

# Digitizing Decision-Making Process in the Context of Clinical Risk Management

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**Abstract:** Several adverse events and medical errors are still observed in healthcare practices. Most of them appear to be not compliant with established best practices and organizational protocols, prescribed by regulatory directives and international standards. In response to this pressing concern, a research project was developed with the primary scope of digitize business and decision-making processes in the healthcare sector, based on Business Process Model Notation (BPMN) and Decision Model and Notation (DMN) methodologies. The paper reports the results of the research project after an extended period of the experimental phase and using DMN to map decision-making processes. The digitization also allowed the definition and computation of Key Performance Indicators (KPIs), thereby enabling a comprehensive, long-term evaluation of the efficacy of the proposed solution. The ramifications of this holistic enhancement in the quality of care are palpable not only for patients’ safety but also for the medical and administrative staff efficacy in healthcare facilities.

**Keywords:** Workflow digitalization, Clinical risk, Drugs Management, Healthcare Processes, BPMN, DMN.

## 1. Introduction

The need to standardize modern healthcare processes, thereby reducing the risk of non-compliant outcomes has been emphasized due to rapid technological advancement. The convergence of the Internet of Things (IoT) and cloud computing technologies has dismantled traditional barriers to real-time data communication. As a result, services can now be tailored with greater scalability and customization, helping patients, healthcare professionals and managers (Al-Jaroodi et al., 2020).

This transformation is required because non-compliance is not merely a performance or economic concern, but it poses potential risks to patient health and safety. The integration of modern technologies and robust IT infrastructures ensures more accurate results and reduces errors related to medical malpractice, incorrect decision-making process or miscommunication among healthcare professionals (Marques da Rosa et al., 2021). Moreover, it enhances the efficiency and effectiveness of medical care delivery. These advancements indirectly result in a decrease in compensation claims by patients affected by medical errors or malpractice. Consequently, they contribute to an overall enhancement in service quality and foster greater patient confidence.

The proposed work, aims to develop a tool that uses information technology to highlight potential risk factors for patients associated with deviations from correct healthcare procedures and medical practices.

To achieve these goals, executable models of processes, based on best practices suggested by Joint Commission International (JCI, 2021) were realized using Business

Process Management Notation (BPMN<sup>TM</sup>) 2.0. (OMG, 2014; von Rosing et al., 2015). Additionally, Decision Management Notation (DMN<sup>TM</sup>) was used to map decision-making processes (OMG, 2023).

BPMN stands as a clearly defined standard (OMG, 2020) aimed at generating workflow diagrams to foster a shared comprehension of their significance among various stakeholders. Furthermore, DMN offers a comprehensible tabular format for modelling the combination of factors crucial for complex clinical decisions.

The BPMN model was integrated with the ERP software used by the clinics to track the individual activities and tasks performed by healthcare workers. This monitoring ensures compliance with company policies, the prevailing legal framework, and established reference standards.

The paper is organized as follows: it begins with a Literature Review (Section 2), which examines previous research and relevant studies in the field; Section 3 discusses structured processes and decision-making in healthcare, outlining elements for System Integration (Section 4); Section 5 provide details on the experimental setup and results, while Section 6 presents the conclusions of the study.

## 2. Literature review

Legislation in the healthcare sector mandates the adoption of risk management protocols to reduce occurrence and mitigate adverse effects of medical errors, improving quality of care and patient safety. Over the last decades, how to identify, assess and avoid medical errors become a

high-interest area (Cagliano et al., 2011; Card & Klein, 2016; Aggarwal et al., 2019; Crotti et al., 2020; Donaldson et al., 2021).

ICT innovation is certainly an enabling factor for increasing technological advancements, regulatory requirements, and organizational transformations (Osama et al., 2023), and Business Process Management also requires it (Ahmad and Van Looy, 2020). In the healthcare sector, such innovation aids in facilitating daily operations, optimizing processes and assessing regulatory compliance through the utilization of IT validation systems. Some authors presented exploratory investigations of the upside of digital technologies derived from Healthcare 4.0 in contributing to resilient healthcare services (Marques da Rosa et al., 2021; Tlapa et al., 2022).

As suggested by various authors (Antonacci et al., 2016; Sbayou et al., 2019), the use of Business Process Management (BPM) in healthcare sector allows to capture dynamics of the processes. More recent studies have proposed the implementation of BPM in medical specializations (Tomaskova and Kopecky, 2020). Among these, most interesting is the case of the integration between healthcare process models, created by using the BPMN 2.0 standard (OMG, 2014), and the electronic medical record (Gomes et al., 2018). This work advocates for a structured and standardized approach, as proposed by Object Management Group (OMG, 2020). BPMN best practice and common challenges of process modelling in healthcare are extensively discussed by (Pufahl et al., 2022).

The authors of the current paper also conducted a research project to demonstrate how a real-time monitoring of healthcare processes can be effective in mitigating potential patient risks throughout care pathways (Cartelli et al., 2023), and in simplifying workflows to avoid operational deviations and non-conformities (Longo et al., 2024). In this paper, the previous works were enhanced by reporting the results of an extended experimental period and incorporating the DMN approach to map decision-making processes.

### 3. Healthcare Processes

The scope of the research was to develop a digital representation of healthcare processes, on both structured procedures and decision-making processes. This representation aimed at facilitating the monitoring of their accurate execution within a live healthcare setting. In fact, deviations from established protocols can result in inefficiencies or, in critical instance, may cause risks to patients. The primary goal of our approach was to create a real-time monitoring and analysis tool capable of identifying potential patient risks, enhancing risk management.

To achieve this goal, two types of processes were examined: structured processes, governed by company or governmental policies, and repeatable decision-making processes, which rely on predefined rules and domain

knowledge. The realized digital models employed BPMN 2.0 and DMN standard notations to represent both structured and decision-making processes, respectively. As known, BPMN 2.0 and DMN are business analysis standards endorsed by the Object Management Group (OMG®), offering complementary notations for process modelling. One notable advantage of these standards is their seamless integration with actual IT infrastructures. In the proposed approach, by evaluating and comparing recorded data on the real process execution within the ERP software with predefined tasks, it was possible to assess deviations in process execution and identify potential risk factors for patients’ safety.

#### 3.1 Structured processes

To develop the process models, three main processes were identified and selected for the subsequent modelling and analysis phases:

- Laboratory analysis processes;
- Surgical room processes;
- Drug management and administration processes.

The identified processes were studied and assessed, to efficiently design their execution workflow according to hospital policies and legal framework. Once a sufficient knowledge about the processes was acquired, their digital models were developed using the academic Signavio editor, which provides tools for BPM process modelling.

As an example, the workflow concerning the drugs administration to the patient is shown in Figure 1.

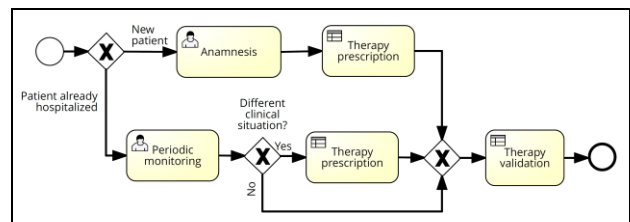


Figure 1: Medical examination process.

In the BPMN 2.0 standard, circular elements represent events. Events can be initial, intermediate, or final. Rectangular elements within the models represent elementary tasks encompassing distinct types, such as script tasks, manual tasks, user tasks, which are used to model different elementary actions. Other important elements are represented by gateways, represented by a rhombus shape and are used to split or join some different model branches, with a XOR or an AND gate logic. The first circular element on the left denotes a start event. Following the start event, the execution workflow diverges into two distinct branches: the first one concerns the execution path followed for new patients, while the second one regards patients already admitted. Each process execution instance follows only one of these branches, determined by the exclusive (XOR) logic of the

gateway. A specific human task is associated with each branch. For new patients, this task involves completing the anamnesis form within the ERP software, while for hospitalized patients, it entails periodic updates of the medical record. In the latter scenario, if there are changes in the patient’s medical situation or if a new medication prescription is required, the *Therapy prescription* task is triggered; otherwise, the process execution continues. The *Therapy prescription* always follows the Anamnesis step for new patients. Validation of the therapy prescription by a second medical professional is mandatory for both new and hospitalized patients. Regarding the Anamnesis and the Periodic monitoring human task, their execution involves information exchange between the process models and the ERP software via specifically developed web-services. Each user task is associated with a specific endpoint. Completion is contingent upon receipt of the appropriate Javascript Object Notation (JSON) request message from the ERP software registration. Upon reception of the JSON message, the process engine automatically executes user tasks. Data included in the messages are internally stored within the process execution engine and serve as process variables for the next decision tasks.

**3.2 Decision making processes.**

Following the execution of the script tasks, the final process branch starts the *Therapy prescription* and *Therapy validation* decision tasks.

The execution of the decision tasks concerns the evaluation of multiple input, recorded by medical personnel within the ERP software and stored as process variables, and the verification of the associated conditions. This process aims to model decision-making procedures using the DMN standard notation. A DMN model includes a Decision Requirements Diagram (DRD), which provides a graphical representation of the decision-making process. Additionally, decision tables are essential components of a DMN model, which include the combination of the input values and their corresponding outputs within the decision-making procedure. Decision tables serve as structured representation of the decision logic, allowing to depict complex decision logic in a clear way. Structurally, they adopt a matrix format, where columns stand for a specific input clause, and each row is a unique combination of input decision-making values.

The DRD associated to the *Therapy prescription* and *Therapy validation* decision tasks is shown in Figure 2. Both the decision processes are represented in the same DRD, given their sequential nature. More specifically, the therapy prescribed by Doctor A, must undergo further validation by doctor B in the next decision step.

The rectangular elements in the diagram represent single decisions, as they figure out an output value based on input values. Input values are re with circular shapes, and they can include Boolean values, numeric or date conditions on process variables, etc. The squared shape with the waved border stands for a knowledge source, then the authority responsible for making or evaluating a

decision. The therapy validation DRD consists of three main decisions.

Prescription completion and medical record evaluation serve as the starting decisions, as their output values stand for the input values for the *Therapy validation* decision. The knowledge source for the *Therapy validation* decision is the doctor responsible for confirming the therapy. Each one of the single decision elements are related to a decision table. The decision table for the *Therapy validation* decision is shown in Figure 3.

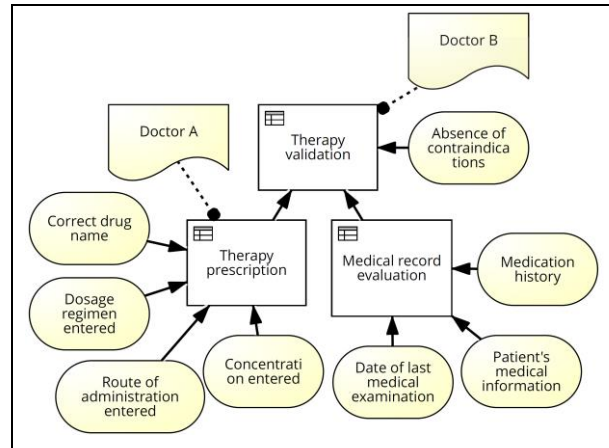


Figure 2: Therapy validation DRD.

A	Inputs			Outputs
	Prescription completion	Medical record evaluation	Absence of contraindications	Therapy validation
	Boolean	{Complete; Incomplete}	Boolean	Boolean
1	= true	= Complete	= true	true
2	= false	-	-	false
3	-	= Incomplete	-	false
4	-	-	= false	false

Figure 3: Therapy validation decision table.

As shown in the decision table, the *Prescription completion* and *Medical record evaluation*, which are the outputs of the previous decisions, are Boolean and string variable type, respectively. The *Absence of contraindications* input is a Boolean variable. The decision output is true, i.e. the therapy is validated, only when both the prescription and the medical record evaluation are complete, and there are no medical contraindications to drug administration. Otherwise, the decision output is false, i.e. the therapy is not validated.

**3.3 KPI**

A comprehensive set of indicators has been developed, specifically tailored to monitor the processes modeled in previous phases and seamlessly integrated with existing indicators already utilized in healthcare facilities, as shown in Table 1. The primary aim of this indicator set is to continuously monitor process progression and ensure the accurate execution of each phase, thereby preventing errors resulting from deviations from established company procedures.

To achieve this, the indicators were designed to be measured over various time frames, allowing for a comprehensive view of process performance and enabling timely intervention if anomalies or risks are detected.

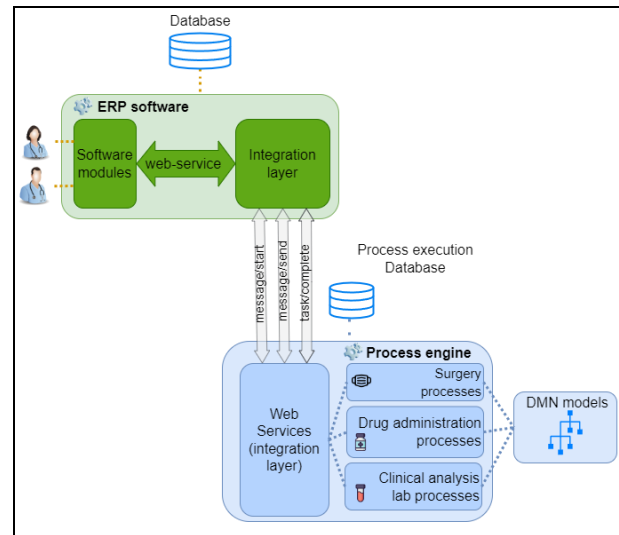
**Table 1: Example of process-related KPI**

KPI	Formula	Notes
Prescriptions validated during the day compared to daily medical visits	$(\text{Validated prescriptions}) / (\text{Medical visits})$	Measures the percentage of prescriptions validated per medical visit
Prescriptions validated compared to bed capacity	$(\text{Validated prescriptions}) / (\text{Beds})$	Measures the percentage of prescriptions validated per bed
LASA drug prescriptions compared to total prescriptions	$(\text{LASA prescriptions}) / (\text{Prescriptions})$	LASA drugs prescribed compared to prescriptions per bed. LASA drugs may cause confusion.
Narcotic prescriptions compared to total prescriptions	$(\text{Narcotic prescriptions}) / (\text{Prescriptions})$	Percentage of narcotics compared to prescriptions
Therapies validated compared to prescribed therapies within a specified period	$(\text{Validated therapies}) / (\text{Prescriptions})$	In the clinic, this aspect has not been previously quantified, but the clinical manager’s perception is that it is low.
Adverse reactions compared to administrations	$(\text{Adverse reactions}) / (\text{Administrations})$	Provides a measure of the incidence of adverse reactions following administration
Incidence of administration errors compared to total administrations	$(\text{Errors}) / (\text{Administrations})$	Probability that a given administration is erroneous
Therapies reassessed compared to unvalidated therapies	$(\text{Reassessed therapies}) / (\text{Unvalidated therapies})$	A negative value indicates the need to reassess prescriptions made during the same day.

#### 4. System Integration

The developed process models were interfaced with the ERP software used in the analysed healthcare facilities. The two systems communicated through the exchange of JSON messages, in which the execution information is used to execute the process models. The exchange of JSON messages is managed by some specifically created REST web-services. Based on the process engine operation, three distinct types of web-services were developed (Longo et al., 2024):

- Message/start web-service: when this message is received by the engine, a new process instance is starting;
- Message/send web-service: when this message is received by the engine, data about the processes are exchanging between systems;
- Task/complete web-service: when this message is received by the engine, a specific instance of a thread is completed, enabling the process execution to continue.



**Figure 4: System integration.**

As shown in Figure 4, medical workers’ registration is collected through the software modules within the ERP software.

Some web-services were implemented both in the software modules and in the designed integration layer, which allows the system to be interfaced with the process engine where process models are executed, through the exchange of JSON messages.

Communications between the integration layers of the ERP software and in the process engine are highlighted on the left side of the figure. The integration layer contained in the process engine was developed to sort communication to the proper process model, shown on the right side, evaluating the content of the message

received from the ERP software. Once a process instance is executed, its process execution data are stored in a specifically designed Process execution database, shown in Figure 4, to retrieve instance status information useful for the next data analysis step.

Each process model is also connected to the corresponding DMN diagrams, which are not executed by the process engine. The connections between the systems were designed to run in background, to avoid affecting the medical workers operations, and to track their real behaviours. Alerts and error messages were not included in the ERP software also to highlight the most critical tasks, which could be a risk factor for patients’ safety in a real healthcare facility. Through the execution of process models, execution data, which represent the operating behaviour of medical and nursing workers were collected and analysed, with the aim of highlighting the operational non-conformities with respect to the operating procedures set up by the management of the structures involved.

The goal of the validation phase was to evaluate the system reliability and functioning, and the correctness of the communication with the existing ERP software, as well as ensuring their stability over time and effective maintenance conditions of any overload of data transferred and communications exchanged. Subsequently, the test environment was replicated within the healthcare facilities servers, updating the existing software version and installing and configuring a new server exclusively dedicated to the Business Process Management Suite (BPMS) system.

### 5. Experimental Phase

The last phase of the project aimed to collect data on the actual execution of the evaluated processes, through the proposed architecture interfaced with the ERP software employed in healthcare facilities. Through the evaluation of the process execution, it was possible to assess the adherence of clinic activities to operational procedures and the legal and regulatory framework. During the experimental phase, no constraints or alerts were introduced into the ERP software, allowing the analysis to be conducted on the job, with healthcare workers performing routine registration operations. The identification of bottlenecks within processes and non-conformities in their execution were found through the analysis of the status codes returned by the system. Specifically, the status code 0 indicates a communication error between the ERP software and the BPMS server; status code 1 stands for the correct execution of a single process instance; status code 100 signifies deviation by the company’s operational policies.

The proposed framework allowed to highlight processes most affected by operational discrepancies in model execution. The status codes percentage distributions for the secretariat and for the drugs administration (Hospital unit) processes are shown in Figure 5.

With 69.4% of drug administration process instances affected by operational non-conformities, the analysis also allowed to highlight tasks in which the execution anomalies are prominent. The distributions of the status codes across drug administration process tasks and over time are shown in Figure 6 and Figure 7.

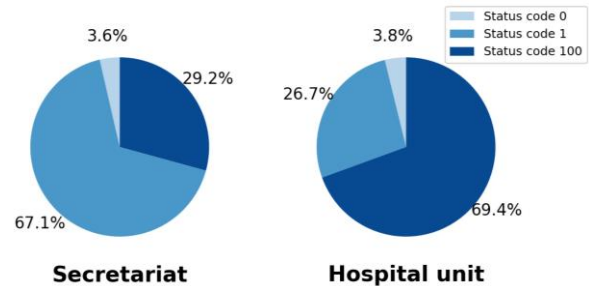


Figure 5: Status code distribution over different processes.

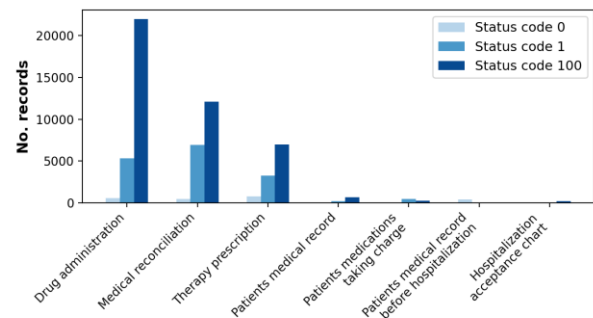


Figure 6 Status codes distribution of drugs administration process tasks.

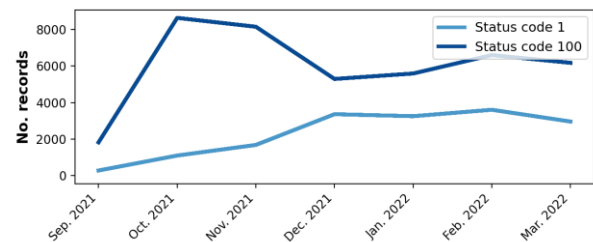


Figure 7: Status codes time distribution.

About KPIs, some results are shown in Figure 8 about Validated prescriptions during the day compared to daily medical visits. The diagrams show the transition from values estimated through the analysis of a sample of data provided by healthcare facilities, which were sometimes overly optimistic, to the measured values of the indicators following the implementation of the system.

It is noteworthy that the Healthcare Information System (HIS) of the clinics registers data useful for assessing the values of some of the introduced Key Performance Indicators (KPIs) even prior to the implementation of BPMN, despite healthcare managers are not aware of this capability and the data sometimes are incomplete. By extracting data from the HIS, it was possible to obtain estimated values for the KPIs, validated by clinic



personnel's experience, as the baseline values (before system integration).

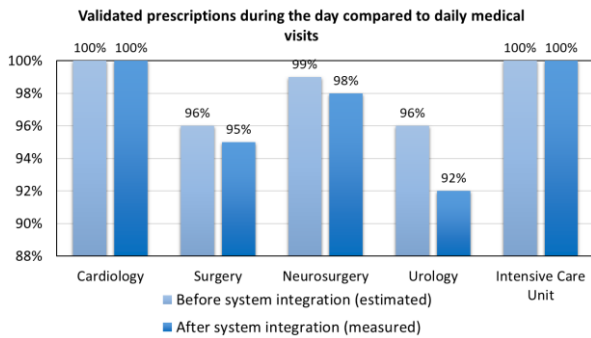


Figure 8: KPI Validated prescriptions during the day compared to daily medical visits (before - estimated - and after - measured - system integration)

Figure 9 also shows improvements in the average indicator values post-system integration, highlighting the resultant corrective actions undertaken in the workers' operations.

Another interesting result is about *Validated drugs prescriptions* compared to *Drugs prescribed*, with a KPI value of 98%.

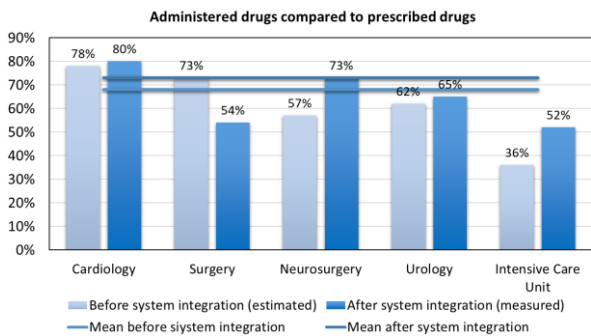


Figure 9: KPI Administered drugs compared to prescribed drugs (before - estimated - and after - measured - system integration)

The adoption of standardized procedures and the ability to consult decision tables through DMN empowers healthcare personnel within facilities to make informed decisions, thereby reducing the likelihood of errors.

Prior to implementing DMN in the company's ERP software, a testing period for decision tables is considered necessary for knowledge dissemination among healthcare workers. Furthermore, in ongoing development, when specific risk conditions arise within the process, alarm systems (“alerts”) will be promptly triggered. These alerts will notify the individual responsible for a particular decision, enabling timely intervention and mitigation of potential risks.

## 6. Conclusions

The proposed approach, distinguished by its enhanced structuring of the phases delineating healthcare pathways within the studied healthcare facilities, has facilitated the tracking of daily operations executed by healthcare workers. This methodology effectively identifies any deviations and anomalies that could potentially generate risk factors for patients. In fact, the processes under analysis, inherently reliant on manual operations and human interactions, exhibit a notable susceptibility to operational non-conformities. These non-conformities predominantly manifest itself as deviations from established standard procedures mandated by companies, which, in turn, are founded upon the legal and regulatory framework.

The integration of BPMN 2.0 and DMN in the interface modules, have shown its capability in real-time monitoring of process execution, especially in contexts dealing with structured procedures. This capability ensures adherence to safe procedures within patient care pathways. Moreover, the developed system could be adopted in different departments and in other contexts with structured processes beyond those demonstrated, as the process engine was specifically designed to be easily implemented with other processes.

The limitations of the proposed approach pertain to the development of executable process models, which should be formalized using BPMN 2.0 standard notation, and to the implementation of proper communications within both the ERP software and the process engine, requiring the development of new JSON communications. Regarding the scalability of the system, it is ensured by the hosting cloud infrastructure, allowing the system to scale up as the volume of communications increases.

The anomalies identified serve as potential risk factors, which, in the discussed example, are primarily caused by lapses in prescription registration or therapy validations. Moreover, the detection of deviations triggers a procedure review process, capable of highlighting both procedural errors stemming from inadequate training or information dissemination among employees, as well as non-value-added process phases that may be circumvented by proficient operators. This initiates a potential review of processes and procedures from a lean perspective. Following the review process, further refinement of the system could entail the introduction of operational constraints aimed at rendering operational procedures more stringent. This measure aims to mitigate instances of operator coercion and minimize patient risks.

Complementing BPMN, Case Management Model and Notation (CMMN) could offer added functionalities tailored for unstructured behaviours, which are activated and perpetually shaped by the influx of information into the case.

## 7. Acknowledgements

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