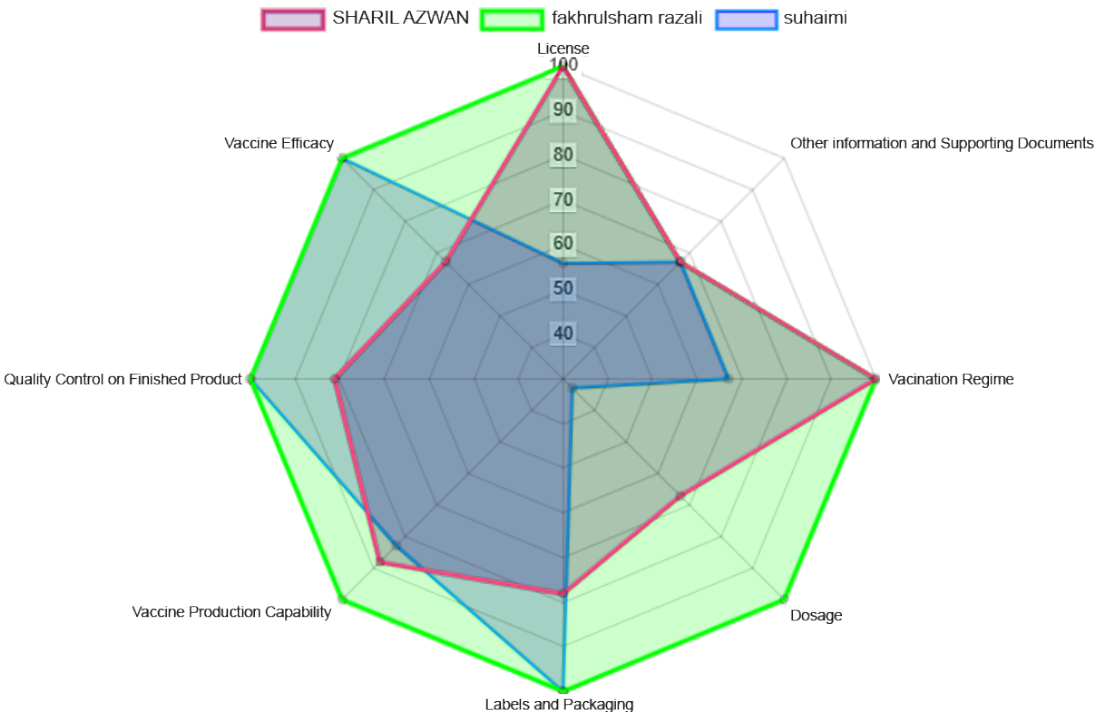

Figure 2. The radar chart gives an overview of the evaluation results with a web spider-like display showing the scoring in percent position by each category and is also able to compare evaluation between multiple dossier evaluators.

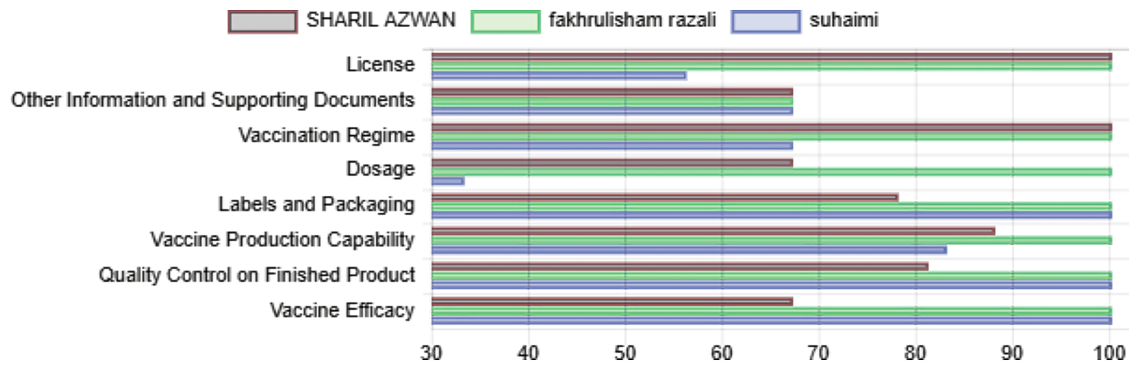

Figure 3. Overall evaluation of a dossier in percent may also be presented via bar graphs according to categories and dossier evaluators.

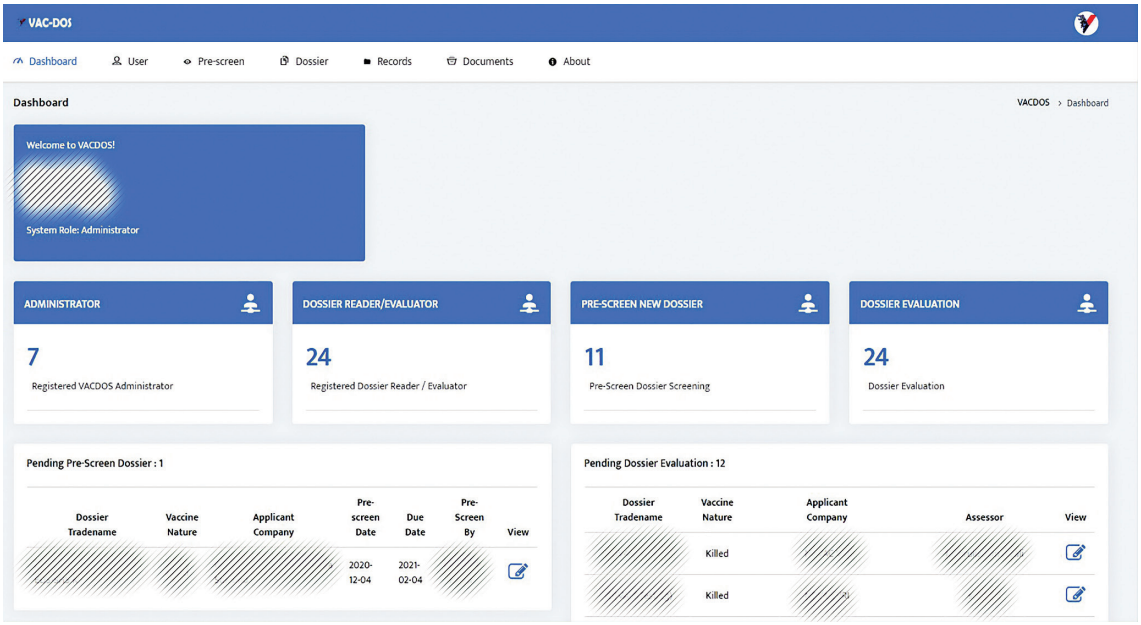

Figure 4. VACDOS main dashboard panel for administrator. Apart from displaying the menu, this dashboard also displays the figure and list of dossier numbers that are still pending to facilitate monitoring of dossier reading.

these scoring parameters has its weight that will determine the overall score. Dossier readers will evaluate the vaccine dossier and fill up the score by choosing the appropriate parameter according to the criteria. Other than that, the reader of dossiers may insert additional details or comment for each criterion in a text box. All information and data from the user will be downloaded into the database to be stored, processed, analysed and extracted as needed by the user.

Reporting

Report will be generated as soon as the user submits the entire assessment. The report will be in the form of charts and tables according to evaluation categories as shown in Figure 2 and Figure 3. Evaluation comparisons between evaluators can also be generated to see differences in evaluation results and help the final evaluation process. Other than displaying infographics in the report, this system can generate assessment results in PDF format by using the mPDF module. mPDF is a PHP library that generates PDF files from UTF-8 encoded HTML.

RESULTS AND DISCUSSION

The assessment of this vaccine dossier is critical to ensure that only vaccines that are perfectly safe to use are being used to ensure the animals' safety and health and ensure that the quality of livestock-produced food does not affect human health. By ensuring that only quality vaccines are

VACCINE DOSSIER MAPPING TOOL

Vaccine Dossier Form

DEPARTMENT OF VETERINARY SERVICES
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Dossier ID:
Evaluator:
Evaluator Email:
Submission Date:

Trade Name:
Manufacturer Name:
Local Agent Address:
Local Agent Contact:
Plant Affiliation: Public/Government
Main Plant Activity: Diagnostic
Type of Vaccine: Killed

A. LICENSE

		Scores				Assessor	Comments and Additional Information	
#	Sub Category	4	3	2	1	Assessor Score	Assessor Comments	Additional Information
1	Copy of manufacturing license or registration certificate of the manufacturer in the country of origin	Availabity of current License and GMP certificates, written in English	Availability of Current License and GMP certificate written in other language	Availabiity of Current License only	License not submitted	4		
2	Country of Origin	European	North America	Japan, Australia, Asean	Others	4		
3	Copy of letter of attorney or authorization letter by the manufacturer	Availability of the current letter by the manufacturer with endorsement from relevant authority or third party.	Availability of the current letter by the manufacturer .	The letter is written in other than English language	The letter not submitted, or date has expired.	4		

Figure 5. PDF format report explaining the scoring for each vaccine dossier assessment category.

used can prevent the spread of livestock and zoonotic diseases and increase the production of animals in Malaysia. Computer based decision tools can help to integrate information to facilitate the decision making process that directs development, acceptance, adoption and management aspects (Ellis *et al.*, 2004).

In developing this system, bootstrap is used to design a responsive, interactive and user-friendly GUI. Bootstrap is the most popular open-source frontend framework for interactive web design, mobile-first web and application development (Silvio *et al.,* 2017). It mainly works on a grid structure using rows and columns to create page design and supports all browsers in multiple platforms. By using bootstrap, it enables delivering the right user experience to the suitable device.

The backend focuses on the file system and database that is used to make the frontend possible. It consists of a server, file system and a database. To make the server, file system and database communicate, the backend use server-side languages like PHP to build an application and tools like MySQL and SQL Server to find, save or manipulate data and serve it back to the user in front-end code with GUI display on the web (Hugh and David, 2002).

The administrator module is the main module that will control the entire VACDOS System. This system is mainly used to support the evaluation of vaccine dossiers in facilitating the evaluator to make an assessment based on the pre-set criteria set out in the system and produce a score or benchmark that can assist the secretariat in decision making for vaccine approval. In user management, the system administrator can add members and assign roles to admin or evaluators and set users' status to be active or inactive. This user management is crucial because the data obtained from this evaluation is considered confidential. The assessment results should not be disclosed to non-member because it involves detailed information on the applicant company. The administrator will register a new dossier and assign up to three (3) dossier evaluators based on the list of evaluators registered in the system. The dossier that has been assigned to the evaluator's name will be accessible by the evaluator as soon as the evaluator logs into the system. The administrator will be able to generate a full evaluation report rendered in PDF format, including scoring data and relevant infographics (Figures 2 to 5) once the evaluation has been done in full.

In the evaluator module, the dossier evaluator can access the dossier once logged into the system. The evaluation method uses a form with the dropdown score option where the evaluator only needs to examine the stated criteria and give the appropriate marks and comments. Once the evaluation is completed, the evaluator must submit the evaluation results to the secretariat through the system for further action.

This application is expected to replace the old subjective and non-scale evaluation methods. By using this application, vaccine dossier assessment can be carried out more quickly, transparently and systematically and the relevant data can be stored digitally to facilitate data retrieval process. This scaled evaluation method will make it easier for decision-makers to examine the proposed vaccine's capabilities and state the final

results based on the findings from the dossier evaluator. Besides, new dossier assessors who are still inexperienced can efficiently carry out the work because it provides the criteria to focus on during the evaluation process.

CONCLUSION

A user friendly web-based tool was developed by enhancing the old evaluation methods to computerise evaluation methods using PHP and MySQL codes. Due to its interactive features, VACDOS has some advantage over the old vaccine evaluation process by enabling faster, and more transparent and efficient vaccine dossier evaluation, whilst maintaining the confidentiality of the assessment. Continuous improvement should be performed such as upgrading the interface to be more compact and interactive, optimising the use of databases as well as increasing security capabilities to ensure that the system becomes faster, more reliable, more stable and provides a good user experience.

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